TITLE 180 CONTROL OF RADIATION

CHAPTER 1 GENERAL PROVISIONS

ATTACHMENTS

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at: http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 1 GENERAL PROVISIONS

1-001 SCOPE AND AUTHORITY:

1-001.01 Except as otherwise specifically provided, Title 180 applies to all persons who receive, possess, use, transfer, own, or acquire: (1) any radiation generating equipment; (2) any naturally occurring or accelerator produced radioactive material; including special nuclear material in quantities not sufficient to form a critical mass. The regulations are authorized by and implement the Radiation Control Act, Neb. Rev. Stat. §§ 71-3501 to 71-3520.

1-001.02 10 Code of Federal Regulations (CFR), as published on January 1, ~~2005~~2013; 40 CFR as published on July 1, 2013~~2005~~ and 49 CFR as published on October 1, 2013 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509 or from the U.S. Government Printing Office, Code of Federal Regulations website at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

1-002 DEFINITIONS: As used in Title 180 , these terms have the definitions set forth below. Additional definitions used only in certain Title 180 Chapters will be found in that Chapter.

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A of 180 NAC 13, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of 180 NAC 013.

A_2 means the maximum activity of radioactive material, other than special form, Low Specific Activity (LSA) and Surface Contaminated Object (SCO) material, permitted in a Type A package. These values are either listed in Appendix A of 180 NAC 13, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of 180 NAC 013.

Absorbed Dose (D) means the energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI Unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

Accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, Particle accelerator is an equivalent term.

Accelerator produced material means any material made radioactive by a particle accelerator.

Act means Radiation Control Act Neb. Rev. Stat. §§ 71-3501 to 71-3520.

Activity means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

Adult means an individual 18 or more years of age.

Agency means the Department of Health and Human Services.

Agreement State means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689). Non-agreement State means any other State.

Airborne radioactive material means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials exist in concentrations

(1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of 180 NAC 4, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC-hours.

As low as is reasonably achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

Background radiation means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. Background radiation does not include sources of radiation from radioactive materials regulated by the Department.

Becquerel (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

Bioassay means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of Title 180, radiobioassay is an equivalent term.

Brachytherapy means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

Byproduct material means:

1. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by solution extraction operations do not constitute byproduct material.

3. Any
   A. Discrete source of radium-226 that is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity; or
   B. Material that has been made radioactive by use of a particle accelerator; and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that;

   A. The United State Nuclear Regulatory Commission, in consultation with the Administrator of the United States Environmental Protection Agency, the United States Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
   B. Is extracted or converted after extraction for use in a commercial, medical, or research activity.

Calendar quarter means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year will begin in January and subsequent calendar quarters will be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or

registrant shall change their method for determining calendar quarters except at the beginning of a year.

Calibration means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

CFR means Code of Federal Regulations.

Chelating agent means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

Civil penalty means any monetary penalty levied on a licensee or registrant because of violations of statutes, rules, regulations, licenses, or registration certificates, but does not include criminal penalties.

Collective dose means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Committed dose equivalent (CDE) ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent (CEDE) ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

Constraint (dose constraint) means a value above which specified licensee actions are required.

Critical Group means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Curie ~~means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E+10 disintegrations or transformations per second (dps or tps).~~means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

Custodial care means the continued observation, monitoring, and care of a management facility for a minimum of one hundred years following transfer of ownership of the management facility from the operator to the Department.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use or release of the property under restricted conditions and termination of license.

Decommissioning means final operational activities at a facility to dismantle site structures, to decontaminate site surfaces and remaining structures, to stabilize and contain residual radioactive material, and to carry out any other activities to prepare the site for postoperational care.

Deep dose equivalent (DDE) (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

Department means the Department of Health and Human Services.

Depleted uranium means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

Director means Director of Public Health of the Division of Public Health or his/her designee.

Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of 180 NAC, radiation dose is an equivalent term.

Dose equivalent (H_t) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

Dose limits means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, limits is an equivalent term.

Effective dose equivalent (EDE) (H_E means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

Electronic product means any manufactured product, device, assembly, or assemblies of such products or devices which, during operation in an electronic circuit, can generate or emit a physical field of radiation.

Embryo/fetus means the developing human organism from conception until the time of birth.

Entrance or access point means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials.

This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Explosive material means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

E (Exponent) indicates that the number 10 is to be raised to a given power. This power is indicated to the right of the symbol E. For example: 3E+4 symbolizes 3×10^{4} and 3E-4 symbolizes 3×10^{-4}.

Exposure means being exposed to ionizing radiation or to radioactive material.

Exposure[1] means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). See 180 NAC 1-015.01 Units of Exposure and Dose for the special unit.

Exposure rate means the exposure per unit of time, such as roentgen per minute (R/min) or milliroentgen per hour (mR/h).

External dose means that portion of the dose equivalent received from any source of radiation outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

Generally applicable environmental radiation standards means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Gray (Gy) means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray [1 Gy=100 rad].

Hazardous waste means those wastes designated as hazardous in 40 CFR Chapter I, Part 261, Subpart A, §§ 261.2 - 261.4 and Subpart D.

[1]When not underlined as above [or indicated as "exposure" (X)] the term "exposure" has a more general meaning in Title 180.

Healing arts means diagnostic and/or healing treatment of human and animal maladies including but not limited to the following which are duly licensed by the State of Nebraska for the lawful practice of: medicine and its associated specialties, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

High-level radioactive waste means:

1. Irradiated reactor fuel;

2. Liquid wastes resulting from the operation of the first cycle solvent extraction system or equivalent and the concentrated wastes from subsequent extraction cycles or the equivalent in a facility for reprocessing irradiated reactor fuel; and

3. Solids into which such liquid wastes have been converted.

4. Other highly radioactive waste material as defined by the U.S. Nuclear Regulatory Commission.

High radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Human use means the internal or external administration of radiation or radioactive material to human beings.

Indian tribe means an Indian or Alaska native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

Individual means any human being.

Individual monitoring means the assessment of:

1. Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

2. Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See the definition of DAC-hours in 180 NAC 4.]

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, termoluminescence dosimeters (TLD's), pocket ionization chambers, and personal ("lapel") air sampling devices. For the purposes of these regulations, personnel dosimeter and dosimeter are equivalent terms.

Inspection means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department. The licensee or registrant is notified of any items of noncompliance and/or recommendation of the Department.

Interlock means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.

Lens dose equivalent(LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

License means a license issued by the Department in accordance with the regulations adopted by the Department.

Licensed material means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.

Licensed practitioner means a person licensed to practice medicine, dentistry, podiatry, chiropractic, osteopathic medicine and surgery, or as an osteopathic physician.

Licensee means any person who is licensed by the Department in accordance with these regulations and the Act.

Limits [See Dose limits]

Lost or missing source of radiation means source of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Low-level radioactive waste means radioactive waste not defined as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in 180 NAC 1-002 byproduct material item 2**.**

Major processor means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 180 NAC 13-002**,** and in 10 CFR Chapter I, Part 71, Subpart A, § 71.4.

Management facility means the land, buildings, and equipment which is intended to be used for the management of radioactive wastes.

Management of low-level radioactive waste means the handling, processing, storage, reduction in volume, disposal, or isolation of such waste from the biosphere in any manner.

Member of the public means any individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Mixed waste means low-level radioactive waste that also contains hazardous waste that is identified in Title 128, Nebraska Administrative Code.

Monitoring means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For the purposes of Title 180 radiation monitoring and radiation protection monitoring are equivalent terms.

NARM means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of 180 NAC 4. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Natural radioactivity means radioactivity of naturally occurring nuclides.

Nuclear Regulatory Commission (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from licensed/registered or unlicensed/unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 180 NAC 7-037, from voluntary participation in medical research programs, or as a member of the public.

Package means the packaging together with its radioactive contents as presented for transport.

Particle accelerator [See "Accelerator"]

Person means any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

Personnel dosimeter: [See Individual monitoring devices].

Personnel monitoring equipment [See Individual monitoring devices].

Pharmacist means any person who is licensed by the State of Nebraska to practice pharmacy.

Physician means any person authorized to practice medicine in this state as provided in Neb. Rev. Stat. §§38-2024 to 38-2045.

Positron Emission Tomography (PET) radionuclide production facility is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

Public dose means the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 180 NAC 7-037, or from voluntary participation in medical research programs.

Pyrophoric liquid means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4 °C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

Quality factor (Q) means the modifying factor, listed in Tables I and II of 180 NAC 1-015, that is used to derive dose equivalent from absorbed dose.

Rad means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

Radiation means ionizing and nonionizing radiation as follows: (a) Ionizing radiation means gamma rays, x-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other atomic or nuclear particles or rays, but does not include sound or radiowaves or visible, infrared, or ultraviolet light; and (b) nonionizing radiation means (i) any electromagnetic radiation which can be generated during the operations of electronic products to such energy density levels as to present a biological hazard to occupational and public health and safety and the environment, other than ionizing electromagnetic radiation, and (ii) any sonic, ultrasonic, or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and to such energy density levels as to present a biological hazard to occupational and public health and safety, and the environment.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation Dose [See "Dose]

Radiation generating equipment means any manufactured product or device, component part of such a product or device, or machine or system which during operation can generate or emit radiation except devices which emit radiation only from radioactive material.

Radiation safety officer means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

Radioactive material means any material whether solid, liquid, or gas, which emits ionizing radiation spontaneously. Radioactive material includes, but is not limited to, accelerator-produced material, byproduct material, naturally occurring material, source material, and special nuclear material.

Radioactivity means the transformation of unstable atomic nuclei by the emission of radiation.

Radiobioassay. [See Bioassay]

Registrant means any person who is registered with the Department and is legally obligated to register with the Department pursuant to Title 180 and the Act.

Registration means registration with the Department pursuant to the Act and in accordance with the regulations adopted by the Department.

Regulations of the U.S. Department of Transportation means the regulations in 49 CFR Parts 100-189.

Rem means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

Research and development means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 180 NAC 4.

Restricted area means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation.

Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "Exposure" and 180 NAC 1-015).

Sealed source means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material .

Shallow dose equivalent (SDE) (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as a dose equivalent at a tissue depth of 0.007 centimeter (7mg/cm^2).

SI means the abbreviation for the International System of Units.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

Source material means:

(1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) Ores which contain by weight one-twentieth of 1%(0.05%) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

Source material milling means any processing of ore, including underground solution extraction of unmined ore, primarily for the purpose of extracting or concentrating uranium or thorium there from and which results in the production of source material mill tailings.

Sources of radiation means any radioactive material, any radiation-generating equipment or any device or equipment emitting or capable of emitting radiation or radioactive material.

Special form radioactive material means radioactive material that satisfies the following conditions:

(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

(3) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed in accordance with the Nuclear Regulatory

Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

Special nuclear material means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any material listed in part (1) of this definition, but does not include source material.

Special nuclear material in quantities not sufficient to form a critical mass means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination must not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175(grams\,contained\ U\text{-}235)}{350}+\frac{50(grams\,U\text{-}233)}{200}+\frac{50(grams\,Pu)}{200}=1$$

Spent nuclear fuel means irradiated nuclear fuel that has undergone at least one year of decay since being used as a source of energy in a power reactor. Spent nuclear fuel includes the special nuclear material, byproduct material, source material, and other radioactive material associated with fuel assemblies.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

Test means the process of verifying compliance with an applicable regulation.

These regulations mean all Chapters of Title 180 “Control of Radiation”.

Total effective dose equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Total organ dose equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 180 NAC 4-052.01, item 1.

Transuranic waste means radioactive waste material containing alpha-emitting radioactive elements, with radioactive half-lives greater than five years, having an atomic number greater than 92 in concentrations in excess of 100 nanocuries per gram.

Tribal official means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 *et seq*., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to §§ 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to § 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

Unrefined and unprocessed ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, uncontrolled area is an equivalent term.

Violation means an infringement of any rule, license or registration condition, order of the Department, or any provision of the Act.

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, mill tailings, discrete sources of Radium 226, and discrete sources of naturally occurring radioactive material.

Waste handling licensees mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

Week means 7 consecutive days starting on Sunday.

Whole body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

Worker means an individual engaged in work under a license or registration issued by the Department and controlled by a licensee or registrant, but does not include the licensee or registrant.

Working level (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

Working level month (WLM) means an exposure to 1 working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

X-ray system means an assemblage of components for the controlled production of x-rays, including but not limited to, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

Year means the period of time beginning in January used to determine compliance with the provisions of Title 180. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

1-003 EXEMPTIONS

1-003.01 General Provision: The Department may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of Title 180 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

1-003.02 U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors: Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

1. Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

3. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

4. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:

    a. That the exemption of the prime contractor or subcontractor is authorized by law; and

b. That, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

1-004 RECORDS: Each licensee and registrant must maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in Title 180.

1-005 INSPECTIONS

1-005.01 Each licensee and registrant must afford the Department at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

1-005.02 Each licensee and registrant must make available to the Department for inspection, upon reasonable notice, records maintained pursuant to Title 180.

1-006 TESTS: Each licensee and registrant must perform upon instructions from the Department, or must permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

1. Sources of radiation;
2. Facilities wherein sources of radiation are used or stored;
3. Radiation detection and monitoring instruments; and
4 Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

1-007 ADDITIONAL REQUIREMENTS: The Department may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

1-008 VIOLATIONS: An injunction or other court order may be obtained prohibiting any violation of any provision of the Act. Any person who violates any provision of the Act may be guilty of a Class IV misdemeanor and, upon conviction, may be punished as determined by the court. (See 180 NAC 17.)

1-009 IMPOUNDING: Sources of radiation are subject to impounding pursuant to § 71-3516 of the Act.

1-010 PROHIBITED USES

1. A hand-held fluoroscopic screen must not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

2. A shoe-fitting fluoroscopic device must not be used.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

1-011 TESTS FOR LEAKAGE AND/OR CONTAMINATION OF SEALED SOURCES

1-011.01 The licensee or registrant in possession of any sealed source must assure that:

1. Each sealed source, except as specified in 180 NAC 1-011.02, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant.

2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Department, after evaluation of information specified by 180 NAC 3-014.12, item 4 and 5 of these regulations, or by an Agreement State, or the U.S. Nuclear Regulatory Commission.

3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Department, after evaluation of information specified by 180 NAC 3-014.12, item 4 and 5, or by an Agreement State or the U.S. Nuclear Regulatory Commission.

4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant must assure that the sealed source is tested for leakage or contamination before further use.

5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, must be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples must be taken from the sealed source or from the surfaces of the container in which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

6. The test for leakage for brachytherapy sources manufactured to contain radium must be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

7. Tests for contamination from radium daughters must be taken on the interior surface of brachytherapy source storage containers and must be capable of detecting the presence of 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than four days.

1-011.02 A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

1. Sealed sources containing only radioactive material with a half-life of less than 30 days;
2. Sealed sources containing only radioactive material as a gas;
3. Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material;
4. Sealed sources containing only hydrogen-3;
5. Seeds of iridium-192 encased in nylon ribbon; and
6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant must, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

1-011.03 Tests for leakage or contamination from sealed sources must be performed by persons specifically authorized by the Department, an Agreement State, or the U.S. Nuclear Regulatory Commission to perform such services.

1-011.04 Test results must be kept in units of Becquerel or microcurie and maintained for inspection by the Department.

1-011.05 The following must be considered evidence that the sealed source is leaking:

1. The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample.
2. Leakage of 37 Bq (0.001 μCi) of radon-22 per 24 hours for brachytherapy sources manufactured to contain radium.
3. The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

1-011.06 The licensee or registrant must immediately withdraw a leaking sealed source from use and must take action to prevent the spread of contamination. The leaking sealed source must be repaired or disposed of in accordance with180 NAC 1.

1-01 1.07 Reports of test results for leaking or contaminated sealed sources must be made pursuant to 180 NAC 4-064.

1-011.08 No sealed source shall be stored for a period of more than three years without being tested for leakage or contamination.

1-012 COMMUNICATIONS: All communications and reports concerning Title 180, and applications filed thereunder, should be addressed to the Department at its office located at

Nebraska Department of Health and Human Services

Division of Public Health
Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, Nebraska 68509-5026

1-013 CITIZENSHIP ATTESTATION: All applicants and renewals for registration or licensure must: Attest that the applicant is a citizen of the United States or a qualified alien under the Federal Immigration and Nationality Act, for the purpose of complying with Neb. Rev. Stat. §§Stat. 4-108 through 4-114. The applicant must provide his/her immigration status and alien number, and agree to provide a copy of his/her United States Citizenship and Immigration Services (USCIS) documentation upon request. If an applicant is not an individual, this section does not apply.

1-014 DISCRIMINATION PROHIBITED: The Department must not exclude any person on the ground of sex from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by this Department. This provision will be enforced through provisions established, with respect to racial and other discrimination, under the Nebraska Fair Employment Act. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

1-015 UNITS OF EXPOSURE AND DOSE

1-015.01 As used in Title 180, the unit of exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58E-4 coulomb per kilogram of air.

1-015.02 As used in 180 NAC, the units of dose are:

1. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
2. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).
3. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).
4. Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

1-015.03 As used in Title 180, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]

X, gamma, or beta radiation and high-energy electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a]Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

1-015.04 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in 001.15C, 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these regulations, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

MEAN QUALITY FACT0RS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} $rem^{-1)}$	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} $sievert^{-1}$)
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170E+6	170E+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16Ex8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

[a]Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b]Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

1-016 UNITS OF ACTIVITY: For the purposes of these regulations, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

1. One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

2. One curie = 3.7E+10 disintegrations or transformations per second (dps or tps) = 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm).

TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES AND SERVICES

FORMS

ATTACHMENT

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TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATION EQUIPMENT FACILITIES AND SERVICES

SCOPE AND AUTHORITY

2-001.01 180 NAC 2 provides for the registration of radiation generating equipment facilities and for the registration of persons providing radiation generating equipment installation, radiation measurements services such as installation, repair, calibration, demonstration, sales, radiation protection, health physics consultations, radiation measurements, survey and facility shielding reviews. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Rev. Stat. §§71-3501 to 71-3520.

2-001.02 In addition to the requirements of 180 NAC 2, all registrants are subject to the applicable provisions of 180 NAC 1, 4, 5, 6, 8, 9, 10, 15, 16, 17, 18, 20 and 21.

2-002 DEFINITIONS: For purposes of 180 NAC 2:

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his/her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Consultation means the act of providing professional or expert advice on radiological matters.

Facility means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

Installation or Install means the assembly, placement, or other actions including but not limited to, initial calibration or operability checks that allow a radiation machine to be used in a new location or after being moved from one location to another.

Radiation Safety Officer (RSO) means an individual who has the knowledge of and the authority and responsibility to apply appropriate radiation protection regulations, and practices, who is specifically named on a certificate of registration, and who is the primary contact with the Department.

Service means the repair, calibration, routine maintenance or other checks or examinations performed on a radiation machine, other than those actions taken during the installation of a radiation machine.

2-003 EXEMPTIONS

2-003.01 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 180 NAC 2, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (5 μSv) per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment will not be exempt.

2-003.02 Radiation generating equipment while in transit or storage incident thereto are exempt from the requirements of 180 NAC 2.

2-003.03 Inoperable x-ray radiation generating equipment is exempt from the requirements of 180 NAC 2. For the purpose of 180 NAC 2, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

2-003.04 Domestic television receivers are exempt from the requirements of 180 NAC 2.

2 -004 APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES: ~~Each person having a radiation generating equipment facility must~~

2-004.01 Each person having a radiation generating equipment facility must a~~A~~pply for registration of such facility with the Department within thirty (30) days following the commencement of the operation of a radiation generating equipment facility. Application for registration must be completed on form NRH-4 furnished by the Department and contain all the information required by the form NRH-4 and accompanying instructions.

2-004.02 Each person having a radiation generating equipment facility must d~~D~~esignate on the application form an individual to be responsible for radiation protection. A radiation safety officer will be designated on the application form. The radiation safety officer will carry out the following responsibilities:

1. Preparing operating and safety procedures and keeping them updated;
2. Informing this Department of lost or stolen radiation generating equipment or overexposures;
3. Knowing policies and procedures;
4. Stopping unsafe practices;
5. Keeping records;
6. Training employees; and
7. Insuring that 180 NAC is followed.

2-004.03 ~~Each person must~~ Each person having a radiation generating equipment facility must prohibit any person from furnishing radiation generating equipment servicing or services as described in 180 NAC 2-005.04 to his/her radiation generating equipment facility until such person provides evidence that s/he has been registered

with the Department as a provider of services in accordance with 180 NAC 2-005. A list of these registrants will be available for distribution by the Department.

2-004.04 The Department at any time after the filing of the original application may require further statements in order to enable the Department to determine whether the certification or registration should be issued or denied.

2-004.05 Each application for a certificate of registration must be accompanied by the fee prescribed in 180 NAC 18-008.

2-004.06 The applicant's proposed radiation generating equipment, facilities, and operating and safety procedures must be adequate to minimize danger to occupational and public health and safety.

2-004.07 Failure to register or reregister sources of radiation in accordance with rules and regulations adopted and promulgated by the department must ~~To register or reregister sources of radiation in accordance with rules and regulations adopted and promulgated by the Department will~~ be subject to a fine of not less than fifty dollars nor more than two hundred dollars.

2-004.08 An application for use of a radiation generating equipment must be signed by the applicant and the radiation safety officer if the radiation safety officer is someone other than the applicant.

2-005 APPLICATION FOR REGISTRATION OF SERVICING AND SERVICES

2-005.01 Each person who is engaged in the business of installing radiation generating equipment or is engaged in the business of furnishing radiation generating equipment servicing, radiation measurements, and/or other services must apply for registration of such services with the Department at least 30 days prior to furnishing any such services.

2-005.02 The application for registration must be completed on form NRH-9 furnished by the Department. It must contain all the information required by the form NRH-9 and be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrants behalf.

1. The Department at any time after the filing of the original application may require further statements in order to enable the Department to determine whether the certification or registration should be issued or denied.
2. Each application for a certificate of registration must be accompanied by the fee prescribed in 180 NAC 18-008.

2-005.03 Each person applying for registration under 180 NAC 2 must specify:

1. That s/he has read and understands the requirements of 180 NAC 2; and
2. The services for which s/he is applying for registration; and

3. The training and experience that qualify him/her to discharge the services for which s/he is applying for registration. The applicant must submit to the Department written documentation of the specific training and experience that qualifies each individual to provide the service. (See 180 NAC 15-013 and 15-033).

2-005.04 For the purpose of 180 NAC 2-005, services may include but are not limited to:

1. Installation/Service: This includes installation/assembly (including initial electronic calibration) and the service/repair of radiation generating equipment and associated radiation generating equipment components. It also includes the measurement of radiation generating equipment output. (See 180 NAC 15-033 for training requirements);

2. Calibration: This includes the calibration of diagnostic radiation generating equipment other than Computed Tomography (CT) facilities (See 180 NAC 15-033 for training requirements), CT (See 180 NAC 15-013.01 and 15-013.02 for training requirements); therapeutic radiation generating equipment (See 180 NAC 15-013.01 for training requirements); and non-medical radiation generating equipment (See 180 NAC 15-033 for training requirements);

3. Consultations: This includes health physics consultation for diagnostic radiation generating facilities other than CT facilities (See 180 NAC 15-013.01, 15-013.02 or 15-013.03 for training requirements), CT facilities (See 180 NAC 15-013.01 or 15-013.02 for training requirements), therapeutic (See 180 NAC 15-013.01 for training requirements); and non-medical radiation generating facilities (See 180 NAC 15-013.02 or 15-013.03 for training requirements);

4. Reviews: This includes area surveys and shielding reviews of diagnostic radiation generating facilities other than CT and therapeutic facilities(See 180 NAC 15-013.01, 15-013.02 or 15-013.03 for training requirements), area surveys and shielding reviews of CT facilities (See 180 NAC 15-013.01, 15-013.02 for training requirements); area surveys and shielding reviews of therapeutic facilities (See 180 NAC 15-013.01 for training requirements) and non-medical radiation generating facilities (See 180 NAC 15-013.02 for training requirements);

5. Demonstration: Demonstration which includes energizing the radiation generating equipment (See 180 NAC 15-033); and

6. Sales: This includes the sales of radiation generating equipment. (No training is required.)

2-005.05 No individual may perform services which are not specifically stated for that individual on the certificate of registration issued by the Department.

2-005.06 In addition to the requirements of 180 NAC 2-005.01 through 2-005.05

1. Assemblers, services and servicing personnel must provide the registrant with instruction manuals, manufacturer specifications and other information, as required by the Federal Performance Standard, and these Regulations, which are applicable to the newly installed x-ray systems or components.

2. Applicants for x-ray facility shielding review must submit procedures.

2-006 ISSUANCE OF CERTIFICATE OF REGISTRATION (NRH-4 AND/OR NRH-9)

2-006.01 Upon a determination that an applicant meets the requirements of the regulations, the Department will issue a Certificate of Registration.

2-006.02 The Department may incorporate in the Certificate of Registration at the time of registration or thereafter by rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation generating equipment, radiation source servicing, radiation measurements and/or services it deems appropriate or necessary in order to:

1. Minimize danger to occupational and public health and safety;
2. Require additional records and keeping of additional records as maybe appropriate or necessary; and
3. Prevent loss or theft of radiation generating equipment subject to Title 180.

2-007 SPECIFIC TERMS AND CONDITIONS OF CERTIFICATES OF REGISTRATION

2-007.01 Each certificate of registration issued in accordance to 180 NAC 2 will be subject to the applicable provisions of the Nebraska Radiation Control Act, Neb. Rev. Stat. §§ 71-3501 to 17-3520 now or hereafter in effect, and to the applicable rules and order of the Department.

2-007.02 A certificate of registration issued or granted under 180 NAC 2 can not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the Department authorizes the transfer in writing.

2-007.03 Each person registered by the Department for radiation generating equipment use in accordance with 180 NAC 2 will confine use and possession of the radiation generating equipment registered to the locations and purposes authorized in the certificate of registration.

2-007.04 The registrant is responsible for complying with 180 NAC and any conditions of the certificate of registration.

2-008 RESPONSIBILITES OF THE REGISTRANT

2-008.01 The registrant will notify the Department in writing within 30 days of any change which would render the information contained in the application for registration no longer accurate.

2-008.02 The following criteria applies to temporary replacement radiation generating equipment and radiation generating equipment used for clinical trial evaluations. Radiation generating equipment used for clinical trial evaluations, temporary replacement, or demonstration may be used for up to 60 days without adding the radiation generating equipment to an existing certificate of registration. If the use period will exceed 60 days, the facility will be required to add the radiation generating equipment to their certificate of registration and a fee will be assessed. Radiation generating equipment must be registered in accordance with 180 NAC 2.

No fees will be assessed for the operation of radiation generating equipment for clinical trial evaluations or loaner or demonstration radiation generating equipment used for a period of 60 days or less at a facility with a current certificate of registration.

2-008.03 The following applies to voluntary or involuntary petitions for bankruptcy:

1. Each registrant will notify the Department, in writing, immediately following the filing of voluntary or involuntary petition for bankruptcy.
2. The notification will include the bankruptcy court in which the petition for bankruptcy was filed; and the date of the filing of the petition.
3. A copy of the "petition for bankruptcy" must be submitted to the Department along with the written notification.

2-008.04 Receipt, transfer, and disposal of radiation generating equipment. The registrant will ensure that records of receipt, transfer, and disposal of radiation generating equipment are made and/or maintained for each unit of radiation generating equipment. Records of receipt, transfer, and disposal of radiation generating equipment will include the following:

1. Manufacturer's name and model and serial number from the control panel; and
2. Date of the receipt, transfer, and disposal.

2-008.05 Approval not implied: No person, in any advertisement, will refer to the fact that s/he or his/her facility is registered with the Department pursuant to the provision of 180 NAC 2-004, and no person will state or imply that any activity under such registration has been approved by the Department.

2-008.06 Inventory

2-008.06A Each registrant will annually inventory all radiation generating equipment possessed. The inventory will include the manufacturer's name, model, and serial number of the control panel and will be made and maintained for inspection by the Department in accordance with 180 NAC 4-046.

2-008.06B Notification is required within 30 days of any change of radiation generating equipment inventory. This includes installation or removal and the disposition of any equipment disposed of or transferred. The assembler's notification of installation may be accepted in lieu of notification by the registrant. This does not relieve the registrant of the responsibility to assure that proper notification had been made.

2-009 EXPIRATION/TERMINATION OF CERTIFICATE OF REGISTRATION

2-009.01 Expiration of Certificate

2-009.01A Except as provided by 180 NAC 2-010.02, each certificate of registration will expire annually on the anniversary of the date issued. Expiration does not relieve the registrant of the requirements of 180 NAC 2.

2-009.01B If a registrant does not renew the certificate of registration per 180 NAC 2, the registrant will on or before the expiration date on the certificate of registration:

1. Terminate use of all radiation generating equipment;
2. Submit a record of disposition of the radiation generating equipment; and
3. Pay any outstanding fees per 180 NAC 18-008.

2-009.02 Termination of Registration: When a registrant decides to terminate all activities involving radiation generating equipment authorized under the certificate of registration the registrant must notify the Department immediately and:

1. Request termination of the certificate of registration in writing;
2. Submit a record of disposition of the radiation generating equipment, and
3. Pay any outstanding fees per 180 NAC 18-008.

2-010 RENEWAL OF CERTIFICATE OF REGISTRATION

2-010.01 Application for renewal of Registration must be filed in accordance with 180 NAC 2-004 or 180 NAC 2-005.

2-010.02 In any case in which a registrant has filed an application in proper form for renewal, such existing certificate of registration will not expire until the application status has been finally determined by the Department.

2-011 ASSEMBLER AND/OR TRANSFER OBLIGATION[1]

2-011.01 Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation generating equipment or components which affect radiation output in this State must notify the Department within 15 days of:

1. The full name and address of persons who have received this equipment;
2. The manufacturer, model, and serial number of each radiation generating equipment transferred; and

[1]In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with requirements of 21 CFR Chapter 1, Section 1020.30(d), ~~attached hereto as pages 611-612, except the stricken text of Attachment Number 2-1 and incorporated herein by this reference, shall~~ must suffice in lieu of any other report by the assembler.

3. The date of transfer of each radiation generating equipment.

2-011.02 No person may make, sell, lease, transfer, lend, assemble, or install radiation generating equipment or the components used in connection with such equipment unless such components and equipment, when properly placed in operation and used, meet the requirements of 180 NAC.

2-012 OUT-OF-STATE RADIATION GENERATING EQUIPMENT

2-012.01 Except, as provided by 180 NAC 2-008.02, whenever any radiation generating equipment which is registered in another state or by the federal government is to be brought into the State, for any temporary use, the person proposing to bring such equipment into the State shall give written notice to the Department (at least ~~2~~three working days) before such equipment is to be used in the State. The notice must include:

1. The type of radiation generating equipment;
2. The nature, duration, and scope of use; and
3. The exact location(s) where the radiation generating equipment is to be used; and
4. States in which this equipment is registered.

2-012.02 If, for a specific case, the (two working-day) period would impose an undue hardship on the person, upon application to the Department, permission to proceed sooner may be granted.

2-012.03 The person referred to in 180 NAC 2-012 .01 shall:

1. Comply with all applicable regulations of the Department;
2. Supply the Department with such other information as the Department may reasonably request; and
3. Not operate within the State on a temporary basis in excess of 180 calendar days per year.
4. Submit the appropriate fee as specified in 180 NAC 18-008.

Department of Health & Human Services
DHHS
NEBRASKA

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Type or print except where indicated.
Retain one copy for your records.
Refer to NRH-4 Instructions as needed.

Submit original application to:

Nebraska Dept. of Health and Human Services
Office of Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026

Department Use Only	
County	Reg. Number
State	Region
Priority	Label
Renewal Date	Fee

1.a LEGAL NAME AND STREET ADDRESS (INSTITUTION, FIRM, PERSON, ETC.)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone :		FAX:	
E-Mail:			
1.b RADIATION GENERATING EQUIPMENT LOCATION (IF DIFFERENT THAN 1.a)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone:		FAX:	
Temporary job sites throughout Nebraska? ☐ Yes ☐ No			
2. BILLING INFORMATION			
Address (if different than 1.a):			
City, State, Zip:			
Telephone:		FAX:	
Contact Person:			
3. PRACTICE TYPE (SEE NRH-4 INST)			

4. RADIATION GENERATING EQUIPMENT (use additional sheets if necessary – NRH-4a)

List each machine on a separate line.

Machine Type (See NRH-4 Inst)	Number Tubes	Control Manufacturer	Control Model No.	Control Serial No.	Manufacture Date	Install Date	Master Control Location

5. RADIATION SAFETY OFFICER (RSO) (see 180 NAC 2-004.02 or 21-007.01B)

Radiation Safety Officer (Print or Type)	Signature	Date

6. ATTESTATION AND CERTIFICATION

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

Check only ONE box below:

☐ I am a citizen of the United States

☐ I am a qualified alien under the Federal Immigration and Nationality Act.
Immigration status and alien number: _____
USCIS documentation enclosed.

☐ Application is for a separate legal entity (Ex: corporation, partnership, etc.) **Explain:** _____

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

The applicant and any official executing this document on behalf of the applicant named in Item 1.a. certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Title 180 Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of their knowledge.

Certifying Official (Print or Type)	Applicant/Facility Name (see item 1.a)

Signature	Date

Department of Health & Human Services
DHHS
NEBRASKA

For Department Use Only

NEBRASKA DEPARTMENT OF HEATLH AND HUMAN SERVICES
RADIOLOGICIAL HEALTH
X-RAY PROGRAM

Regist. No. _____
State _____ Co. _____
Region

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Instructions: Type or Print except where indicated. Retain one copy for your files and submit original application to: Nebraska Dept. of Health and Human Services , Radiological Health, 301 Centennial Mall South, P O Box 95026, Lincoln, NE 68509-5026.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip: _____

Telephone #: _____

FAX #: _____

eMail Address:

1.b Street address(es) at which Radiation Generating Equipment will be used. (If different than 1.a)

(1) Permanent Address: _____

_____

City, State Zip: _____

(2) Temporary Job Sites Throughout Nebraska? ☐ Yes ☐ No

2. Billing Information

Address(if different than 1.a):

_____

_____

Person to Contact: _____

Telephone #: _____

3. Radiation Safety Officer (RS0) (See 180 NAC 2-004.02,or 21-007.01B)

_____

Title: _____

Telephone #: _____

4. Type of Practice (see Instruction Sheet) _____

5. RADIATION GENERATING EQUIPMENT (USE ADDITIONAL SHEETS IF NECESSARY)

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Control. Model No.	Control. Serial No.	Date Installed	Date Manufactured	Control Room #

6. I do hereby accept the responsibility of radiation safety officer.

Type or print name of Radiation Safety Officer from item 3. | Signature of Radiation Safety Officer | Date

7. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____

OR

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last) | Signature | Date

8. CERTIFICATION
(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services,, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge.

_____
Applicant Name from Item 1.a.

By: _____ *Date:* _____
Signature of certifying official authorized to act on behalf of applicant

_____
Print Name and Title of certifying official

Your Application will not be processed without items 6., 7., and 8. being completed.

Department of Health & Human Services
DHHS
NEBRASKA

NRH – 4 - ADDITIONAL MACHINES

Type or print machine information in correct fields.
List each machine on separate line.
Provide registration number if known. Registration #_____

Machine Type (See NRH-4 INST)	Number Tubes	Control Manufacturer	Control Model No.	Control Serial No.	Manufacture Date	Install Date	Master Control Location

~~FORM NRH-4a (Additional Machines)~~ ~~Registration No.~~
~~Effective Date February 24, 2013~~

~~5a. LIST ADDITIONAL MACHINES ON THIS SHEET~~

~~List each machine on a separate line.~~

~~Type~~	~~# Tubes~~	~~Control~~	~~Control~~	~~Control.~~	~~Date~~	~~Date~~	~~Control~~
~~Manufacturer~~		~~Model No.~~	~~Serial No.~~		~~Installed~~	~~Manufactured~~	~~Room #~~

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
RADIOLOGICAL HEALTH

APPLICATION FOR REGISTRATION OF SERVICES FOR RADIATION GENERATING EQUIPMENT

INSTRUCTIONS: (Use additional sheets where necessary.)
■**Type or print except where indicated**.
■Retain one copy for your files
■Submit original application to: Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
■Submit annual fee per 180 NAC 18-008.
■Upon approval of the application a "Certificate of Registration for Radiation Generating Equipment." will be issued.

1. Name and Street Address of Applicant's Business (Individual or Company)

Applicant Name: _____

Address: _____

_____

City, State Zip+4 _____

Telephone #: _____ FAX# _____

E-mail Address: _____

2. Name of Person Responsible to Contact Regarding this Application

Name_____ Telephone #_____

3. Types of Services to be performed (Please check all appropriate boxes.)	**Training Requirements References:**
☐ A. Installation/Service (If "A" is checked, please check at least one of the 3 items below.)	
☐ A1. Installation/Assembly (including initial Electronic Calibration) of Radiation Generating Equipment	180 NAC 15-033
☐ A2. Service/repair of Radiation Generating Equipment	180 NAC 15-033
☐ A3. Measurement of Radiation Generating Equipment output	180 NAC 15-033
☐ B. Calibration (If "B" is checked, please check at least one the 3 items below)	
☐ B1. Calibration of Diagnostic Radiation Generating Equipment	180 NAC 15-033
☐ B2. Calibration of CTs	180 NAC 15-013.01 or 15-013.02
☐ B3. Calibration of Therapeutic Radiation Generating Equipment	180 NAC 15-013.01
☐ B4. Calibration of Non-Medical Radiation Generating Equipment	180 NAC 15-033
☐ C. Consultations (If "C" is checked, please check at least one the 3 items below)	
☐ C1. Health Physics Consultations of Diagnostic Radiation Generating Facilities	180 NAC 15-013.01 or 15-013.02 or 15-013.03
☐ C2. Health Physics Consultations for CT Facilities	180 NAC 15-013.01 or 15-013.02
☐ C3. Health Physics Consultations for Therapeutic Facilities	180 NAC 15-013.01
☐ C4. Health Physics Consultations for Non-Medical Radiation Generating Facilities	180 NAC 15-013.02 or 15-013.03
☐ D. Reviews (If "D" is checked, please check at least one of the 3 items below.)	
☐ D1. Area Surveys and shielding reviews of Diagnostic Radiation Generating Facilities	180 NAC 15-013.01 or 15-013.02 or 15-013.03
☐ D2. CT Shielding Facility Reviews	180 NAC 15-013.01 or 15-013.02
☐ D3. Therapeutic Facility Reviews	180 NAC 15-013.01
☐ D4. Non-Medical area Surveys and shielding reviews of Radiation Generating Facilities	180 NAC 15-013.02
☐ E. Demonstration which includes energizing the radiation generating equipment	180 NAC 15-033
☐ F. Sales	No training is required
☐ G. Other	Dependent on service requested.

4. Training: (At least one individual must be qualified for each of the requested service(s) listed in 3.A through E and G)

4.A. Submit name of individual qualified and which service the individual is to provide.

4.B. Attach training requirements for each individual. (See item 3. On Page 1 of this form for training requirements references.)

4.C. Each individual applying for registration must read and understand the requirements of 180 NAC 2.

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4 D1, D2, D3, D4 E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4 D1, D2, D3, D4 E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4 D1, D2, D3, D4 E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4, D1, D2, D3, D4, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4, D1, D2, D3, D4, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4, D1, D2, D3, D4, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Name of Individual____

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, B4 C1, C2, C3, C4 D1, D2, D3, D4 E, G

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of 180 NAC 2

Use additional sheet(s) for additional names and information

IF APPLICABLE

5. Attach procedures for x-ray facility shielding reviews. (See 180 NAC 2-005.04, item 4)

6. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____
_____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

7. CERTIFICATION
(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

_____
Applicant Name From Item 1.

By:_____Date:_____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

Registration Does Not Imply Approval or Disapproval of Service

Your Application will not be processed without items 6. and 7. being completed.

~~**ATTACHMENT 2-1**~~

~~**21 CFR 1020.30(d)**~~

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(d) *Assemblers' responsibility.* An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by §1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, CDRH. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements.* Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to CDRH in the report required under §1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv)(A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component
This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in §1010.3 of this chapter, manufacturers of components subject to this section and §§1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.

TITLE 180 CONTROL OF RADIATION

CHAPTER 3 LICENSING OF RADIOACTIVE MATERIAL

APPENDICES

FORMS

Form NRH 5 Application for Radioactive Material License
Form NRH-11 Certificate – Use of Depleted Uranium Under General License
Form NRH-17 Certificate – In Vitro Testing With Radioactive Material General License
Form NRH-60 Certificate of Disposition of Materials
Form NRH 653, A & B Transfers of Industrial Devices Report

ATTACHMENT

Attachment 3 – 11 U.S. C. 101(2) and (15)

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 3 LICENSING OF RADIOACTIVE MATERIAL

3-001 SCOPE AND AUTHORITY

3-001.01 180 NAC 3 provides for the licensing of radioactive material. No person will manufacture, produce, receive, possess, use, transfer, own, dispose or acquire radioactive material except as authorized in a specific or general license issued pursuant to 180 NAC 3 or as otherwise provided in 180 NAC 3, 5, 7, 9, 12, 13 or 19. The regulations are authorized by and implement the Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

3-001.02 In addition to the requirements of 180 NAC 3, all licensees are subject to the requirements of 180 NAC 1, 4, 10, 13, 15, 17, and 18. Licensees engaged in industrial radiographic operations are subject to the requirements of 180 NAC 5, licensees using sealed and unsealed sources in the healing arts are subject to the requirements of 180 NAC 7, licensees engaged in the management of radioactive waste are subject to the requirements of 180 NAC 12, licensees engaged in well logging and subsurface tracer studies are subject to the requirements of 180 NAC 14, and licensees using sealed sources containing radioactive materials in irradiators are subject to the requirements of 180 NAC 19.

3-001.03 10 Code of Federal Regulations (CFR), as published on January 1, 2013 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509 or from the U.S. Government Printing Office, Code of Federal Regulations website at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR..

3-002 DEFINITIONS: As used in 180 NAC 3.

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Principal activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no license material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) means naturally occurring radioactive material whose radionuclide concentration are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include "source material: and "byproduct material."

Unrefined and unprocessed ore means ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

EXEMPTIONS

3-003 SOURCE MATERIAL

3-003.01 Any person is exempt from 180 NAC 3 to the extent that the person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 % (0.05 %) of the mixture, compound, solution, or alloy.

3-003.02 Any person is exempt from 180 NAC 3 to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, the person must not refine or process such ore.

3-003.03 Any person is exempt from the requirements of the 180 NAC 3 and 4, and 10 to the extent that the person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in:

    a. incandescent gas mantles,
    b. vacuum tubes,
    c. welding rods,
    d. electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

e. germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,
f. rare earth metals and compounds, mixtures, and products containing not than 0.25% by weight thorium, uranium, or any combination of these, or
g. personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

2. Source material contained in the following products:

a. glazed ceramic tableware manufactured before August, 27, 2013, provided that the glaze contains not more than 20% by weight source material,
b. glassware, containing not more than 2~~10~~% by weight source material or for glassware manufactured before August 27, 2013, 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, or ceramic used in construction,
c. glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983,[1] or
d. piezoelectric ceramic containing not more than 2% by weight source material;

3. Photographic film, negatives, and prints containing uranium or thorium;

4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that the exemption contained in this subpart does not authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

~~a. the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR 40;~~

[1]On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.

~~b.~~a. ~~e~~Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",[2]

~~c.~~b. ~~e~~Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",[3] and

~~d.~~c. ~~t~~The exemption contained in this division does not authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

6. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

   a. The shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM", and
   b. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2mm).

7. Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than ~~3~~10% by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30% by weight of thorium; and that the exemption contained 180 NAC 3-003.03, item 7 does not authorize either:

   a. the shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror, or
   b. the receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

~~8. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 185 Bq (0.005 microcurie) of uranium; or~~

---

[2]The requirements specified in 180 NAC 3-003.03, items 5.b. and 5.c. need not be met by counter weights manufactured prior to December 31, 1969; provided, that such counter weights were manufactured under a specific license issued by the Atomic Energy Commission and were ~~are~~ impressed with the legend, required by CFR 30.13 (c)(5)(ii) in effect on June 30, 1969. ~~"CAUTION, RADIOACTIVE MATERIAL - URANIUM", as previously required by Title 180.~~

[3]Ibid. p. 3

8. ~~9.~~ Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

   a. the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and
   b. the thorium content in the nickel-thoria alloy does not exceed 4% by weight.

9. No person may initially transfer for sale or distribution a product containing source material to persons exempt under this 180 NAC 3-003.03, or equivalent regulations of an U.S. Nuclear Regulatory Commission or Agreement State, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

   a. Persons initially distributing source material in products covered by the exemptions in 180 NAC 3-003.03 before the effective date of these regulations, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the U.S. Nuclear Regulatory Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.
   b. Persons authorized to manufacture, process, or produce these materials or products containing source material by the U.S. Nuclear Regulatory Commission or an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 180 NAC 10 CFR 40.52 for distribution only and are exempt from the requirements of 180 NAC 4 and 10, and 180 NAC 3-011, item 1 and 2.

3-003.04 The exemptions in 180 NAC 3-003.03 do not authorize the manufacture of any of the products described.

3-003.05 Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in 180 NAC 3, 7 and 24 to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

3-004 RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

3-004.01 Exempt Concentrations.

1. Except as provided in 3-004.01, item 3 and 4, any person is exempt from 180 NAC 3 to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in 180 NAC 3, Appendix 3-A.
2. 180 NAC 3-004.01 must not be deemed to authorize the import of radioactive material or products containing radioactive material.
3. A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license in 180 NAC 3-004, 3-005, 3-006, 3-008, 3-013,

3-014, 3-016 through 3-024, 180 NAC 5, 7, 14 and 19 to the extent that they transfer radioactive material contained in a product or material in concentrations not in excess of those specified in 180 NAC 3, Appendix 3-A and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

4. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 180 NAC 3-004.01, item 1 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State, except in accordance with a specific license issued pursuant to 10 CFR 32.11.

3-004.02 Exempt Quantities.

1. Except as provided in 180 NAC 3-004.02 , items 3 through 5, any person is exempt from Title 180 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in 180 NAC 3, Appendix 3-B.
2. Any person who possesses radioactive material received or acquired, prior to September 25, 1971, in accordance with the general license provided in 180 NAC 3-008 or similar general license of the U.S. Nuclear Regulatory Commission or another Agreement State is exempt from the requirements for a license set forth in Title 180 if that person possesses, uses, or transfers such radioactive material.
3. 180 NAC 3-004.02 does not authorize the production, packaging, repackaging, or transfer of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in 180 NAC 3, Appendix 3-B knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 180 NAC 3-004.02 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.18 which license states that the radioactive material may be transferred by the licensee to persons exempt under 180 NAC 3-004.02 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State.
5. No person may, for purposes of producing an increase radiation level combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in 180 NAC 3, Appendix 3B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulation in 180 NAC 3.

3-004.03 Exempt Items.

1. Certain Items Containing Radioactive Material.

a. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or for distribution the following products containing radioactive material any person is exempt from Title 180 to the extent that s/he receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

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(a) 925 MBq (25 millicuries) of tritium per timepiece.
(b) 185 MBq (5 millicuries) of tritium per hand.
(c) 555 MBq (15 millicuries) of tritium per dial (The Department considers bezels when used to be part of the dial).
(d) 3.7 MBq (100 microcuries) of promethium-147 per watch or 7.4 MBq (200 microcuries) of promethium-147 per any other timepiece.
(e) 0.74 MBq (20 microcuries) of promethium-147 per watch hand or 1.48 MBq (40 microcuries) of promethium-147 per other timepiece hand.
(f) 2.22 MBq (60 microcuries) of promethium-147 per watch dial or 4.44 MBq (120 microcuries) of promethium-147 per other timepiece dial (bezels when used will be considered as part of the dial).
(g) 0.037 megabecquerel (1 micorcuries) of radium per timepiece in intact timepieces manufactured prior to August 22, 1981.
(h) The radiation dose rate from hands and dials containing promethium-147 will not exceed the following, when measured through 50 milligrams per square centimeter of absorber:

(i) For wrist watches, 1 μGy (0.1 millirad) per hour at 10 centimeters from any surface.
(ii) For pocket watches, 1 μGy (0.1 millirad) per hour at 1 centimeter from any surface.
(iii) For any other timepiece, 2 μGy (0.2 millirad) per hour at 10 centimeters from any surface.

(2) ~~(Reserved)~~ Static elimination devices and ion generating tubes

(a) Static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not

more than 18.5 MBq (500 µCi) of polonium-210 per device.

(b) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(c) Such devices previously authorized for use under the general license and equivalent regulations of the Department, the U.S. Nuclear Regulatory Commission, or Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Department, Agreement State or the U.S. Nuclear Regulatory Commission are now exempt.

(3). Precision balances containing not more than 37 MBq (1 millicurie) of tritium per balance or not more than 18.5 MBq (0.5 millicurie) of tritium per balance part manufactured before December 17, 2007.

(4) Reserved.

(5). Marine compasses containing not more than 27.8 GBq (750 millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) of tritium gas manufactured before December 17, 2007.

(6). Reserved

(7). Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(a) 5.55 GBq (150 millicuries) of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) of tritium per any other electron tube.
(b) 37 kBq (1 microcurie) of cobalt-60.
(c) 185 kBq (5 microcuries) of nickel-63.
(e) 1.11 MBq (30 microcuries) of krypton-85.
(f) 185 kBq (5 microcuries) of cesium-137.
(g) 1.11 MBq (30 microcuries) of promethium-147.

And provide further, that the levels of radiation from each electron tube containing radioactive material will not exceed 10 µGy (1 millirad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[4]

[4]For purposes of this division, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(8). Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material provided that:

(a) Each source contains no more than one exempt quantity set forth in 180 NAC 3, Appendix 3-B, and

(b) Each instrument contains no more than 10 exempt quantities. An instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 180 NAC 3, Appendix 3-B provided that the sum of such fractions does not exceed unity.

(c) For americium-241, 1.85 kBq (0.05 microcurie) is considered an exempt quantity under 180 NAC 3-004.03, item 1.h.

(9) Ionization chamber smoke detectors containing not more than 1 micocurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires..

b. Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in 180 NAC 3-004.03, item 1.a. or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to 180 NAC 3-004.03, item 1.a.

2. Self-luminous products containing radioactive material.

a. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from Title 180 to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to § 32.22 of 10 CFR 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 180 NAC 3-004.03, item 2 does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.
]

b. Radium-226. Any person is exempt from Title 180 to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq (0.1 microcuries) of radium-226 which were acquired prior to August 22, 1982.

c. Any person who desires to manufacture, process, or produce or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, for use under ~~or to initially transfer such products for use in accordance with~~ 180 NAC 3-004.03, item 2.a., should apply for a license in accordance with 10 CFR 32.22, and for a certificate of registration per 10 CFR 32.210 ~~which license states that the product may be initially transferred by the licensee to persons exempt from 180 NAC 3-004.03, item 2.a. C.4c.iii(1) or equivalent regulations of an Agreement State.~~

3. Gas and aerosol detectors containing radioactive material.

a. Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from Title 180 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to that such person receives, possesses, uses, transfers, owns or acquires radioactive material, in gas and aerosol detectors designed to protect health, safety, or property ~~life or property from fires and airborne hazards~~, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.26, ~~pursuant to 180 NAC 3-014.03,~~ which license authorizes the initial transfer of the product for use under 180 NAC 3-004.03. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provision to 10 CFR 32.26 authorizing distribution detectors to persons exempt from regulatory requirements.

b. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use in accordance with 180 NAC 3-004.03, item 3.a. should apply for a license in accordance with 10 CFR 32.26, and for a certificate of registration per 10 CFR 32.210. ~~which license states that the product may be initially transferred by the licensee to persons exempt from 180 NAC 3-014.03, item 3.a. or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.~~

4. Persons who receive, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of 180 NAC 3 with respect to any combination of radium-226 and radium-228 if the material contain, or are contaminated at, concentrations less than 5 pCi/gram (185 becquerel per kilogram) excluding natural background. The progeny of the exempt TENORM radium-226 and radium228 are also exempt.

5. Certain Industrial Devices

a. Except for persons who manufacture, process, produce or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license in the Radiation Control Act and 180 NAC to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.s. Nuclear Regulatory Commission pursuant to 10 CFR 32.30, which license authorizes the initial transfer of the device for use under 180 NAC 3-004.03, item 5. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

b. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under 180 NAC 3-004.03, item 5.a., should apply for a license from the U.S. Nuclear Regulatory Commission pursuant to 10 CRF 32.30 and for a certificate of registration in accordance with 10 CRF 32.210.

LICENSES

3-005 TYPES OF LICENSES: Licenses for radioactive materials are of two types: general and specific:

3-005.01 General licenses provided in 180 NAC 3 are effective without the filing of applications with the Department or the issuance of licensing documents to the particular persons. However, registration or certification with the Department may be required by the particular general license. The general licensee is subject to all other applicable portions of Title 180 and any limitations based on the type and quantity of radioactive material of the general license.

3-005.02 Specific licenses require the submission of an application to the Department and the issuance of a licensing document by the Department. The licensee is subject to all applicable portions of Title 180 as well as any limitations based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s) specified in the licensing document.

3-006 RADIOACTIVE DRUG: CAPSULES CONTAINING CARBON-14 UREA FOR “IN-VIVO” DIAGNOSTIC USE FOR HUMANS

3-006.01 Except as provided in 180 NAC 3-006.02, any person is exempt from the requirements for a license set forth in the Act and from the regulations in 180 NAC 3 and 7 provided that such person receives, possesses, uses, transfers, owns or acquires

capsules containing 37 kBq (1μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use for humans.

3-006.02 Any person who desires to use the capsules for research involving human subjects must apply for and receive a specific license pursuant to 180 NAC 7.

3-006.03 Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules must apply for and receive a specific license from the Nuclear Regulatory Commission pursuant to 10 CFR 32.21.

3-006.04 Nothing in 180 NAC 3-006 relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

GENERAL LICENSES

3-007 GENERAL LICENSES - SOURCE MATERIAL

3-007.01 A general license is hereby issued authorizing commercial and industrial firms;, research, educational; and medical institutions and Federal, State and local government agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, ~~not more than 15 pounds (6.82 kg) of source material at any one~~ for research, development, educational, commercial, or operational purposes in the following forms and quantities: ~~A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.~~

1. No more than 3.3 pounds (1.5 kg) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under 180 NAC 3-007.01 may not receive more than a total of 15.4 pounds (7 kg) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of the effective date of these regulations, may continue to possess up to 15.4 pounds (7 kg) of uranium and thorium at any one time for one year beyond this date, or until the Department takes final action on a pending application submitted on or before one year following the effective date of these regulations, for a specific license for such material; and receive up to 154 pounds (70 kg) of uranium or thorium in any one calendar year until December 31, of the year following the effective date of these regulations or until the Department takes final action on a pending application submitted as referenced above for a specific license for such material; and

2. No more than a total of 15.4 pounds (7 kg) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under

180 NAC 3-007.01 may not receive more than a total of 154 pounds (70 kg) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under 180 NAC 3-007.01 unless it is accounted for under the limits of 180 NAC 3-007.01, item 1; or

3. No more than 15.4 pounds (7 kg) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 154 pounds (70 kg) of uranium from drinking water during a calendar year under this paragraph; or

4. ~~1.~~ No more than 15.4 pounds (7 kg) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 154 pounds (70 kg) of source material in any one calendar year.

3-007.02 Any ~~P~~person~~s~~ who receive~~s~~, possesse~~s~~, use~~s~~, or transfer~~s~~ source material in accordance with ~~pursuant to~~ the general license ~~issued~~ in 180 NAC 3-007.01: ~~are exempt from the provisions of 180 NAC 4 and 10 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption does not apply to any such person who is also in possession of source material under a specific license issued pursuant to 180 NAC 3.~~

1. Are prohibited from administering source material, or the radiation there from, either externally or internally, to human beings except as may be authorized by the Department in a specific license.

2. Must not abandon such source material. Source material may be disposed of as follows:

   a. A cumulative total of 1.1 pounds (0.5 kg) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of 180 NAC 3-007.02 is exempt from the requirements to obtain a license under 180 NAC 3 to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under 180 NAC 3; or

   b. In accordance with 180 NAC 4-039.

3. Are subject to the provisions in 180 NAC 1-005, 1-006, 1-008, 1-012, 1-014, 3-001.01, 3-002, 3-017.01 through 3.017.05, 3-017.010, 3-025, 3-026, 3-027, 3-030, 10-002 and 10-007.03.

4. Must not export such source material except in accordance with 10 CFR 110.

3-007.03 Any person who receives possesses, uses, or transfers source material in accordance with 180 NAC 3-007.01 must conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee must notify the Department at the address listed in 180 NAC 1-012, about such contamination and may consult with the Department as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 180 NAC 4-016. ~~A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material~~.

3-007.04 Depleted Uranium In Industrial Products and Devices.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 180 NAC 3-007.04 items 2 through 5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in 180 NAC 3-007.04, item 1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 180 NAC 3-014.13 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 must:

   a. File Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License," with the Department. The form must be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant must furnish on Department Form NRH-11 the following information and such other information as may be required by that form:

      (1) Name and address of the general licensee;
      (2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 180 NAC 3-007.04, item 1 and designed to prevent transfer of such depleted uranium in any form,

including metal scrap, to persons not authorized to receive the depleted uranium; and

(3) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 180 NAC 3-007.04, item 3.a.(2).

b. Report in writing to the Department any changes in information furnished by him/her in Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License." The report must be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 must:

a. Not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

b. Not abandon such depleted uranium.

c. Transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 180 NAC 3-025 and 4-039. In the case where the transferee receives the depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1, the transferor must furnish the transferee a copy of these regulations and a copy of Department Form NRH-11. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 180 NAC 3-007.04, item 1, the transferor must furnish the transferee a copy of Title 180 and a copy of Department Form NRH-11 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in Title 180.

d. Within 30 days of any transfer, report in writing to the Department the name and address of the person receiving the depleted uranium pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 is exempt from the requirements of 180 NAC 4 and 10 with respect to the depleted uranium covered by that general license.

3-007.05 Persons who receive, possess, use, or transfer source material pursuant to the general license in 180 NAC 3-007.01 are prohibited from administering source material,

or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Department in a specific license.

3-007.06 Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 180 NAC 3-007.01 is exempt from the provisions of 180 NAC 3, 4 and 10 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person must comply with the provisions of 180 NAC 4-016 and 4-039 to the extent necessary to meet the provisions of 180 NAC 3-007.02, item 2 and 3-007.03. However, this exemption does not apply to any person who also holds a specific license issued under this 180 NAC 3.

3-007.07 No person may initially transfer or distribute source material to persons generally licensed under paragraph 180 NAC 3-007.01, item 1 and 2, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, unless authorized by a specific license issued in accordance with 180 NAC 3-007.08 or equivalent provisions of the U.S. Nuclear Regulatory Commission or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by 180 NAC 3-007.01 on or before the date of these regulations, without specific authorization may continue for 1 year beyond this date. Distribution may also be continued until the Department takes final action on a pending application for license or license amendment to specifically authorize distribution submitted one year after the effective date of these regulations.

3-007.08 An application for a specific license to initially transfer source material for use under 180 NAC 3-007.01 or equivalent regulations the U.S. Nuclear Regulatory Commission or of an Agreement State, will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011; and

2. The applicant submits adequate information on, and the Department approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

3-007.09 Each person licensed under 180 NAC 3-007.08 must:

1. Label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, “radioactive material.”
2. Ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

3. Provide the information specified in 180 NAC 3-007.09 to each person to whom source material is red for use under180 NAC 3-007.01 or equivalent provisions in the U.S. Nuclear Regulatory Commission or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

a. A copy of 180 NAC 3-007.01 and 3-025, or relevant equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

b. Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

4. Each person licensed under 180 NAC 3-007.08 must report transfers as follows:

a. File a report with the Manager, Office of Radiological Health, Nebraska Department of Health and Human Services, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509 The report must include the following information:

(1) The name, address, and license number of the person who transferred the source material;

(2) For each general licensee under180 NAC 3-007.022 or equivalent U.S. Nuclear Regulatory Commission or Agreement State provisions to whom greater than 50 grams (0.11 pounds) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(3) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

b. File a report with each responsible U.S. Nuclear Regulatory Commission and Agreement State agency that identifies all persons, operating under provisions equivalent to 180 NAC 3-007.01, to whom greater than 50 grams (0.11 pounds) of source material has been transferred within a single calendar quarter. The report must include the following information specific to those transfers made to the U.S. Nuclear Regulatory Commission or Agreement State being reported to:

(1) The name, address, and license number of the person who transferred the source material; and

(2) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(3) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or U.S. Nuclear Regulatory Commission.

c. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 180 NAC 3-007.01 or equivalent U.S. Nuclear Regulatory Commission or Agreement State provisions during the current period, a report must be submitted to the Commission indicating so. If no transfers have been made to general licensees in a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency

5. Each person licensed under 180 NAC 3-007.08 must maintain all information that supports the reports required by this 180 NAC 3-007 concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Department, U.S. Nuclear Regulatory Commission or to an Agreement State agency.

3-008 GENERAL LICENSES - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL[5]

3-008.01 Reserved ~~Certain Devices and Equipment: A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of 180 NAC 1-004 through 009, 180 NAC 3-004.01, item 2, 180 NAC 3-017, 3-025, and 3-026, 3-030, 180 NAC 4,[6] and 180 NAC 10, 13, 17 and 18.~~

~~1. Static Elimination Device. Devices designed for use as static eliminators which contain, as sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device.~~

~~2. Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device or a total of not more than 1.85 GBq (50 millicuries) of hydrogen-3 (tritium) per device.~~

~~3. A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of 180 NAC 3, a general licensee under this 180 NAC 3-008 is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.~~

[5]Note: Different general licenses are issued in 180 NAC 3-008, each of which has its own specific conditions and requirements.

[6]~~Attention is directed particularly to the provisions of 180 NAC 4 which relate to the labeling of containers.~~

3-008.02 Reserved

3-008.03 Reserved

3-008.04 Certain Detecting, Measuring, Gauging or ~~and~~ Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere[7]

1. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of 180 NAC 3-008.04, items, 2, 3 and 4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

2. The general license in 180 NAC 3-008.04, item 1 applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specification contained in a specific license issued under 180 NAC 3-014.04; or an equivalent specific license issued by the U. S. Nuclear Regulatory Commission or an Agreement State with provisions comparable to 180 NAC 3.014.04.

   The devices must have been received from one of the specific licensees described in this paragraph or through a transfer made under 180 NAC 3-008.04, item 3.i.

3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 180 NAC 3-008.04, item 1 must:

   a. Assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and comply with all instructions and precautions provided by such labels;

   b. Assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however,

[7]Persons possessing radioactive material in devices under 180 NAC 3-008.04 before January 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 180 NAC 3-008.04 in effect on January 14, 1975.

(1) Devices containing only krypton need not be tested for leakage of radioactive material, and
(2) Devices containing only tritium or not more than 3.7 MBq (100 microcuries) of other beta and/or gamma emitting material or 0.37 MBq (10 microcuries) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

c. Assure that the tests required by 180 NAC 3-008.04, item 3.b. and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(1) In accordance with the instructions provided by the labels; or
(2) By a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such activities;

d. Maintain records showing compliance with the requirements of 180 NAC 3-008.04, items 3.b. and 3.c. The records must show the results of the tests. The records also must show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. The licensee must retain these records as follows:

(1) Each record of tests for leakage of radioactive material required by 180 NAC 3-008.04, item 3.b. must be retained for three years after the next required leak test is performed or ~~maintained~~ until the sealed source is transferred or disposed of.
(2) Each record of tests of the on/off mechanism and indicator required by 180 NAC 3-008.04, item 3.b. must be retained for three years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of.
(3) Each record which is required by 180 NAC 3-008.04, item 3.c. must be retained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;

e. Immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 becquerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by this Department, the U.S. Nuclear Regulatory Commission or by an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the

radioactive material in the device or as otherwise approved by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becqueral (0.005 microcurie) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Department within 30 days. Under these circumstances, the criteria set out in 180 NAC 4-016, "Radiological Criteria for Unrestricted Use," may be applicable, as determined by the Department on a case-by-case basis;

f. Not abandon the device containing radioactive material;

g. Not export the device containing radioactive material except in accordance with 10 CFR 110.

h. Transfer or Disposal of Device Containing Radioactive Material

(1) Transfer or dispose of the device containing radioactive material only by export as provided by 180 NAC 3-008.04 item 3.g., by transfer to another general licensee as authorized in paragraph 180 NAC 3-008.04, item 3. i., or to a person authorized to receive the device by a specific license issued under 180 NAC 3, or 180 NAC 12 that authorized waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under 180 NAC 3-008.04, item 3. h.

(2) Furnish a report to the Department within 30 days after the transfer of a device to a specific licensee or export. The report must contain:

(a) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;
(b) The name, address, and license number of the person receiving the device (license number not applicable if exported); and
(c) The date of the transfer.

(3) Obtain written Department approval before transferring the device to any other specific licensee not specifically identified in 180 NAC 3-008.04 item 3.h.(1). However a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(a) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(b) Removes, alters, covers, or clearly and unambiguously augments the existing label otherwise required by 180 NAC 3-008.04, item 3.a. so that the device is labeled in compliance with 180 NAC 4-036; however the manufacturer, model number, and serial number must be retained;

(c) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(d) Reports the transfer under paragraph 180 NAC 3-008.04, item 3.h.(2).

i. Transfer the device to another general licensee only if:

(1) The device remains in use at a particular location. In such case the transferor must give the transferee a copy of 180 NAC 3-008.01, 3-030, 4-057, and 4-058, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor must report to the Department:

(a) The manufacturer’s (or initial transferor’s) name;
(b) The model number and the serial number of the device transferred;
(c) The transferee’s name and mailing address for the location of use; and
(d) The name, title, and phone number of the responsible individual identified by the transferee in accordance with 180 NAC 3-008.04, item 3., l. to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(2) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

j. Comply with the provisions of 180 NAC 4-057 and 4-058 for reporting radiation incidents, theft, or loss of licensed material, but will be exempt from the other reporting requirements of 180 NAC 4 and 10.

k. Respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it must, within the same time period, request a longer period to supply information by submitting a letter to the Radioactive Material Program Manager, Nebraska Department of Health and Human Services, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026 and provide written justification as to why it cannot comply.

l. Appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

m. Register general license devices.

(1) Register, in accordance with 180 NAC 3-008.04, item 3., m., (2) and (3), devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 millicurie) of radium-226,or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described in 180 NAC 3-008.04, item 3., m., (3), d., represents a separate general licensee and requires a separate registration and fee.

(2) If in possession of a device meeting the criteria of 180 NAC 3-008.04, item 3., m., (1), must register these devices annually with the Department and must pay the fee required by 180 NAC 18. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices that meet the criteria of 180 NAC 3-008.04, item 3 m. (1) is subject to the bankruptcy notification requirement in 180 NAC 3-017.05.

(3) In registering devices, the general licensee must furnish the following information and any other information specifically requested by the Department:

(a) Name and mailing address of the general licensee.
(b) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radionuclide and activity (as indicated on the label).
(c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee in 180 NAC 3-008.04, item 3. l.
(d) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.
(e) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of

label information.

(f) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(4) Persons generally licensed by an Agreement State or the NRC, with respect to devices meeting the criteria in paragraph 180 NAC 3-008.04, item 3., m. (1) are not subject to registration requirements if the devices are used in areas subject to Department jurisdiction for a period less than 180 days in any calendar year. The Department will not request registration information from such licensees.

n. Report changes to the mailing address for the location of use (including change in name of general licensee) to the Radioactive Materials Program Manager, Nebraska Department of Health and Human Services, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026 within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

o. Not hold unused devices for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 180 NAC 3-008.04, item 3. b. need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

4. The general license in 180 NAC 3-008.04, item 1. does not authorize the manufacture or import of devices containing radioactive material.

5. The general license provided in 180 NAC 3-008.04, item 1. is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, and 180 NAC 13 .

3-008.05 Luminous Safety Devices for Aircraft

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

a. Each device contains not more than 370 GBq (l0 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147; and

b. Each device has been manufactured, assembled or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 30.33 and 32.53.

2. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 180 NAC 3-008.05, item 1. are exempt from the requirements of 180 NAC 4 and 10 except that they must comply with the provisions of 180 NAC 4-057 and 4-058.

3. This general license does not authorize the manufacture, assembly, repair, or import of luminous safety devices containing tritium or promethium-147.

4. This general license does not authorize ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

5. This general license is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, and 13.

6. This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

3-008.06 Ownership of Radioactive Material: A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 180 NAC 3, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

3-008.07 Calibration and Reference Sources

1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 180 NAC 3-008.07, items 4. and 5., americium-241 in the form of calibration or reference sources:

   a. Any person who holds a specific license issued by the Department which authorizes the licensee to receive, possess, use, and transfer radioactive material; and
   b. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the licensee to receive, possess, use, and transfer special nuclear material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 180 NAC 3-008.07, items 4. and 5. to any person who holds a

specific license issued by the Department which authorizes the licensee to receive, possess, use, and transfer radioactive material.

3. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 180 NAC 3-008.07, items 4 and 5 to any person who holds a specific license issued by the Department which authorizes the licensee to receive, possess, use, and transfer radioactive material.

4. The general licenses in 180 NAC 3-008.07, items 1. through 3. apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 30.33, in accordance with the specifications contained in a specific license issued to the manufacturer by the Department, or any Agreement State pursuant to licensing requirements equivalent to those contained in 10 CFR 30.33.

5. The general licenses provided in 180 NAC 3-008.07, items 1. through 3. are subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, 180 NAC 4, 10, and 13. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses must:

   a. Not possess at any one time, at any one location of storage or use, more than 185 kBq (5 microcuries) of americium-241, 185 kBq (5 microcuries) of plutonium, and 185 kBq (5 microcuries) of radium-226 in such sources;

   b. Not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement.

      (1) The receipt, possession, use and transfer of this source Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

      CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (RADIUM-226) (AMERICIUM-241). (PLUTONIUM)[8] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

[8]Showing only the name of the appropriate material.

_____
Name of manufacturer or importer

c. Not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, or any other Agreement State to receive the source;

d. Store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

e. Not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

6. These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

3-008.08 Reserved

3-008.09 General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 6., the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

   a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
   b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
   c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
   d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.
   e. Colbalt-57, in units not exceeding 0.37MBq (01 microcuries each).

2. No person receives, acquires, possesses, uses or transfers radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until s/he has filed Department Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Department and received from the Department a validated copy of Department Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital must furnish on Department Form NRH-17 the following information and such other information as may be required by that form:

   a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
   b. The location of use; and
   c. A statement that the physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 180 NAC 3-008.09, item 1. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. must comply with the following:

   a. The general licensee must not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).

   b. The general licensee must store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

   c. The general licensee must use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.

   d. The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

   e. The general licensee must dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-039 and 4-044.

4. The general licensee must not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:

   a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 180 NAC 3-008.09 or its' equivalent, and

   b. Unless the following statement, or substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

      This radioactive material is received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

      _____
      Name of Manufacturer

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 180 NAC 3-008.09, item 1. must report in writing to the Department, any changes in the information furnished by him/her in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form NRH-17. The report must be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of 180 NAC 3-008.09, item 1 is exempt from the requirements of 180 NAC 4 and 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1.d. must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

3-008.10 Ice Detection Devices

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 microcuries) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 180 NAC 3-008.10, item 1,

   a. Must upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or must dispose of the device pursuant to the provisions of 180 NAC 4-039;
   b. Must assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and
   c. Are exempt from the requirements of 180 NAC 4 and 10 except that such persons must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

3. This general license does not authorize the manufacture, assembly, disassembly, repair or import of strontium-90 in ice detection devices.

4. This general license is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 180 NAC 3-025, 180 NAC 3-027, and 180 NAC 13.

3-008.11 General license for certain items and self-luminous products containing radium-226.

3-008.11.01A A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of 180 NAC 3-008.11.01B, 3-008.11.01 C and 3-008.11.01D, radium-226 contained in the following products manufactured prior to November 30, 2007:

1. Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

2. Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.
3. Luminous items installed in air, marine, or land vehicles.
4. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.
5. Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the U.S. Nuclear Regulatory Commission.

3-008.11.01B Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in 180 NAC 3-08.11.01A are exempt from the provisions of 180 NAC 4, 10 , 3-026 and 3-030, to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption must not be deemed to apply to any such person specifically licensed under 180 NAC 3.

3-008.11.01C Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in 180 NAC 3-008.11.01A:

1. Will notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of Public Health of the Nebraska Department of Health and Human Services, P.O. Box 95026, Lincoln, NE 68509 within 30 days.

2. Will not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 180 NAC 4-039 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the U.S. Nuclear Regulatory Commission.
3. Will not export products containing radium-226 except in accordance with 10 CFR § 110.
4. Will dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under 180 NAC 3, or equivalent regulations of this Department or an Agreement State, or U.S. Nuclear Regulatory Commission.
5 Will respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot

provide the requested information within the allotted time, it must, within that same time period, request a longer period to supply the information by providing the Director of Public Health of the Nebraska Department of Health and Human Services, by an appropriate method listed in 180 NAC 1-012, a written justification for the request.

3-008.11.01D The general license in 180 NAC 3-008.11.01A does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

3-009 RESERVED

SPECIFIC LICENSES

3-010 FILING APPLICATION FOR SPECIFIC LICENSES

3-010.01 Applications for specific licenses must be filed on form NRH-7 (medical) for all medical licenses and form NRH-5 for all other licenses.

3-010.02 The Department may at any time after the filing of the original application require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

3-010.03 Each application must be signed by the applicant or licensee or a person duly authorized to act for and on his/her behalf.

3-010.04 An application for a license may include a request for a license authorizing one or more activities.

3-010.05 RESERVED

3-010.06 Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

3-010.07 As provided by 180 NAC 3-018 certain applications for specific licenses filed under 180 NAC 3, 5, and 7, must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

3-010.08

1. Except as provided in 180 NAC 3-010.08, items 2, 3, and 4, an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

   a. ~~1.~~ Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR

32.210 or with an Agreement State, or for source or a device containing radium-226 or accelerator-produced radioactive material with the U.S. Nuclear Regulatory Commission or an State under provisions comparable to 10 CFR § 32.210. or

b. ~~2.~~ Contain the information identified in 10 CFR 32.210(c); or

2.. For sources or devices ~~containing naturally occurring or accelerator-produced radioactive material~~ manufactured prior to October 23, 2012 ~~November 30, 2007~~ that are not registered with the U.S. Nuclear Regulatory Commission under 10 CFR § 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CRF § 32.210(c), the applicant must provide:

a. All available information identified in 10 CFR § 32.210(c) concerning the source, and, if applicable, the device; and

b. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

3. For sealed sources and devices allowed to be distributed without registration of safety information per 10 CFR §32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

4. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

3-010.09 Emergency Plans

1. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 180 NAC 3, Appendix 3-E "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release" must contain either:

a. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
b. An emergency plan for responding to a release of radioactive material.

2. One or more of the following factors may be used to support an evaluation submitted under 180 NAC 3-010.09, item 1:

   a. The radioactive material is physically separated so that only a portion could be involved in an accident;
   b. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
   c. The release fraction in the respirable size range would be lower than the release fraction shown in 180 NAC 3, Appendix 3-E due to the chemical or physical form of the material;
   d. The solubility of the radioactive material would reduce the dose received;
   e. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 180 NAC 3, Appendix 3-E;
   f. Operating restrictions or procedures would prevent a release fraction as large as that shown in 180 NAC 3, or
   g. Other factors appropriate for the specific facility.

3. An emergency plan for responding to a release of radioactive material submitted under 180 NAC 3-010.09 must include the following information:

   a. Facility description: A brief description of the licensee's facility and area near the site.
   b. Types of accidents: An identification of each type of radioactive materials accident for which protective actions may be needed.
   c. Classification of accidents: A classification system for classifying accidents as alerts or site area emergencies.
   d. Detection of accidents: Identification of the means of detecting each type of accident in a timely manner.
   e. Mitigation of consequences: A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
   f. Assessment of releases: A brief description of the methods and equipment to assess releases of radioactive materials.
   g. Responsibilities: A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.
   h. Notification and coordination: A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must to be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee must also commit to notify the Department immediately after

notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[9]

i. Information to be communicated: A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.

j. Training: A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training must familiarize personnel with site-specific emergency procedures. Also, the training must thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

k. Safe shutdown: A brief description of the means of restoring the facility to a safe condition after an accident.

l. Exercises: Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee must invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios must not be known to most exercise participants. The licensee must critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

m. Hazardous chemicals: A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, P. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

4. The licensee must allow the offsite response organizations, expected to respond in case of an accident, 60 days to comment on the licensee's emergency plan before submitting it to the Department. The licensee must

[9]These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, P. L. 99-499 or other state or federal reporting requirements.

provide any comments received within the 60 days to the Department with the emergency plan.

3-010.11 An application from a medical facility, or educational institution, to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 180 NAC 7 or equivalent Agreement State or U.S. NRC requirements must include:

1.. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 180 NAC 3, U.S. NRC or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 180 NAC 3-014.10, item 1,b,

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 180 NAC 3-014.10, item 2.b.

4 Information identified in 180 NAC 3-014.10, item 1.c. on the PET drugs to be noncommercially transferred to members of its consortium.

3-011 GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES: A license application will be approved if the Department determines that:

1. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with Title 180 in such a manner as to minimize danger to public health and safety or property;
2. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to the public health and safety or property;
3. The issuance of the license will not be inimical to the health and safety of the public; and
4. The applicant satisfies any applicable special requirements in 180 NAC 3-013, 180 NAC 3-014, or 180 NAC 3-015, 180 NAC 5, 180 NAC 7, 180 NAC 12, 180 NAC 14 or 180 NAC 19.

3-011.01 Environmental Report, Commencement of Construction: In the case of an application for a license to receive and possess radioactive material for commercial waste management, source material milling, or for the conduct of any other activity which the Department determines will significantly affect the quality of the environment, the Department, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion is grounds for denial of a license to receive and possess

radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of the environmental values.

3-011.02 Financial Surety Arrangements for Site Reclamation

1. Pursuant to Radiation Control Act §71-3508.04, Reissued Revised Statues of Nebraska 1943, as amended and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 180 NAC 3-011.02 must be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the Act.

    a. The amount of funds to be ensured by such surety arrangements must be based on Department approved cost estimates equal to meet the requirements of 180 NAC 3-011.02, item 1.
    b. Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

2. The arrangements required in 180 NAC 3-011.02, item 1. must be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility, except as provided in 180 NAC 3-011.02, item 3.

3. If application is made to amend an existing license to fall within the purview of 180 NAC 3-011.06 then the financial surety arrangements for site reclamation must be established prior to the issuance of the amendment.

4. The following specific licensees are required to make financial surety arrangements:

    a. Major processors;
    b. Waste management licensees, except the commercial disposal of low-level radioactive waste in a disposal facility, designated by the Central Interstate Low-Level Radioactive Waste Compact Commission;
    c. Former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities;
    d. Source material milling operations; and
    e. All others except persons exempt pursuant to 180 NAC 3-011.02, item 5.

5. The following persons are exempt from the requirements of 180 NAC 3-011.02, item 1. because they are exempt from licensure:

   a. All State, local, or other government agencies unless they are subject to 180 NAC 3-011.02, item 4.b. or 4.d.,
   b. Persons authorized to possess no more than 1,000 times the quantity specified in 180 NAC 3, Appendix 3-B or combination of radioactive material listed therein as given in 180 NAC 3, Appendix 3-B, Note 1.;
   c. Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or
   d. Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

6. Long-term Care Requirements: Pursuant to Radiation Control Act §71-3508.04, Reissued Revised Statues of Nebraska, 1943, as amended and as otherwise provided, a long-term care fund must be established by the following specific licensees prior to the issuance of the license or prior to the termination of the license if the applicant chooses at the time of the licensure to provide a surety in lieu of a long-term care fund:

   a. Waste management licensees.
   b. Source material milling and mill tailings licensees.

3-012 RESERVED

3-013 SPECIAL REQUIREMENTS FOR SPECIFIC LICENSES OF BROAD SCOPE: 180 NAC 3-013 prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses:

3-013.01 The different types of broad licenses are set forth below:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range, and the limits are based on types of radioactive materials, proposed use and upon the training and experience of the user(s).

2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 180 NAC 3, Appendix 3-C for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I of 180 NAC 3, Appendix 3-C, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 180 NAC 3, Appendix 3-C,

Column l, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 180 NAC 3, Appendix 3-C for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 180 NAC 3, Appendix 3-C, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in 180 NAC 3, Appendix 3-C, Column II for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

3-013.02 An application for a Type A specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011;
2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

    a. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
    b. The appointment of a radiation safety officer who is qualified in training and experience in radiation protection consistent with the requirements of training specified in 180 NAC 15-015.01, item 1, and who is available for advice and assistance on radiation safety matters; and
    c. Authorized users designated by the Radiation Safety Committee must have formal training and experience in the safe handling of radioactive material consistent with the requirements of training specified in 180 NAC 15-015.01, item 2.; and
    d. The establishment of appropriate administrative procedures to assure:

        (1) Control of procurement and use of radioactive material;
        (2) Completion of safety evaluations of proposed uses of radioactive material which takes into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
        (3) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 180 NAC 3-013.02, item 3.d.(2). prior to use of the radioactive material.

3-013.03 An application for a Type B specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011; and
2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

    a. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection consistent with the requirements of training specified in 180 NAC 15-015.01, item 1 and who is available for advice and assistance on radiation safety matters,
    b. Authorized users must have formal training and experience in the safe handling of radioactive material consistent with the requirements of training specified in 180 NAC 15-015.01, item 2; and
    c. The establishment of appropriate administrative procedures to assure:

        (1) Control of procurement and use of radioactive material,
        (2) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and
        (3) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 180 NAC 3-013.03, item 2.c. prior to use of the radioactive material.

3-013.04 An application for a Type C specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011;
2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

    a. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and
    b. At least 40 hours of formal training and 160 hours experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

3-013.05 Specific licenses of broad scope are subject to, based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s), to the following conditions:

1. Unless specifically authorized, persons licensed pursuant to 180 NAC 3-013 must not:

   a. Conduct tracer studies in the environment involving direct release of radioactive material;
   b. Receive, acquire, own, possess, use or transfer devices containing 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources used for irradiation of materials;
   c. Conduct activities for which a specific license issued by the Department under 180 NAC 3-014, 3-015 or 180 NAC 7, and 12 is required; or
   d. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

2. Each Type A specific license of broad scope issued under this 180 NAC 3-013.05 is subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

3. Each Type B specific license of broad scope issued under 180 NAC 3-013.05 is subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

4. Each Type C specific license of broad scope issued under this 180 NAC 3-013.05, item 4 is subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 180 NAC 3-013.04.

3-014 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR, OR DISTRIBUTE COMMODITIES, PRODUCTS, OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL

3-014.01 Reserved

3-014.02 Prohibition of introduction. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 180 NAC 3.004.01 or equivalent regulation of an Agreement State or U.S. Nuclear Regulatory Commission, except in accordance with a license issued under 10 CFR32.11.

3-014.03 Licensing the Incorporation of Naturally Occurring Accelerator-Produced Radioactive Material Into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to

persons exempt under 180 NAC 3-004.03, item 3 will be approved if the application satisfies the requirements of 10 CFR 32.26 . The maximum quantity of radium-226 in each device must not exceed 3.7 kBq (0.1 microcurie).

3-014.04 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 180 NAC 3-008.04

1. An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 180 NAC 3-008.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or an Agreement State will be approved if:

   a. The applicant satisfies the general requirements of 180 NAC 3-011;
   b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

      (1) The device can be safely operated by persons not having training in radiological protection;
      (2) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in 180 NAC 4-005.01; and
      (3) Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	150 mSv (15 rems)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	2 Sv (200 rems)
Other organs	500 mSv (50 rems)

   c. Each device bears a durable, legible, clearly visible label or labels approved by the Department, which contain in a clearly identified and separate statement:

      (1) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device. Documents such as

operating and service manuals may be identified in the label and used to provide this information;

(2) The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(3) The information called for in the following statement, as appropriate in the same or substantially similar form:

The receipt, possession, use, and transfer of this device Model _____[10], Serial No. _____[10], are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of Manufacturer or Distributor[10]

d. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the radionuclide and quantity, the words, "`Caution-Radioactive Material," the radiation symbol described in 180 NAC 4-033.01, and the name of the manufacturer or initial distributor.

e. Each device meeting the criteria of 180 NAC 3-008.04, item 3. m. (1), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in 180 NAC 4-033.01.

f. The device has been registered in the Sealed Source and Device Registry.

2. In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant must include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics

[10]The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified and labeling affixed to the device.

of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider information which includes, but is not limited to:

a. Primary containment or source capsule;
b. Protection of primary containment;
c. Method of sealing containment;
d. Containment construction materials;
e. Form of contained radioactive material;
f. Maximum temperature withstood during prototype tests;
g. Maximum pressure withstood during prototype tests;
h. Maximum quantity of contained radioactive material;
i. Radiotoxicity of contained radioactive material; and
j. Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under 180 NAC 3-008.04, or under equivalent regulations of U.S. Nuclear Regulatory Commission, or an Agreement State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant must include in his/her application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information must demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10% of the annual limits specified in 180 NAC 4-005.01.

4. Conditions of transferring a device for use under a general license in 180 NAC 3-008.04.

a. If a device containing radioactive material is to be transferred for use under the general license in 180 NAC 3-008.04, each person that is licensed under 180 NAC 3-014.04 must provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(1) A copy of the general license contained in 180 NAC 3-008.04, item 3. b. through d. or item 3.m. do not apply to the particular device, those paragraphs may be omitted.
(2) A copy of 180 NAC 3-008.01, 180 NAC 3-030, 180 NAC 4-057 and

4-058;

(3) A list of the services that can only be performed by a specific licensee;

(4) Information on acceptable disposal options including estimated costs of disposal; and

(5) An indication that the Department's policy is to issue high civil penalties for improper disposal.

b. If radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission or an Agreement State, each person that is licensed under 180 NAC 3-014.04 provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(1) A copy of the 180 NAC 3-008.01, 180 NAC 3-008.04, 180 NAC 4-057 and 058 or a copy of equivalent U.S. Nuclear Regulatory Commission or Agreement State's regulations. If a copy of the U.S. Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Department's or Agreement State's regulations, it must be accompanied by a note explaining that use of the device is regulated by the U. S. Nuclear Regulatory Commission or an Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

(2) A list of the services that can only be performed by a specific licensee;

(3) Information on acceptable disposal options including estimated costs of disposal; and

(4) The name or title, address, and phone number of the contact at the Department, U.S. Nuclear Regulatory Commission or Agreement State from which additional information may be obtained.

c. An alternative approach to informing customers may be proposed by the licensee for approval by the Department.

d. Each device that is transferred after April 12, 2003 must meet the labeling requirements in 180 NAC 3-014.04, item 1.c. through d.

e. If a notification of bankruptcy has been made under 180 NAC 3-017.05 or the license is to be terminated, each person licensed under 180 NAC 3-014.04 must provide, upon request, to the Department, the U.S. Nuclear Regulatory Commission and to any appropriate Agreement State, records of final disposition required under 180 NAC 3-014.04, item 5. c.

5. Material transfer reports and records. Each person under 180 NAC 3-014.04 to initially transfer devices to generally licensed persons must comply with the

requirements of 180 NAC 3-014.04, item 5.

a. The person must report all transfers of devices to persons for use under the general license in 180 NAC 3-008.04 and all receipts of devices from persons licensed under 180 NAC 3-008.04 to the Radioactive Material Program Manager, Nebraska Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026. The report must be submitted on a quarterly basis on the NRH Form 653, “Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes:

(a) The identity of each general licensee by name and mailing location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use.
(b) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
(c) The date of transfer;
(d) The type, model number, and serial number of the device transferred; and
(e) The quantity and type of radioactive material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
(3) For devices received from a 180 NAC 3-008.04 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
(4) If the licensee makes changes to a device possessed by a 180 NAC 3-008.04 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
(6) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(7) If no transfers have been made to or from persons generally licensed under 180 NAC 3-008.04 during the reporting period, the report must so indicate.

b. The person must report all transfers of devices to persons for use under a general license in an U.S. Nuclear Regulatory Commission or Agreement State's regulations that are equivalent to 180 NAC 3-008.04 and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commission or Agreement State's jurisdiction to the U.S. Nuclear Regulatory Commission or responsible Agreement State agency. The report must be submitted on the Department's Form 653, "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes:

(a) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use.
(b) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
(c) The date of transfer;
(d) The type, model number, and serial number of the device transferred; and
(e) The quantity and type of radioactive material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
(3) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
(4) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate

the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(7) If no transfers have been made to or from the U.S. Nuclear Regulatory Commission or a particular Agreement State during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission or responsible Agreement State agency upon request of the Department.

c. The person must maintain all information concerning transfers and receipts of devices that supports the reports required by this 180 NAC 3-014.04, Item 5. Records required by 180 NAC 3-014.04, item 5 must be maintained for a period of 3 years following the date of the recorded event.

3-014.05 Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 180 NAC 3-008.05 will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011, and
2. The applicant satisfies the requirements of 10 CFR ~~30.33,~~ 32.53 through 32.56. ~~and 32.101~~
3. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.06 Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under 180 NAC 3-008.07. An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 for distributions to persons generally licensed under 180 NAC 3-008.07 will be approved subject to the following conditions:

1. The applicant satisfies the general requirement of 180 NAC 3-011, and
2. The applicant satisfies the requirements of 10 CFR ~~30.33,~~ 32.57 through 32.59, ~~32.102, and 70.39,~~ and
3. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.07 Reserved

3-014.08 Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to

manufacture or distribute radioactive material for use under the general license of 180 NAC 3-008.09 will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011.
2. The radioactive material is to be prepared for distribution in prepackaged units of:

   a. Iodine-125 in units not exceeding 370 kBq (10 microcuries) each.
   b. Iodine-131 in units not exceeding 370 kBq (10 microcuries) each.
   c. Carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
   d. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 microcuries) each.
   e. Iron-59 in units not exceeding 740 kBq (20 microcuries) each.
   f. Cobalt-57 in units not exceeding 370 kBq (10 microcuries) each.
   g. Selenium-75 in units not exceeding 370 kBq (10 microcuries) each.
   h. Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each.

3. Each prepackaged unit bears a durable, clearly visible label:

   a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10 microcuries) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 microcuries) of hydrogen-3 (tritium); 740 kBq (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each or colbalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

   b. Displaying the radiation caution symbol described in 180 NAC 4-033.01 and the words, "CAUTION, RADIOACTIVE MATERIAL" and "Not for Internal or External Use in Humans or Animals."

4. The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

   This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for In Vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 180 NAC 4-039.

6. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-019.01.

3-014.09 Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium 90. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 180 NAC 3-008.10 will be approved subject to the following conditions: The applicant satisfies the general requirements of 180 NAC 3-011, the criteria of 10 CFR 32.61, and 32.62. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under 180 NAC 7.

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 180 NAC 7, will be approved if:

   a. The applicant satisfies the general requirements specified in 180 NAC 3-011;

   b. The applicant submits evidence that the applicant is at least one of the following:

      (1) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
      (2) Registered or licensed with a state agency as a drug manufacturer;
      (3) Licensed according to 175 NAC 8, Pharmacies; or
      (4) Operating as a nuclear pharmacy within a Federal medical institution; or
      (5) A Positron Emission Tomography (PET) drug production facility registered with the Department.

   c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the

packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(2) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee described by 180 NAC 3-014.10, item 1.b.(3) or 1.b.(4).

a. May prepare radioactive drugs for medical use, as defined in 180 NAC 7-002, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 180 NAC 3-014.10, item 1.b. and d, or an individual under the supervision of an authorized nuclear pharmacist as specified in 180 NAC 7-018.

b. May allow a pharmacist to work as an authorized nuclear pharmacist if:

(1) This individual qualifies as an authorized nuclear pharmacist as defined in 180 NAC 7-002;

(2) This individual meets the requirements specified in 180 NAC 7-024.02 and 7-027 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(3) This individual is designated as an authorized nuclear pharmacist in accordance with 180 NAC 3-014.10, item 2.c.

c. The actions authorized in 180 NAC 3-014.10, items 2.a. and b. are permitted in spite of more restrictive language in license conditions.

d. May designate a pharmacist (as defined in 180 NAC 1-002) as an authorized nuclear pharmacist if the individual is identified as of the effective date of these regulations , as an “authorized user” on a nuclear pharmacy license issued by the Department under 180 NAC 3. if

(1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and
(2) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission.

e. Must provide to the Department a copy of each individual's:
(1) Certification by a specialty board whose certification process has been recognized by the Department, U.S. Nuclear Regulatory Commission, or any Agreement State as specified in 7-024.01 with the written attestation signed by a preceptor as required by 7-024.03; or
(2) The Department, the U.S. Nuclear Regulatory Commission, or any Agreement State license, or
(3) U.S. Nuclear Regulatory Commision master materials licensee permit, or
(4) The permit issued by a licensee or U.S. Nuclear Regulatory Commission master material permittee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or
(5) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission; and
(6) State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 180 NAC 3-014.10, item 2.b.(1) and (3), the individual to work as an authorized nuclear pharmacist.

3. A licensee must possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee must have procedures for use of the instrumentation. The licensee must measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee must:

a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
b. Check each instrument for constancy and proper operation at the beginning of each day of use.

4. Nothing in 180 NAC 3-014.10 relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

5. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with180 NAC 7-045. The licensee must record the results of each test and retain each record for 3 years after the record is made.

6. Positron Emission Tomography (PET)

a. Authorization under 180 NAC 3-010-11 to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

b.. Each licensee authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must:

(1) Satisfy the labeling requirements in 180 NAC 3-014.10, item 1.d. for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(2) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 180 NAC 3-014.10, item 3.

c. A licensee that is a pharmacy authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium will require that any individual that prepares PET radioactive drugs must be:

a. An authorized nuclear pharmacist that meets the requirements in 180 NAC 3-014.10, item 2.b. or

b. An individual under the supervision of an authorized nuclear pharmacist as specified in 180 NAC 7-018.

d. A pharmacy, authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized

nuclear pharmacist, mustl meet the requirements of 180 NAC 3-014.10, item 2.e.

3-014.11 Reserved

3-014.12. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 180 NAC 7 for use as a calibration, transmission or reference source or for the uses listed in 180 NAC 7-055, 7-065, 7-067 and 7-085 will be approved if:

1. The applicant satisfies the general requirements in 180 NAC 3-011.
2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

    a. The radioactive material contained, its chemical and physical form, and amount,
    b. Details of design and construction of the source or device,
    c. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
    d. For devices containing radioactive material, the radiation profile of a prototype device,
    e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
    f. Procedures and standards for calibrating sources and devices,
    g. Legend and methods for labeling sources and devices as to their radioactive content, and
    h. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Department has approved distribution of the (name of the source or device) to persons licensed to use radioactive material identified in 180 NAC 7-032, 7-055, 7-065 and 7-067 as appropriate, and to persons who hold an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

4. The source or device has been registered in the Sealed Source and Device Registry.

5. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months,

the applicant must include in his/her application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

6.5. In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

a. Primary containment or source capsule;
b. Protection of primary containment;
c. Method of sealing containment;
d. Containment construction materials;
e. Form of contained radioactive material;
f. Maximum temperature withstood during prototype tests;
g. Maximum pressure withstood during prototype tests;
h. Maximum quantity of contained radioactive material;
i. Radiotoxicity of contained radioactive material; and
j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

7. ~~6.~~ The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.13 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 180 NAC 3-007.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

a. The applicant satisfies the general requirements specified in 180 NAC 3-011;

b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one year a radiation dose in excess of 10% of the annual limits specified in 180 NAC 4-005.01; and

c. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable

assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under 180 NAC 3-014.13 only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The Department may deny any application for a specific license under 180 NAC 3-014.13 if the end use or uses of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to 180 NAC 3-014.13 item 1 must:

   a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

   b. Label or mark each unit to: (a) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and (b) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;

   c. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

   d. Furnish:

      (1) A copy of the general license contained in 180 NAC 3-007.04 and a copy of Department Form NRH-11 to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in 180 NAC 3-007.04; or

      (2) A copy of the general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 180 NAC 3-007.04 and a copy of the U.S. Nuclear Regulatory Commission or Agreement State's certificate; or alternatively, furnish a copy of the general license contained in 180 NAC 3-007.04 and a copy of Department Form NRH-11 to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use

of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 180 NAC 3-007.04;

e. Report to the Department all transfers of industrial products or devices to persons for use under the general license in180 NAC 3-007.04. Such report must identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 180 NAC 3-007.04 during the reporting period, the report must so indicate;

f. File a report which identifies each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. The licensee must report:

(1) To the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 40.25;

(2) To the responsible State agency all transfers of devices manufactured and distributed pursuant to 180 NAC 3-014.13 for use under a general license in that State's regulations equivalent to180 NAC 3-007.04;

(3) To U.S. Nuclear Regulatory Commission if no transfers have been made by the licensees during the reporting period;

(4) To the responsible Agreement State Agency, upon the request of the Department, if no transfers have been made to general licensees within a particular Agreement State during the reporting period; and

5. Keep records showing the name, address, and point of contact for each general licensee to whom the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 180 NAC 3-008.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records must be maintained for a period of two years and

must show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements.

6. The Radiation Safety Officer and/or authorized user must have training and experience consistent with the requirements of training specified in 180 NAC 15-018.01.

3-014.14 Serialization of Nationally Tracked Sources. Each licensee who manufactures a nationally tracked source after February 6, 2007, must assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

3-014.15 Reserved ~~Acceptance Sampling Procedures Under Certain Specific Licenses.~~

~~1. A random sample shall be taken from each inspection lot of devices licensed under 10 CFR 32.14, 180 NAC 3-014.05, or 3-014.09 for which testing is required in accordance with the appropriate Sampling Table in 180 NAC 3-014.15 determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table 180 NAC 3-014.15, the lot will be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table 180 NAC 3-014.15, the entire inspection lot will be rejected.~~

~~2. Single sampling tables for Lot Tolerance Percent Defective:~~
~~a. Lot Tolerance Percent Defective 0.5 percent:~~

Lot Size	Sample Size	Acceptance No.
1 to 180	All	0
181 to 210	180	0
211 to 250	210	0
251 to 300	240	0
301 to 400	275	0
401 to 500	300	0
501 to 600	320	0
601 to 800	350	0
801 to 1,000	365	0
1,001 to 2,000	410	0
2,001 to 3,000	430	0
3,001 to 4,000	440	0
4,001 to 5,000	445	0
5,001 to 7,000	450	0
7,001 to 10,000	455	0
10,001 to 20,000	460	0
20,001 to 50,000	775	1
50,001 to 100,000	780	1

b. Lot Tolerance Percent Defective 1.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 120	All	0
121 to 150	120	0
151 to 200	140	0
201 to 300	165	0
300 to 400	175	0
401 to 500	180	0
501 to 600	190	0
601 to 800	200	0
801 to 1,000	205	0
1,000 to 3,000	220	0
3,001 to 5,000	225	0
5,001 to 10,000	230	0
10,001 to 100,000	390	1

c. Lot Tolerance Percent Defective 2.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 75	All	0
76 to 100	70	0
101 to 200	85	0
201 to 300	95	0
301 to 400	100	0
401 to 600	105	0
601 to 800	110	0
801 to 4,000	115	0
4,001 to 10,000	195	1
10,001 to 100,000	200	1

d. Lot Tolerance Percent Defective 3.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 40	All	0
41 to 55	40	0
56 to 100	55	0
101 to 200	65	0
201 to 500	70	0
501 to 3,000	75	0
3,001 to 100,000	130	1

e. Lot Tolerance Percent Defective 4.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 35	All	0
36 to 50	34	0
51 to 100	44	0

101 to 200	50	0
201 to 2,000	55	0
2,001 to 100,000	95	1

f. Lot Tolerance Percent Defective 5.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2,001 to 100,000	75	1

g. Lot Tolerance Percent Defective 7.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 25	All	0
26 to 50	24	0
51 to 100	28	0
101 to 200	30	0
201 to 300	31	0
301 to 800	32	0
801 to 1,000	33	0
1,001 to 100,000	55	1

h. Lot Tolerance Percent Defective 10.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	0

3-015 SPECIAL REQUIREMENTS FOR ISSUANCE OF SPECIFIC LICENSES FOR SOURCE MATERIAL MILLING: In addition to the requirements set forth in 180 NAC 3-011, a specific license for source material milling will be issued if the applicant submits to the Department a satisfactory application as described herein and meets the other conditions specified below:

3-015.01 An Application for a License to Receive Title to, Receive, Possess, and Use Source Material for Milling or Radioactive Material as Defined in 180 NAC 1-002 must address the following:

1. Description of the proposed project or action;
2. Area/site characteristics including geology, topography, hydrology, and
3. Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;
4. Environmental effects of accidents;
5. Long-term impacts including decommissioning, decontamination, and reclamation; and meteorology;
6. Site and project alternatives.

3-015.02 Pursuant to 180 NAC 3-011.01, the applicant must not commence construction of the project until the Department has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

3-015.03 At least 1 full year prior to any major site construction, a pre-operational monitoring program must be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program must be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

3-015.04 Prior to issuance of the license, the applicant must establish financial surety arrangements consistent with the requirements of 180 NAC 3-011.02.

1. The amount of funds to be ensured by financial surety arrangements will be based on Department-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. The licensee must submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates will take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the Department may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other Federal or State agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the Department to assure that sufficient funds will be available for completion of the reclamation plan if the

work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability will be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination, and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time (e.g., 5 years) which must be automatically renewed unless the surety agent notifies the beneficiary (the State regulatory agency) and the principal (the licensee) some reasonable time (e.g., 90 days) prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the regulatory agency to collect.

2. The total amount of funds for reclamation or long term surveillance and control will be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include, but are not limited to, sums collected for long term surveillance and control. Such funds do not, however, include monies held as surety where no default has occurred, and the reclamation or other bonded activity has been performed.

3-015.05 The applicant must provide procedures describing the means employed to meet the following requirements during the operational phase of any project:

1. Milling operations must be conducted so that all effluent releases are below the limits of 180 NAC 4 and are as low as is reasonably achievable.
2. The mill operator must conduct daily inspections of any tailings or waste retention systems. Such inspections must be conducted by a qualified engineer or scientist. Records of such inspections must be maintained for review by the Department.
3. The mill operator must immediately notify the Department of the following:

    a. Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and
    b. Any unusual conditions or conditions not contemplated in the design of the retention system which, if not corrected, could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

3-015.06 Continued Surveillance Requirements for Source Material Millings Having Reclaimed Residues.

1. The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections must be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection must be reported to the Department within 60 days following each inspection. The Department may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

2. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in, 180 NAC 3-015.06, item 1 additional funding requirements may be specified by the Department. The charge will be reviewed annually to recognize or adjust for inflation.

3-016 ISSUANCE OF SPECIFIC LICENSES

3-016.01 Upon a determination that an application meets the requirements of the Act and the regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary, based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s).

3-016.02 The Department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material including the requirement of reports, keeping of records and to provide for inspections as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property; and
2. Prevent loss or theft of material subject to 180 NAC 3-016.02.

3-017 SPECIFIC TERMS AND CONDITIONS OF LICENSE

3-017.01 Each license issued pursuant to 180 NAC 3, 5, 7, 12, 14 and 19 will be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Department.

3-017.02

1. No license issued or granted under 180 NAC 3, 5, 7, 12, 14, and 19 and no right to possess or utilize radioactive material granted by any license issued pursuant to 180 NAC 3, 5, 7, 12, 14, and 19 may be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Department , after securing full

information find that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.

2. An application for transfer of license must include:

a. The identity, technical and financial qualifications of the proposed transferee; and

b. ~~a.~~ Financial assurance for decommissioning information required by 180 NAC 3-018.

3-017.03 Each person licensed by the Department pursuant to,180 NAC 3, 5, 7, 12, 14 and 19 must confine use and possession of the material licensed to the locations and purposes authorized in the license.

3-017.04 Each licensee must notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials under the license. This notification requirement applies to all specific licenses issued under,180 NAC 3, 5, 7, 12, 14, and 19.

3-017.05 Each general licensee that is required to register by 180 NAC 3-005 and each specific licensee must notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;
2. An entity (as that term is defined in 11 U.S.C. 101(15)) (attached hereto as Attachment Number 3-1 and incorporated herein by this reference) controlling the licensee or listing the license or licensee as property of the estate; or
3. An affiliate (as that term is defined in 11 U.S.C. 101(2)) (attached hereto as Attachment Number 3-1 and incorporated herein by this reference) of the licensee.
4. This notification must indicate:

a. The bankruptcy court in which the petition for bankruptcy was filed; and
b. The date of the filing of the petition.

~~3-017.06 Security requirements for portable gauges. Each portable gauge licensee must use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.~~

~~3-017.07 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with180 NAC 7-045. The licensee musl record the results of each test and retain each record for 3 years after the record is made.~~

~~3-017.08 Positron Emission Tomography (PET)~~

~~1. Authorization under 180 NAC 3-010-11 to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.~~

~~2. Each licensee authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must:~~

~~a. Satisfy the labeling requirements in 180 NAC 3-014.10, item 1.d. for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.~~

~~b. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 180 NAC 3-014.10, item 3.~~

~~3. A licensee that is a pharmacy authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium will require that any individual that prepares PET radioactive drugs must be:~~

~~a. An authorized nuclear pharmacist that meets the requirements in 180 NAC 3-014.10, item 2.b. or~~

~~b. An individual under the supervision of an authorized nuclear pharmacist as specified in 180 NAC 7-018.~~

~~4. A pharmacy, authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 180 NAC 3-014.10, item 2.e.~~

3-018 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

3-018.01 Each:

1. Applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 180 NAC 4, Appendix 4-F must submit a decommissioning funding plan as described in 180 NAC 3-018.05. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix 4-F of 180 NAC 4.
2. Holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in 180 NAC 4, Appendix 4-F (or when a combination of isotopes is involved if R, as defined

in 180 NAC 3-018.01, item 1, divided by 10^{12} is greater than 1), must submit a decommissioning funding plan as described in 180 NAC 3-018.05.

3-018.02 Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 180 NAC 3-018.04 must either:

1. Submit a decommissioning funding plan as described in 180 NAC 3-018.05 or
2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 180 NAC 3-018.04 using one of the methods described in 180 NAC 3-018.06. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of radioactive material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy 180 NAC 3-018.06 must be submitted to the Department before receipt of radioactive material. If the applicant does not defer execution of the financial instrument, the applicant must submit to the Department as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-018.06.

3-018.03 Each:

1. Holder of a specific license issued on or after May 30, 1994 and of a type described in 180 NAC 3-018.01 or 3-018.02, must provide financial assurance for decommissioning in accordance with the criteria set for 180 NAC 3-018.03.
2. Holder of a specific license issued before May 30, 1994, and of a type described in 180 NAC 3-018.01 must submit, on or before May 30, 1994, and of type described in 180 NAC 3-018.01 must submit a decommissioning funding plan as described in 180 NAC 3-018.05 or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in 180 NAC 3-018.03, item 2. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee must include a decommissioning funding plan in any application for license renewal.
3. Holder of a specific license issued before May 30, 1994, and of a type described in 180 NAC 3-018.02 must submit, on or before May 30, 1994, a certification of financial assurance for decommissioning in accordance with the criteria set forth in 180 NAC 3-018.03.
4. Waste collectors and waste processors, as defined in 180 NAC 4, Appendix 4-D, must provide financial assurance in an amount based on a decommissioning funding plan as described in 180 NAC 3-018.05. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 180 NAC 3. The

decommissioning funding plan must be submitted by (two years from effective date of these regulations).

3-018.04 Table of required amounts of financial assurance for decommissioning by quantity of material. ~~Licensees required to submit the $1,125,000 amount must do so by (one year from effective date of these regulations). Licensees required to submit the $113,000 or $225,000 amount must do so by (one and a half years from effective date of these regulations).~~ Licensees having possession limits exceeding the upper bound of this table must base financial assurance on a decommission funding plan.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of 180 NAC 4, Appendix 4-F in unsealed form. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01, item 1 divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of 180 NAC 4, Appendix 4-F in unsealed form. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01, item 1 divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of 180 NAC 4, Appendix 4-F in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in180 NAC 3-018.01, item 1 divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1.)	$113,000

3-018.05

~~1.~~ Each decommissioning funding plan must be submitted for review and approval and must contain: ~~a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 180 NAC 3-018.06, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed three years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial statement obtained to satisfy the requirements of 180 NAC 3-018.06.~~

a. A detailed cost estimate for decommissioning, in an amount reflecting:

(1.) The cost of an independent contractor to perform all decommissioning activities;

(2.) The cost of meeting the 180 NAC 4-016 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 180 NAC 4-017, the cost estimate may be based on meeting the 180 NAC 4-017 criteria;

(3.) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(4.) An adequate contingency factor.

b. Identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);

c. A description of the method of assuring funds for decommissioning from 180 NAC 3-018.06, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

d. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

e. A signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-018.06 (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

1. At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs.

a. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;
b. Waste inventory increasing above the amount previously estimated;
c. Waste disposal costs increasing above the amount previously estimated;
d. Facility modifications;
e. Changes in authorized possession limits;
f. Actual remediation costs that exceed the previous cost estimate;
g. Onsite disposal; and
h. Use of a settling pond.

3-018.06 The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument

submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

1. Prepayment Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must ~~may~~ be made into ~~the for of~~ a trust ~~escrow~~ account, and the trustee and trust must be acceptable to the Department. ~~government fund, certificate of deposit, or deposit of government securities.~~

2. A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit, ~~or line of credit~~. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3-F. For commercial corporation that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 180 NAC 3 Appendix 3-D. ~~A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 180 NAC 3-018.06, item 2.~~ For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3-G. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3H. Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. ~~A guarantee of funds by the applicant or licensee for decommissioning based on a financial test may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3-D. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of 180 NAC 3-018.06, item 2 or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company.~~ Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

   a. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration

without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within 30 days after receipt of notification of cancellation.

b. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

c. The surety method or insurance must remain in effect until the Department has terminated the license.

3. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust. ~~escrow account, government fund, certificate of deposit, or deposit of government securities.~~ If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety~~, or~~ insurance, or other guarantee provisions must be as stated in 180 NAC 3-018.06, item 2.

4. In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 180 NAC 3-018.04, and indicating that funds for decommissioning will be obtained when necessary.

5. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

3-018.07 Each person licensed under 180 NAC 3, 5, 7, 12, 14 and 19 must keep records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, licensees must transfer all records described in 180 NAC 3-018.07 to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning consists of:

1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup

procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

2. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

3. Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

   a. All areas designated and formerly designated as restricted areas as defined under 180 NAC 1-002 ;
   b. All areas outside of restricted areas that require documentation under 180 NAC 3-018.07, item 1.;
   c. All areas outside of restricted areas where current and previous wastes have been buried as documented under 180 NAC 4-054; and
   d. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 180 NAC 4-040.

4. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

3-018.08 Each person applying for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form must submit a decommissioning funding plan as described in 180 NAC 3-018.05.

3-018.09 Each person applying for a specific license authorizing the possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

1. Submit a decommissioning funding plan as described in 180 NAC 3-018.05 or
2. Submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 using one of the methods described in 180 NAC 3-018.06. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a

signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-018.06 must be submitted to Department prior to receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant must submit to Department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-18.06.

3-018.10 In providing financial assurance under 180 NAC 3-018, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the Department, as follows:

1. If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

2. If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

3. Within 30 days of taking the actions required by180 NAC 3-018.10, item 1 or 2, the licensee must provide a written report of such actions to the Director, of Public Health and state the new balance of the fund.

3-019 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDINGS OR OUTDOOR AREAS

3-019.01 Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 180 NAC 3-020 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Department makes a final determination to deny the renewal application or if the determination states an expiration date, the expiration date stated in the determination.

3-019.02 Each specific license revoked by the Department expires at the end of the day on the date of the Department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

3-019.03 Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee must-

1. Limit actions involving radioactive material to those related to decommissioning; and

2. Continue to control entry to restricted area until they are suitable for release in accordance with Department requirements.

3-019.04 Within 60 days of the occurrence of any of the following, consistent with the administrative directions in 180 NAC 1-012, each licensee must provide notification to the Department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Department requirements, or submit within 12 months of notification a decommissioning plan, if required by 180 NAC 3-019.07 and begin decommissioning upon approval of that plan if -

1. The license has expired pursuant to180 NAC 3-019.01 and 3-019.02; or
2. The licensee has decided to permanently cease principal activities, as defined in 180 NAC 3-002, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements; or
3. No principal activities under the license have been conducted for a period of 24 months; or
4. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements.

3-019.05 Coincident with the notification required by 180 NAC 3-019.04, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to 180 NAC 3-018 in conjunction with a license issuance or renewal or as required by 180 NAC 3-019.05. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 180 NAC 3-019.07, item 4.e.

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so.
2. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Department.

3-019.06 The Department may grant a request to extend the time periods established in 180 NAC 3-019.04 if the Department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 180 NAC 3-019.04. The schedule for decommissioning set forth in 180 NAC 3-019.04 may not commence until the Department has made a determination on the request.

3-019.07 Decommissioning Plans

1. A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the

site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or to the public; such as in the following cases;

a. Procedures would involve techniques not applied routinely during cleanup or maintenance operations;
b. Workers could be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
c. Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or
d. Procedures could result in significantly greater releases of radioactive materials to the environment than those associated with operation.

2. The Department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 180 NAC 3-019.04 if the Department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

3. Procedures such as those listed in 180 NAC 3-019.07, item 1 with potential health and safety impacts may not be carried out prior to the approval of the decommissioning plan.

4. The proposed decommissioning plan for the site or separate building or outdoor area must include:

a. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
b. A description of planned decommissioning activities;
c. A description of methods used to ensure the protection of workers and the environment against radiation hazards during decommissioning;
d. A description of the planned final radiation survey; and
e. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.
f. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in 180 NAC 3-019.09.

5. The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

3-019.08 Decommissioning

1. Except as provided in 180 NAC 3-019.09, licensees must complete decommissioning of the site or separate building or outdoor area as soon as is practicable but no later than 24 months following the initiation of decommissioning.

2. Except as provided in 180 NAC 3-019.09, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

3-019.09 The Department may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Department determines that the alternative is warranted by consideration of the following:

1. Whether it is technically feasible to complete decommissioning within the allotted 24 month period;
2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24 month period;
3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
4. Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
5. Other site-specific factors which the Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

3-019.10 As the final step in decommissioning, the licensee must:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Department Form NRH-60 or equivalent information; and

2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee must, as appropriate:

    a. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, becquerels (picocuries) per gram for solids such as soil or concrete; and

    b. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

3-019.11 Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines:

1. Radioactive material has been properly disposed;

2. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

3. Demonstration of suitability for release.

   a. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Department requirements; or
   b. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Department requirements.

4. Records required by 180 NAC 3-030.06 and 3-030.08 have been received.

3-020 RENEWAL OF LICENSES

3-020.01 Applications for renewal of specific licenses must be filed in accordance with 180 NAC 3-010.

3-020.02 In any case in which a licensee, not less than 30 days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license will not expire until the application has been finally determined by the Department.

3-021 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE: Applications for amendment of a license must be filed in accordance with 180 NAC 3-010 and must specify the respects in which the licensee desires his/her license to be amended and the grounds for such amendment.

3-022 DEPARTMENT ACTION ON APPLICATIONS TO RENEW AND AMEND: In considering an application by a licensee to renew or amend his/her license, the Department will apply the criteria set forth in 180 NAC 3-011, 3-013 or 3-014, and 3-015 and in 180 NAC 5, 7, 12, 14 or 19 as applicable.

3-023 RESERVED

3-024 RESERVED

3-025 TRANSFER OF MATERIAL

3-025.01 No licensee shall transfer radioactive material except as authorized pursuant to180 NAC 3-025.

3-025.02 Except as otherwise provided in his/her license and subject to the provisions of 180 NAC 3-025.03 and 3-025.04, any licensee may transfer radioactive material:

1. To the Department;[11]
2. To the U.S. Department of Energy;
3. To any person exempt from the regulations to the extent permitted under such exemption;
4. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, or any Agreement State, or
5. As otherwise authorized by the Department in writing.
6. To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under § 274 of the Atomic Energy Act of 1954[12]

3-025.03 Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State, or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material must verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

3-025.04 The following methods for the verification required by 180 NAC 3-025.03 are acceptable:

1. The transferor may have in his/her possession, and read, a current copy of the transferee's specific license or registration certificate;
2. The transferor may have in his/her possession a written certification by the transferee that s/he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;
3. For emergency shipments the transferor may accept oral certification by the transferee that s/he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten days;

[11]A licensee may transfer material to the Department only after receiving prior approval from the Department.

[12]Ibid. p. 64

4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or
5. When none of the methods of verification described in 180 NAC 3-025.04, items 1. through 4. are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

3-025.05 Preparation for shipment and transport of radioactive material must be in accordance with the provisions of 180 NAC 13.

3-026 REPORTING REQUIREMENTS

3-026.01 Immediate Report: Each licensee must notify the Department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of radioactive material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

3-026.02 Twenty-Four Hour Report: Each licensee must notify the Department within 24 hours after the discovery of any of the following events involving radioactive material:

1. An unplanned contamination event that:

    a. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
    b. Involves a quantity of material greater than five times the lowest annual limit on intake specified in 180 NAC 4, Appendix 4-B for the material; and
    c. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

    a. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
    b. The equipment is required to be available and operable when it is disabled or fails to function; and
    c. No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
4. An unplanned fire or explosion damaging any radioactive material or any device, container, or equipment containing radioactive material when:

   a. The quantity of radioactive material involved is greater than five times the lowest annual limit on intake specified in 180 NAC 4, Appendix 4-B for the material; and
   b. The damage affects the integrity of the radioactive material or its container.

3-026.03 Preparation and submission of reports: Reports made by licensees in response to the requirements of 180 NAC 3-026.03 must be made as follows:

1. Licensees must make reports required by 180 NAC 3-026.01 and 3-026.02 by telephone to the Department.[13] To the extent that the information is available at the time of notification, the information provided in these reports must include:

   a. The caller's name and call back telephone number;
   b. A description of the event, including date and time;
   c. The exact location of the event;
   d. The isotopes, quantities, and chemical and physical form of the radioactive material involved; and
   e. Any personnel radiation exposure data available.

2. Written report. Each licensee who makes a report required by 180 NAC 3-026.01 or 180 NAC 3-026.02 must submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to:

   Nebraska Department of Health and Human Services
   Division of Public Health, Radiological Health
   301 Centennial Mall South
   P.O. Box 95026
   Lincoln, NE 68509-5026

   The reports must include the following:

[13]The telephone number for the Department is (402) 471-2168.

a. A description of the event, including the probable cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned;
b. The exact location of the event;
c. The isotopes, quantities, and chemical and physical form of the radioactive material involved;
d. Date and time of the event;
e. Corrective actions taken or planned and the results of any evaluations or assessments; and
f. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

3-027 MODIFICATION AND REVOCATION OF LICENSES: The terms and conditions of all licenses will be subject to amendment, revision, modification, limitation, suspension or revocation upon:

3-027.01 Amendments to the Radiation Control Act or the rules and regulations adopted pursuant thereto;

3-027.02 Voluntary application for license amendment, revision, modification, limitation, suspension or surrender made by the licensee;

3-027.03 Disciplinary action pursuant to 180 NAC 17 ;or

3-027.04 Pursuant to emergency order as provided by § 71-3513(6) of the Act.

RECIPROCITY

3-028 RECIPROCAL RECOGNITION OF LICENSES

3-028.01 Licenses of Radioactive Material Except Special Nuclear Material in Quantities Sufficient to Form a Critical Mass

1. Subject to Title 180, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any Agreement State, and issued by the Department having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any 12 consecutive months. provided that:

   a. The licensing document does not limit the activity authorized by such document to specified installations or locations;
   b. The out-of-state licensee notifies the Department in writing at least three (3) days prior to engaging in such activity. Such notification must include:

(1) Name of company for whom services will be performed, an individual to be contacted representing the company and telephone number.
(2) The exact location, start date, duration, and type of activity to be conducted.
(3) The name(s), documentation of training, and in-state address(es) of the individual(s) performing the activity,
(4) The identification of the sources of radiation to be used,
(5) A copy of the pertinent license,
(6) A copy of the licensee's operating and emergency procedures, and
(7) An annual fee as specified in 180 NAC 18 .
(8) The out-of-state licensee notifies the Department of changes in work locations, radioactive material, or work activities different from the information contained on the initial notification.

If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 180 NAC 3-028.01.

c. The out-of-state licensee complies with all applicable regulations of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Department;
d. The out-of-state licensee maintains a current copy of the appropriate license, and all amendments thereto, issued by the Department;
e. The out-of-state licensee supplies such other information as the Department may request;
f. The out-of-state licensee must not transfer or dispose of radioactive material possessed or used under the general license provided in 180 NAC 3-028.01, item 1 except by transfer to a person:
(1) Specifically licensed by the Department or by the U.S. Nuclear Regulatory Commission to receive such material, or
(2) Exempt from the requirements for a license for such material under 180 NAC 3-004.01.

2. Notwithstanding the provisions of 180 NAC 3-028.01, item 1 any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in 180 NAC 3-008.04, item 1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

a. Such person must file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each report must identify each general licensee to whom the device is transferred by name and address, the type and model of device transferred, and the quantity and type of radioactive material contained in the device;

b. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

c. Such person must assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

d. The holder of the specific license must furnish to each general licensee to whom s/he transfers the device or on whose premises s/he installs the device a copy of the general license contained in 180 NAC 3-008.04.

3. The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to achieve compliance with Title 180 or to prevent undue hazard to public health and safety or property.

3-028.02 Recognition of Agreement State Licensees

1. Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site must be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.

   a. In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the U.S. Nuclear Regulatory Commission, and

   b. Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction must be obtained from the U.S. Nuclear Regulatory Commission by either (1) filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or (2) by applying for a specific U.S. Nuclear Regulatory Commission license.

2. Before radioactive material can be used at a temporary job site in another State, authorization must be obtained for the State if it is an Agreement State, or from the U.S. Nuclear Regulatory Commission for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

3-029 RESERVED

3-030 RECORDS

3-030.01 Each person who receives radioactive material pursuant to a license issued pursuant to 180 NAC 3, 5, 7, 12, 14, and 19 must keep records showing the receipt, use, transfer, and disposal of such radioactive material.

3-030.02 Records which are required pursuant to 180 NAC 3-030.01 must be maintained for the period specified by the appropriate regulation. If a retention period is not otherwise specified by regulation such records must be maintained for a period of one year after the records of the licensee have been inspected by the Department unless any litigation, claim, negotiation, audit, licensure action, or other action involving the records has been initiated before the expiration of the one-year period, in which case the records must be retained until the completion of the action and resolution of all issues, or until the end of the regular one-year period, whichever is later.

3-030.03 Records of receipt of radioactive material which must be maintained pursuant to 180 NAC 3-030.01 will be maintained as long as the licensee retains possession of the radioactive material and for five years following transfer, or disposition of the radioactive material and;

1. Records of transfer of radioactive material must be maintained by the licensee who transferred the material until the Department authorizes their disposition and;
2. Records of disposal of radioactive material must be maintained in accordance with 180 NAC 4-054.
3. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner which makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, evaluative techniques such as first-in-first-out may be used for purposes of the records retention requirements of 180 NAC 3-030.

3-030.04 Records which must be maintained pursuant to 180 NAC 3-030.01 may be the original or reproduced copy of microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate and complete record during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

3-030.05 If there is a conflict between the Department's regulations in 180 NAC 3, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in 180 NAC 3-030 for such records will apply unless the Department pursuant to 180 NAC 1-003.01 has granted a specific exemption from the record retention requirements specified in 180 NAC 3-030.05.

3-030.06 Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, must forward the following records to the Department:

1. Records of disposal of licensed material made under 180 NAC 4-040, 4-041, 4-042 and 4-043; and
2. Records required by 180 NAC 4-048.02, item 4.

3-030.07 If licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, must transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

1. Records of disposal of licensed material made under, 180 NAC 3-038, 3-039, 3-040, 3-041 and
2. Records required by 180 NAC 4-048.02, item 4.

3-030.08 Prior to license termination, each licensee must forward the records required by 180 NAC 3-018.07 to the Department.

SEALED SOURCES AND DEVICE REGISTRATION

3-031 REGISTRATION OF PRODUCT INFORMATION

3-031,01 Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Department for evaluation of radiation safety information about its product and for its registration.

3-031.02 The request for review must be sent to the Department at the address in 180 NAC 1-012.

3-031.03 The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

3-031.04 The Department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Department must use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. 10 CFR 32, Subpart A includes specific criteria that apply to certain exempt products, 180 NAC 3-014.04 thru 3-014.09 includes specific criteria applicable to certain generally licensed

devices, and 180 NAC 3-014.10, 3-014.12 and 3.014.14 includes specific provisions that apply to certain specifically licensed items.

3-031.05 After completion of the evaluation, the Department issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

3-031.06 The person submitting the request for evaluation and registration of safety information about the product must manufacture and distribute the product in accordance with:

1. The statements and representations, including quality control program, contained in the request; and

2. The provisions of the registration certificate.

3-031.07 Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

1. Calibration and reference sources containing no more than:

   a. 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or
   b. 0.37 MBq (10 µCi), for alpha emitting radionuclides; or

2, The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

   a. The intended recipients are licensed under 180 NAC 3-013, U.S. Nuclear Regulatory Commission 10 CFR 33 or comparable provisions of an Agreement State; or
   b. The recipients are authorized for research and development; or
   c. The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

3-031.08 After the certificate is issued, the Department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Department will complete its evaluation in accordance with criteria specified in 180 NAC 3-031. The Department may request such additional

information as it considers necessary to condu ct its review and the certificate holder must provide the information as requested.

3-032 INACTIVATION OF CERTIFICATES OF REGISTRATION OF SEALED SOURCES AND DEVICES

3-032.01 A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Department must request inactivation of the registration certificate. Such a request must be made to the Department and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder must request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

3-032.02 If a distribution license is to be terminated in accordance with 180 NAC 3-019, the licensee must request inactivation of its registration certificates associated with that distribution license before the Department will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

3-032.03 A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

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Appendix 3-A

EXEMPT CONCENTRATIONS:

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Antimony (51)	Sb-122		3E-4
	Sb-124		2E-4
	Sb-125		1E-3
Argon (18)	Ar-37	1E-3	
	Ar-41	4E-7	
Arsenic (33)	As-73		5E-3
	As-74		5E-4
	As-76		2E-4
	As-77		8E-4
Barium (56)	Ba-131		2E-3
	Ba-140		3E-4
Beryllium (4)	Be-7		2E-2
Bismuth (83)	Bi-206		4E-4
Bromine (35)	Br-82	4E-7	3E-3
Cadmium (48)	Cd-109		2E-3
	Cd-115m		3E-4
	Cd-115		3E-4
Calcium (20)	Ca-45		9E-5
	Ca-47		5E-4
Carbon (6)	C-14	1E-6	8E-3
Cerium (58)	Ce-141		9E-4
	Ce-143		4E-4
	Ce-144		1E-4
Cesium (55)	Cs-131		2E-2
	Cs-134m		6E-2
	Cs-134		9E-5
Chlorine (17)	Cl-38	9E-7	4E-3
Chromium (24)	Cr-51		2E-2
Cobalt (27)	Co-57		5E-3
	Co-58		1E-3
	Co-60		5E-4

Appendix 3-A

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Copper (29)	Cu-64		3E-3
Dysprosium (66)	Dy-165		4E-3
	Dy-166		4E-4
Erbium (68)	Er-169		9E-4
	Er-171		1E-3
Europium (63)	Eu-152 (T/2=9.2hrs)		6E-4
	Eu-155		2E-3
Fluorine (9)	F-18	2E-6	8E-3
Gadolinium (64)	Gd-153		2E-3
	Gd-159		8E-4
Gallium (31)	Ga-72		4E-4
Germanium (32)	Ge-71		2E-2
Gold (79)	Au-196		2E-3
	Au-198		5E-4
	Au-199		2E-3
Hafnium (72)	Hf-181		7E-4
Hydrogen (1)	H-3	5E-6	3E-2
Indium (49)	In-113m		1E-2
	In-114m		2E-4
Iodine (53)	I-126	3E-9	2E-5
	I-131	3E-9	2E-5
	I-132	8E-8	6E-4
	I-133	1E-8	7E-5
	I-134	2E-7	1E-3
Iridium (77)	Ir-190		2E-3
	Ir-192		4E-4
	Ir-194		3E-4
Iron (26)	Fe-55		8E-3
	Fe-59		6E-4
Krypton (36)	Kr-85m	1E-6	
	Kr-85	3E-6	
Lanthanum (57)	La-140		2E-4
Lead (82)	Pb-203		4E-3

Appendix 3-A

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
Lutetium (71)	Lu-177		1E-3
Manganese (25)	Mn-52		3E-4
	Mn-54		1E-3
	Mn-56		1E-3
Mercury (80)	Hg-197m		2E-3
	Hg-197		3E-3
	Hg-203		2E-4
Molybdenum (42)	Mo-99		2E-3
Neodymium (60)	Nd-147		6E-4
	Nd-149		3E-3
Nickel (28)	Ni-65		1E-3
Niobium (Columbium)(41)	Nb-95		1E-3
	Nb-97		9E-3
Osmium (76)	Os-185		7E-4
	Os-191m		3E-2
	Os-191		2E-3
	Os-193		6E-4
Palladium (46)	Pd-103		3E-3
	Pd-109		9E-4
Phosphorus (15)	P-32		2E-4
Platinum (78)	Pt-191		1E-3
	Pt-193m		1E-2
	Pt-197m		1E-2
	Pt-197		1E-3
Potassium (19)	K-42		3E-3
Praseodymium (59)	Pr-142		3E-4
	Pr-143		5E-4
Promethium (61)	Pm-147		2E-3
	Pm-149		4E-4
Rhenium (75)	Re-183		6E-3
	Re-186		9E-4
	Re-188		6E-4
Rhodium (45)	Rh-103m		1E-1

Appendix 3-A

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
	Rh-105		1E-3
Rubidium (37)	Rb-86		7E-4
Ruthenium (44)	Ru-97		4E-3
	Ru-103		8E-4
	Ru-105		1E-3
	Ru-106		1E-4
Samarium (62)	Sm-153		8E-4
Scandium (21)	Sc-46		4E-4
	Sc-47		9E-4
	Sc-48		3E-4
Selenium (34)	Se-75		3E-3
Silicon (14)	Si-31		9E-3
Silver (47)	Ag-105		1E-3
	Ag-110m		3E-4
	Ag-111		4E-4
Sodium (11)	Na-24		2E-3
Strontium (38)	Sr-85		1E-3
	Sr-89		1E-4
	Sr-91		7E-4
	Sr-92		7E-4
Sulfur (16)	S-35	9E-8	6E-4
Tantalum (73)	Ta-182		4E-4
Technetium (43)	Tc-96m		1E-1
	Tc-96		1E-3
Tellurium (52)	Te-125m		2E-3
	Te-127m		6E-4
	Te-127		3E-3
	Te-129m		3E-4
	Te-131m		6E-4
	Te-132		3E-4
Terbium (65)	Tb-160		4E-4
Thallium (81)	Tl-200		4E-3
	Tl-201		3E-3

Appendix 3-A

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml*	Column II Liquid and Solid Concentration μCi/ml**
	Tl-202		1E-3
	Tl-204		1E-3
Thulium (69)	Tm-170		5E-4
	Tm-171		5E-3
Tin (50)	Sn-113		9E-4
	Sn-125		2E-4
Tungsten (Wolfram)(74)	W-181		4E-3
	W-187		7E-4
Vanadium (23)	V-48		3E-4
Xenon (54)	Xe-131m	4E-6	
	Xe-133	3E-6	
	Xe-135	1E-6	
Ytterbium (70)	Yb-175		1E-3
Yttrium (39)	Y-90		2E-4
	Y-91m		3E-2
	Y-91		3E-4
	Y-92		6E-4
	Y-93		3E-4
Zinc (30)	Zn-65		1E-3
	Zn-69m		7E-4
	Zn-69		2E-2
Zirconium (40)	Zr-95		6E-4
	Zr-97		2E-4
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		1E-10	1E-6

*Values are given in Column I only for those materials normally used as gases.

**μCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in 180 NAC 3, Appendix 003-A the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 180 NAC 3-004 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Appendix 003-A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = \leq 1$$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above value by 37.

EXAMPLE: Zirconium (40) Zr-97 2E-4 μCi/ml multiplied by 37 is equivalent to 74E+4 MBq /l)

APPENDIX 3-B

Radioactive Material	Microcuries

EXEMPT QUANTITIES

Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100

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Radioactive Material	Microcuries
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10

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Radioactive Material	Microcuries
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10

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Radioactive Material	Microcuries
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10

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Radioactive Material	Microcuries
Yttrium 88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

NOTE: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

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LIMITS FOR BROAD LICENSES 180 NAC 3-013:

Radioactive Material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.0
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.0
Cesium-134m	100	1.0
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.0
Chromium-51	100	1.0
Cobalt-57	10	0.1
Cobalt-58m	100	1.0
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.0
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01

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Radioactive Material	Col. I curies	Col. II curies
Fluorine-18	100	1.0
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.0
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.0
Indium-113m	100	1.0
Indium-114m	1	0.01
Indium-115m	100	1.0
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.0
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.0
Osmium-185	1	0.01

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Radioactive Material	Col. I curies	Col. II curies
Osmium-191m	100	1.0
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.0
Platinum-193	10	0.1
Platinum-197m	100	1.0
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.0
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.0
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.0
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1

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Radioactive Material	Col. I curies	Col. II curies
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.0
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.0
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.0
Xenon-133	100	1.0
Xenon-135	100	1.0
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.0
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

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NOTE: To convert curies (Ci) to SI units of gigabecquerels (GBq) multiply the above values by 37

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)

APPENDIX 3-D

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

~~1.~~I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section ~~2.~~II of this ~~A~~appendix. The terms of this self-guarantee are in Section ~~3.~~III of this ~~A~~appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for obtaining a self-guarantee.

~~2.~~II. Financial Test

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix D criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the facility and site. These criteria include: ~~To pass the financial test, a company must meet all of the following criteria:~~

(1) Tangible net worth of at least $21 million, and total net worth at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all facilities or parts thereof (or the current amount required if certification is used). ~~Tangible net worth of at least 10 times the total current decommissioning cost estimate (or the current amount if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and a parent-guarantor.~~

(2) Assets located in the United States amounting to at least 90% of total assets or at least 10 times the amount of decommissioning funds being assured by a self-guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all facilities or parts thereof (or the current amount required if certification is used). ~~the total current decommissioning cost estimate (or the current amount if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and a parent-guarantor.~~

(3) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and –) as issued by Standard and Poor's, or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's. ~~A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.~~

B. To pass the financial test, a company must meet all of the following additional requirements:

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(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II, paragraph A of this appendix. In connection with the auditing ~~that~~ procedure, the licensee must inform the Department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Department within 90 days after the close of each succeeding fiscal year. ~~repeat the passage of the test within 90 days after the close of each succeeding fiscal year.~~

C. If the company no longer meets the requirements of Section II..A. of this appendix, the licensee must send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's regulations within 120 days of such notice.

3. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department. Cancellation may not occur, however during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by the return receipt.

B. The licensee must provide alternative financial assurance as specified in the Department's regulations within 90 days following receipt by the Department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

D. The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities

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and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A–" and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee will notify the Department n writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix. ~~If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moody's, the licensee will provide notice in writing of such fact to the Department within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by both Standard and Poors or Moody's, the licensee no longer meets the requirements of Section 2.A. of this Appendix~~

F. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will ~~set up~~ fund ~~a~~the standby trust in the amount guaranteed by the self-guarantee agreement. ~~of the current cost estimate for decommissioning.~~

G. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

H. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

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(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

I. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph H of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

APPENDIX 3-E

Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.

Radioactive material[1]	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000
Bismuth-207	0.01	5,000
Bismuth-210	0.01	600
Cadmium-109	0.01	1,000
Cadmium-113	0.01	80
Calcium-45	0.01	20,000
Californium-252	0.00	19 (20 mg)
Carbon-14 (Non CO)	0.01	50,000
Cerium-141	0.01	10,000
Cerium-144	0.01	300
Cesium-134	0.01	2,000
Cesium-137	0.01	3,000
Chlorine-36	0.5	100
Chromium-51	0.01	300,000
Cobalt-60	0.001	5,000
Copper-64	0.01	200,000
Curium-242	0.001	60
Curium-243	0.001	3
Curium-244	0.001	4
Curium-245	0.001	2
Europium-152	0.01	500
Europium-154	0.01	400
Europium-155	0.01	3,000
Germanium-68	0.01	2,000
Gadolinium-153	0.01	5,000
Gold-198	0.01	30,000
Hafnium-172	0.01	400
Hafnium-181	0.01	7,000
Holmium-166m	0.01	100
Hydrogen-3	0.5	20,000
Iodine-125	0.5	10
Iodine-131	0.5	10

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Radioactive material[1]	Release fraction	Quantity (curies)
Indium-114m	0.01	1,000
Iridium-192	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	0.01	8
Manganese-56	0.01	60,000
Mercury-203	0.01	10,000
Molybdenum-99	0.01	30,000
Neptunium-237	0.001	2
Nickel-63	0.01	20,000
Niobium-94	0.01	300
Phosphorus-32	0.5	100
Phosphorus-33	0.5	1,000
Polonium-210	0.01	10
Potassium-42	0.01	9,000
Promethium-145	0.01	4,000
Promethium-147	0.01	4,000
Radium-226	0.001	100
Ruthenium-106	0.01	200
Samarium-151	0.01	4,000
Scandium-46	0.01	3,000
Selenium-75	0.01	10,000
Silver-110m	0.01	1,000
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulfur-35	0.5	900
Technetium-99	0.01	10,000
Technetium-99m	0.01	400,000
Tellurium-127m	0.01	5,000
Tellurium-129m	0.01	5,000
Terbium-160	0.01	4,000
Thulium-170	0.01	4,000
Tin-113	0.01	10,000
Tin-123	0.01	3,000
Tin-126	0.01	1,000
Titanium-44	0.01	100
Vanadium-48	0.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	0.01	2,000
Zinc-65	0.01	5,000
Zirconium-93	0.01	400
Zirconium-95	0.01	5,000
Any other beta-gamma emitter	0.01	10,000

APPENDIX 3-E

Radioactive material[1]	Release fraction	Quantity (curies)
Mixed fission products	0.01	1,000
Mixed Corrosion products	0.01	10,000
Contaminated equipment beta-gamma	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material, solid noncombustible	0.001	10,000
Mixed radioactive waste, beta-gamma	0.01	1,000
Packaged mixed waste, beta-gamma[2]	0.001	10,000
Any other alpha emitter	0.001	2
Contaminated equipment, alpha	0.0001	20
Packaged waste, alpha[2]	0.0001	20
Combinations of radio-active materials listed above[1]	-----	-----

[1]For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in 180 NAC 3, Appendix 003-E exceeds one.

[2]Waste packaged in Type B containers does not require an emergency plan.

APPENDIX 3-E

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APPENDIX 3-F

Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section. For purposes of applying the Appendix F criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the facility and site.1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the ~~current~~amount of decommissioning being issued by a parent company guarantee ~~cost estimates~~ for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $~~10~~21 million; and

(iv) Assets located in the United States amounting to at least 90% of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

2. The parent company must have:

(i) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, A, or BBB (including adjustments of + and –) as issued by Standard and Poor's or AAA, AA, A, or Baa (including adjustment of 1, 2, or 3) as issued by Moody's; and ~~bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and~~

(ii) Net working capital and tangible net worth each at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all facilities or parts tereof (or prescrived amount if a certification is used); and ~~Tangible net worth each at least six times the current decommissioning cost~~

~~estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and~~

(iii) Tangible net worth of at least $~~10~~21 million; and

(iv) Assets located in the United States amounting to at least 90% of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used)

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the parent company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the parent company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of paragraph A of this section. In connection with ~~that~~the auditing procedure, the licensee must inform the Department within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must annually pass the test and provide documentation of its continued eligibility to use the parent company guarantee to the Department ~~repeat the passage of the test~~ within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in the Department's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the yearend financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Department, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Department's regulations within 90 days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide ~~such~~ alternative financial assurance that meets to provision of the Department's regulation in the name of the licensee.

APPENDIX 3-F

C. The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license, accepted in writing the parent company's alternate financial assurances, or accepted in writing the licensee's financial assurances.

D. ~~If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.~~ A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the parent company guarantee agreement is submitted. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee, whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

E. The guarantor must agree that it would be subject to Department orders to make payments under the guarantee agreement.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

1. Declare that the financial assurance guaranteed by the parent company guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. 1. The guarantor must agree to notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code, or the occurrence of any other event listed in paragraph F of this Appendix, by or against:

(i) The guarantor;

(ii) The licensee;

(iii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

APPENDIX 3-F

(iv) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

2. This notification must include:

(i) A description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the parent company guarantee for decommissioning will be transferred to the standby trust as soon as possible;

(ii) If a petition of bankruptcy was filed, the identity of the bankruptcy court in which the petition for bankruptcy was filed; and

(iii) The date of filing of any petitions.

Form NRH-5
Effective Date:

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH - RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

INSTRUCTIONS - (Use additional sheets where necessary.)
New or Renewal Application - Complete Items 1. through 15.
Amendment to License - Complete Items1.a, 3., and 15. And indicate other changes as appropriate.
Retain one copy for your files and submit original application to: Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for the Control of Radiation and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip +4: _____

Telephone #: _____

FAX #: _____

E-Mail Address:

1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)

(1) Permanent Address: _____

_____

City, State Zip+4: _____

(2) Temporary Job Sites Throughout Nebraska? ☐ Yes ☐ No

2. Department to Use Radioactive Material

_____

Person to Contact:_____

Telephone #:_____

3. This is an application for:

☐ New License

☐ Amendment to License No._____

☐ Renewal of License No._____

4. Individual User(s)

☐ Individual users approved by the Licensee's radiation safety committee.

☐ Individual users approved by the Licensee's radiation safety officer.

☐ Individual users satisfy the requirements of 180 NAC 3-013

OR

☐ Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials. Give training and experience in Items 7. And 8.

First Name + Middle Initial | Last Name | Title

5. Radiation Safety Officer (RSO)
(Name and Title of Individual designated as Radiation Safety Officer.

_____

Telephone #:_____

Attach documentation of his/her training and experience as in Items 7. and 8.

Department Use Only

Date Received Stamp

6. Radioactive Material Data

☐ Type B Broad Scope, 180 NAC 3-013.01, item 2

☐ Type C Broad Scope, 180 NAC 3-013.01, item 3

☐ Specific License, Radioactive Material Listed below:

6.a. Element and Mass Number	6.b. Chemical or Physical Form (Make and Model if sealed source)	6.c. Maximum Activity Requested (Expressed as Curies, Millicuries or Microcuries)	6.d. Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

7. Training of Individuals in Items 4. and 5.

Name of Individual:

	Formal Course Title	Location and Date(s) of Training	Clock Hours in Lecture or Laboratory
7.a. Radiation Physics and Instrumentation			
7.b. Radiation Protection			
7.c. Mathematics Pertaining to the Use and Measurement of Radioactivity			
7.d. Biological Effects of Radiation			

8. Experience with Radiation of Individuals in Items 4. and 5.

(Actual use of Radioisotopes or Equivalent Experience)

Name of Individual:

Isotope	Maximum Activity	Where Experience Was Gained	Months/Years	Type of Use

9. Radiation Detection Instruments

Type of Instrument	Manufacturers Name	Model Number	Number Available	Radiation Detected	Sensitivity Range
	‘				

10. Calibration of Instruments Listed in Item 9.

□ **a. Calibrated by Service Company** Name and Address of Service Company and Frequency of Calibration	□ **b. Calibrated by Applicant**

11. Personnel Monitoring Devices
(Check and/or complete as appropriate)

Type	Supplier (Service Company)	Exchange Frequency
□ Film Badge □ TLD □ DOSL □ Other (Specify) □_____		□ Monthly □ Quarterly □ Other (specify) _____

Information to be Submitted on Additional Sheets

12. Facilities and Equipment

Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Attach an explanatory sketch of the facility.

13. Radiation Protection Program

Describe the radiation protection program as appropriate for the material to be used, including: the duties and responsibilities of the Radiation Safety Officer (RSO); control measures; bioassay procedures (if needed); day-to-day general safety instructions to be followed; etc. If the application is for sealed sources also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

14. Waste Disposal

If a commercial waste disposal service is employed, specify the name and address of the company. Otherwise, submit a detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. If the application is for sealed sources and devices and they will be returned to the manufacturer, so state.

15. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____
_____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

□ I am a citizen of the United States OR

□ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

16. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services , Title 180, Regulations for the Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. I am authorized to make binding commitments and to sign official documents on the behalf of the applicant.

_____
Applicant Name From Item 1.a.

By: _____ *Date:* _____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

Your Application will not be processed without items 15 and 16 being completed.

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

CERTIFICATE - USE OF DEPLETED URANIUM UNDER GENERAL LICENSE

180 NAC 3-007.04 establishes a general license authorizing a person to receive, acquire, possess, use, or transfer in accordance with the provisions of 180 NAC 3-007.04, items 2, 3, 4 and 5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

Possession of depleted uranium is not authorized under 180 NAC 3-007.04 until a licensee has filed Form NRH-11 and received from the Department a validated copy of NRH-11 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 3-007.04

3-007.04 Depleted Uranium In Industrial Products and Devices.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 180 NAC 3-007.04 items 2. through 5., depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in 180 NAC 3-007.04, item 1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 180 NAC 3-014.13 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 must:

   a. File Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License," with the Department. The form must be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant must furnish on Department Form NRH-11 the following information and such other information as may be required by that form:

      (1) Name and address of the general licensee;

      (2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 180 NAC 3-007.04, item 1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

      (3) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 180 NAC 3-007.04, item 3.a.(2).

b. Report in writing to the Department any changes in information furnished by him in Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License." The report must be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 must:

a. Not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

b. Not abandon such depleted uranium.

c. Transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 180 NAC 3-025. In the case where the transferee receives the depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1., the transferor must furnish the transferee a copy of this regulation and a copy of Department Form NRH-11. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 180 NAC 3-007.04, item 1., the transferor must furnish the transferee a copy of Title 180 and a copy of Department Form NRH-11 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in Title 180.

d. Within 30 days of any transfer, report in writing to the Department the name and address of the person receiving the depleted uranium pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to the depleted uranium covered by that general license.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

A certification number will be assigned and a validated copy of NRH-11 will be returned.

(Print or Type)

1. Licensee Information

Legal Name of Licensee _____

Address of Licensee: _____

_____

City, State and Zip+4 of Licensee _____

Person Authorized to sign binding documents for the Licensee _____

Address of authorized person _____

City, State amd Zip+4 of authorized person. _____

Telephone # of authorized person _____

2. I hereby apply for a Certificate number pursuant to 180 NAC 3-007.04 on behalf of the above Licensee.

3. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.)

_____ _____

OR

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

□ I am a citizen of the United States OR

□ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

4. Certification:

   I certify that:

   a. All information in this certificate is true and complete.

   b. I understand the Department's regulations require that any change in the information furnished on this certificate be reported to the Department within 30 days from the date of such change.

   c. I have read and understand the provisions of 180 NAC 3-007.04 of the Department's regulations, and I understand that I am required to comply with those provisions as to the depleted uranium which I receive, possess, use, or transfer under the general license.

_____

(Signature of Authorized Person listed in Item 1.) (Date)

4. To be completed by the Department:

Certification Number_____Date_____

Radioactive Materials Program Manager_____

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

CERTIFICATE - IN VITRO TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

180 NAC 3-008.09 establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for In Vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under 180 NAC 3-008.09 is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed Form NRH-17 and received from the Department a validated copy of Form NRH-17 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 180 NAC 3-008.09

3-008.09 General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 6., the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

    a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
    b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
    c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
    d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.

2. No person receives, acquires, possesses, uses or transfers radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until s/he has filed Department Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Department and received from the Department a validated copy of Department Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital must furnish on Department Form NRH-17 the following information and such other information as may be required by that form:

    a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
    b. The location of use; and
    c. A statement that the physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with

radioactive material as authorized under the general license in 180 NAC 3-008.09, item 1. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. must comply with the following:

    a. The general licensee must not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).

    b. The general licensee must store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

    c. The general licensee must use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.

    d. The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

    e. The general licensee must dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-039 and 4-040.

4. The general licensee must not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:

    a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 180 NAC 3-008.09 or its' equivalent, and

    b. Unless the following statement, or substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package

This radioactive material must be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory commission or of a State in which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 180 NAC 3-008.09, item 1. must report in writing to the Department, any changes in the information furnished by him/her in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form NRH-17. The report must be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of 180 NAC 3-008.09, item 1. is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1.d. must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services, Division of Public Health , Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

A certification number will be assigned and a validated copy of NRH-17 will be returned.

(Print or Type)

1. Licensee Information

Legal Name: (Physician, Veterinarian, Clinical Laboratory or Hospital) _____

Address: _____

_____

City, State and Zip+4 _____

Person Authorized to sign binding documents for the Licensee _____

2. I hereby apply for a Certificate Number pursuant to 180 NAC 3-008.09 for use of radioactive materials for:

[ ] a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine, or a veterinarian licensed to practice veterinary medicine.

[ ] b. The above named clinical laboratory.

[ ] c. The above named hospital.

3. If place of use is different from address in Item 1, please give complete address:

4. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ _____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

□ I am a citizen of the United States OR

□ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

5. Certification:

I certify that:

a. All information in this certificate is true and complete.

b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 180 NAC 3-008.09. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive materials.

c. I understand that Department regulations require that any change in the information furnished on this certificate be reported to the Department within 30 days from the date of such change.

d. I have read and understand the provisions of 180 NAC 3-008.09 of the Department regulations; and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certification number is filed with the Department.

_____

(Signature of Person listed in Item 1.) (Date)

4. To be completed by the Department:

Certification Number _____ ***Date***_____

Radioactive Materials Program Manager_____

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
RADIOACTIVE MATERIALS PROGRAM

CERTIFICATION OF DISPOSITION OF MATERIALS

INSTRUCTIONS - (Use additional sheets where necessary.)
Type or Print except where indicated.
Retain one copy for your files and submit original application to: Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this Certification of Disposition of Materials the licensee will receive a termination notice of this radioactive material license.

1. Licensee Information

Licensee Number:_____

License Expiration Date:_____

2. Person to Contact Regarding this Application

_____

Telephone #:_____

Licensee Name and Street Address:

Applicant Name: _____

Address: _____

_____

City, State Zip+4 _____

Telephone #: _____

FAX#: _____

E-mail Address:

3. Materials Data

☐ No Materials have ever been procured or possessed by the Licensee under this License.

☐ All Materials procured and/or possessed by the Licensee under the License Number cited above have been disposed of in the following manner:

☐ Transfer
Specify the date of the transfer, the name of the licensed recipient and the recipient's Department, U.S. Nuclear Regulatory Commission or Agreement State license number.
Describe specific materials transfer actions and if there were radioactive wastes generated in terminating this license, the disposal actions, including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.

☐ Disposed of directly by Licensee
Describe specific disposal procedures (e.g. decay in storage).

4. Other Data

☐ Our License has not yet expired, please terminate it.
A Radiation Survey was conducted to confirm the absence of licensed radioactive materials and to determine whether any contamination remains on the premises covered by the license:

☐ NO (Attach Explanation)

☐ YES, the results:

☐ Are attached

☐ Were forwarded to the Department on (Date)_____

4. Other Data *(Continued)*

Address all future correspondence regarding this license to:

Name:

Address:

City, State Zip+4:

Telephone #:

FAX#:

E-mail Address:

5. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services , Title 180, Regulations for the Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____ *Date:* _____
Signature

Print Name and Title of certifying official authorized to act on behalf of the applicant

Form NRH 653
Effective Date February 24, 2013

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT

(Continue on Form NRH 653, 653A or 653B, as appropriate)

NAME OF VENDOR	REPORTING PERIOD	
	FROM	TO
LICENSE NUMBER:		

For each "person" to whom a devices(s) has been transferred during the reporting period, supply the following:

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	INDIVIDIUAL TITLE OF RESPONSIBLE	TELEPHONE

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	INDIVIDIUAL TITLE OF RESPONSIBLE	TELEPHONE

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEE)

For each "person" to whom a devices(s) has been transferred during the reporting period, supply the following:

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

Form NRH 653B

Effective Date February 24, 2013

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)

For each device for which required label information has been changed, supply the following::

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITYAND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITYAND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITYAND UNITS

Attachment 3-1

11 U.S.C. 101(2) AND (15)

CITE-
11 USC CHAPTER 1 - GENERAL PROVISIONS 01/03/05

TITLE 11 - BANKRUPTCY
CHAPTER 1 - GENERAL PROVISIONS

-HEAD-
Sec. 101. Definitions

-STATUTE-
In this title -

(2) **"affiliate"** means -

(A) entity that directly or indirectly owns, controls, or holds with power to vote, 20% or more of the outstanding voting securities of the debtor, other than an entity that holds such securities -

(i) in a fiduciary or agency capacity without sole discretionary power to vote such securities; or

(ii) solely to secure a debt, if such entity has not in fact exercised such power to vote;

(B) corporation 20% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by the debtor, or by an entity that directly or indirectly owns, controls, or holds with power to vote, 20% or more of the outstanding voting securities of the debtor, other than an entity that holds such securities -

(i) in a fiduciary or agency capacity without sole discretionary power to vote such securities; or

(ii) solely to secure a debt, if such entity has not in fact exercised such power to vote;

(C) person whose business is operated under a lease or operating agreement by a debtor, or person substantially all of whose property is operated under an operating agreement with the debtor; or

(D) entity that operates the business or substantially all of the property of the debtor under a lease or operating agreement;

(15) **"entity"** includes person, estate, trust, governmental unit, and United States trustee;

http://uscode.house.gov/download/pls/11C1.txt

TITLE 180 CONTROL OF RADIATION

CHAPTER 4 STANDARDS FOR PROTECTION AGAINST RADIATION

ADDITIONAL REQUIREMENTS

APPENDIXES

FORMS

ATTACHMENT

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 4 STANDARDS FOR PROTECTION AGAINST RADIATION

4-001 SCOPE AND AUTHORITY

4-001.01 180 NAC 4 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

4-001.02 The requirements of 180 NAC 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in 180 NAC 4. However, nothing in 180 NAC 4 will be construed as limiting actions that may be necessary to protect health and safety.

4-001.03 Except as specifically provided in other Chapters of Title 180, 180 NAC 4 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in 180 NAC 4 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 180 NAC 7-037 or to voluntary participation in medical research programs.

4-001.04 40 CFR as published on July 1, 20~~06~~13 and 49 CFR as published October 1, 20~~06~~13 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

4-001.05 National Council on Radiation Protection and Measurement (NRCP) ~~91~~116, International Commission on Radiological Protection (ICRP) 23 and Compressed Gas Association Publication G7.1 as referred to in this Chapter are herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

4-002 DEFINITIONS

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix 180 NAC 4-B.

Assigned protection factor (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Class means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the face piece by inhalation.

Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for working year of 2,000 hours under conditions of light work, (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table I, Column 3, of Appendix 180 NAC 4-B.

Derived air concentration-hour (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator

are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

Dose *or* radiation dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

Dosimetry processor means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Inhalation class [See "Class"].

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lung class [See "Class"].

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Nonstochastic effect means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, a "deterministic effect" is an equivalent term.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet

covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Quarter means a period of time equal to one-fourth of the year observed by the licensee or registrant, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Reference man means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection Report, ICRP Publication 23, "Report of the Task Group on Reference Man."

Respiratory protective equipment means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

Sanitary sewerage means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Stochastic effect means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Supplied-air respirator (SAR) *or* airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

User seal check (fit check*)* means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive

pressure check, irritant smoke check, or isoamyl acetate check.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.[1]

Weighting factor w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red Bone Marrow	0.12
Lung	0.12
Thyroid	0.03
Bone Surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

4-003 IMPLEMENTATION

4-003.01 Any existing license condition that is more restrictive than 180 NAC 4 remains in force until there is an amendment or renewal of the license.

[1]At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

4-003.02 If a license condition exempts a licensee from a provision of 180 NAC 4 in effect on or before May 30, 1994, it also exempts the licensee from the corresponding provision of 180 NAC 4.

4-003.03 If a license condition cites provisions of 180 NAC 4 in effect prior to May 30, 1994, which do not correspond to any provisions of 180 NAC 4, the license condition remains in force until there is an amendment or renewal of the license that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

4-004 RADIATION PROTECTION PROGRAMS

4-004.01 Each licensee or registrant must develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of 180 NAC 4. See 180 NAC 4-047 for recordkeeping requirements relating to these programs.

4-004.02 The licensee or registrant must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

4-004.03 The licensee or registrant must, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

4-004.04 To implement the ALARA requirements of 180 NAC 4-004.02 and notwithstanding the requirements in 180 NAC 4-013, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters must be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 mSv ~~10 mrem~~ (10 mrem ~~0.1 mSv~~) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee must report the exceedance as provided in 180 NAC 4-059 and promptly take appropriate corrective action to ensure against a recurrence.

OCCUPATIONAL DOSE LIMITS

4-005 OCCUPATIONAL DOSE LIMITS FOR ADULTS

4-005.01 The licensee or registrant must control the occupational dose to individual adults, except for planned special exposures pursuant to 180 NAC 4-010, to the following dose limits:

1. An annual limit, which is the more limiting of:

   a. The total effective dose equivalent being equal to 0.05 Sv (5 rem); or
   b. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

2. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

   a. A lens dose equivalent of 0.15 Sv (15 rem), and
   b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

4-005.02 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 4-010 item 5.a. and 5.b.

4-005.03

1. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the U.S. Nuclear Regulatory Commission. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

2. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in 180 NAC 4-022.01, item 5, the effective dose equivalent for external radiation must be determined as follows:

   a. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent must be the effective dose equivalent for external radiation; or
   b. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25% of the limit specified in 180 NAC 4-005.01, the reported deep dose equivalent value multiplied by 0.3 must be the effective dose equivalent for external radiation; or
   c. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation must be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04

4-005.04 Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix 180 NAC 4-B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See180 NAC 4-052.

4-005.05 Notwithstanding the annual dose limits, the licensee must limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix 180 NAC 4-B.

4-005.06 The licensee or registrant must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See180 NAC 4-009.05.

4-006 COMPLIANCE WITH REQUIREMENTS FOR SUMMATION OF EXTERNAL AND INTERNAL DOSES

4-006.01 If the licensee is required to monitor pursuant to both 180 NAC 4-022.01 and 4-022.02, the licensee must demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 180 NAC 4-022.01 or only pursuant to 180 NAC 4-022.02 then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 180 NAC 4-006.02 through 4-006.04. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

4-006.02 Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

1. The sum of the fractions of the inhalation ALI for each radionuclide, or
2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data usin appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50,}$ per unit intake is greater than 10% of the maximum weighted value of $H_{T,50,}$ (i.e., $w_T H_{T,50,}$) per unit intake for any organ or tissue.

4-006.03 Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee or registrant must account for this intake and include it in demonstrating compliance with the limits.

4-006.04 Intake through Wounds or Absorption through Skin. The licensee or registrant must evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to 180 NAC 4-006.04.

4-007 DETERMINATION OF EXTERNAL DOSE FROM AIRBORNE RADIOACTIVE MATERIAL

4-007.01 Licensees must, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix 180 NAC 4-B, footnotes 1 and 2.

4-007.02 Airborne radioactivity measurements and DAC values must not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual must be based upon measurements using instruments or individual monitoring devices.

4-008 DETERMINATION OF INTERNAL EXPOSURE

4-008.01 For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee must, when required under 180 NAC 4-022 take suitable and timely measurements of:

1. Concentrations of radioactive materials in air in work areas; or
2. Quantities of radionuclides in the body; or
3. Quantities of radionuclides excreted from the body; or
4. Combinations of these measurements.

4-008.02 Unless respiratory protective equipment is used, as provided in 180 NAC 4-028 or the assessment of intake is based on bioassays, the licensee must assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

4-008.03 When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may:

1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee must document that information in the individual's record; and
2. Upon prior approval of the Department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix 180 NAC 4-B.

4-008.04 If the licensee chooses to assess intakes of Class Y material using the measurements given in 180 NAC 4-008.01, item 2 or 3, the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 180 NAC 4-058 or 4-059. This delay permits the licensee to make additional measurements basic to the assessments.

4-008.05 If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either:

1. The sum of the ratios of the concentration to the appropriate DAC value, (for example, D, W, or Y) from Appendix 180 NAC 4-B for each radionuclide in the mixture; or
2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

4-008.06 If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

4-008.07 When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 180 NAC 4-005 and in complying with the monitoring requirements in 180 NAC 4-022, and
2. The concentration of any radionuclide disregarded is less than 10% of its DAC, and
3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.

4-008.08 When determining the committed effective dose equivalent, the following information may be considered:

1. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

2. For an ALI (and the associated DAC) determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), (the stochastic ALI) is listed in parentheses in Table I of Appendix 180 NAC 4-B. The licensee may,

as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee must also demonstrate that the limit in 180 NAC 4-005.01, item 1.b. is met.

4-009 DETERMINATION OF PRIOR OCCUPATIONAL DOSE

4-009.01 For each individual who may enter the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 180 NAC 4-022, the licensee or registrant must:

1. Determine the occupational radiation dose received during the current year; and
2. Attempt to obtain the records of cumulative occupational radiation dose.

4-009.02 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant must determine:

1. The internal and external doses from all previous planned special exposures; and
2. All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

4-009.03 In complying with the requirements of 180 NAC 4-009.01, a licensee or registrant may:

1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year;
2. Accept, as the record of cumulative radiation dose, an up-to-date Department Form NRH-1, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and
3. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, electronic media, or letter. The licensee or registrant must request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

4-009.04 The licensee or registrant must record the exposure history, as required by 180 NAC 4-009.01, on Department Form NRH-1, or other clear and legible record, including all of the information required on that form.

1. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed

by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant must use the dose shown in the report in preparing Department Form NRH-1 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant must place a notation on Department Form NRH-1 indicating the periods of time for which data are not available.

2. Licensees or registrants are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further, occupational exposure histories obtained and recorded on Department Form NRH-1 before the May 30, 1994, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

4-009.05 If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant must assume:

1. In establishing administrative controls under 180 NAC 4-005.06 for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
2. That the individual is not available for planned special exposures.

4-009.06 The licensee or registrant must retain the records on Department Form NRH-1 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant must retain records used in preparing Department Form NRH-1 or equivalent for three years after the record is made. This includes records required under the standards for protection against radiation in effect prior to May 30, 1994.

4-010 PLANNED SPECIAL EXPOSURES: A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 180 NAC 4-005 provided that each of the following conditions is satisfied:

1. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.
2. The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.
3. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

   a. Informed of the purpose of the planned operation; and
   b. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

c. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

4. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 180 NAC 4-009.02 during the lifetime of the individual for each individual involved.
5. Subject to 180 NAC 4-005.02, the licensee or registrant must not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

   a. The numerical values of any of the dose limits in 180 NAC 4-005.01 in any year; and
   b. Five times the annual dose limits in 180 NAC 4-005.01 during the individual's lifetime.

6. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 180 NAC 4-051 and submits a written report in accordance with 180 NAC 4-060.
7. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures must not be considered in controlling future occupational dose of the individual pursuant to 180 NAC 4-005.01 but must be included in evaluations required by 180 NAC 4-010.04 and 4-010.05.

4-011 OCCUPATIONAL DOSE LIMITS FOR MINORS: The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in 180 NAC 4-005.

4-012 DOSE EQUIVALENT TO AN EMBRYO/FETUS

4-012.01 The licensee or registrant must ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See 180 NAC 4-052 for record keeping requirements.

4-012.02 The licensee or registrant must make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 180 NAC 4-012.01.[2]

4-012.03 The dose equivalent to an embryo/fetus is the sum of:

1. The deep dose equivalent to the declared pregnant woman; and

[2]The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 ”Recommendations on Limits for Exposure to Ionizing Radiation” (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo\fetus be received in any one month.

2. The equivalent dose to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

4-012.04 If the dose equivalent to the embryo/fetus is found to have exceeded 5 mSv (0.5 rem), or is within 0.5 mSv (0.05 rem) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee or registrant must be deemed to be in compliance with 180 NAC 4-012.01 if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

4-013 DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

4-013.01 Each licensee or registrant must conduct operations so that:

1. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 180 NAC 7-037, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with 180 NAC 4-041, and
2. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 180 NAC 7-037, does not exceed 0.02 mSv (0.002 rem) in any one hour.

4-013.02 If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

4-013.03 Notwithstanding 180 NAC 4-013.01, item 1 a licensee may permit visitors to an individual who cannot be released, under 180 NAC 7-037, to receive a radiation dose greater than 1 mSv (0.1 rem) if:

1. The radiation dose received does not exceed 5 mSv (0.5 rem); and
2. The authorized user, as defined in 180 NAC 7, has determined before the visit that it is appropriate.

4-013.04 A licensee, registrant, or an applicant for a license or registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application must include the following information:

1. Demonstration of the need for and the expected duration of operations in excess of the limit in 180 NAC 4-013.01; and

2. The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and
3. The procedures to be followed to maintain the dose ALARA.

4-013.05 In addition to the requirements of 180 NAC 4, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 must comply with those standards.

4-013.06 The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

4-014 COMPLIANCE WITH DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

4-014.01 The licensee or registrant must make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in 180 NAC 4-013.

4-014.02 A licensee or registrant must show compliance with the annual dose limit in 180 NAC 4-013 by:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
2. Demonstrating that:

    a. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix 180 NAC 4-B; and
    b. If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

4-014.03 Upon approval from the Department, the licensee or registrant may adjust the effluent concentration values in Appendix 180 NAC 4-B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

4-015 GENERAL PROVISIONS AND SCOPE

4-015.01 The criteria in 180 NAC 4 apply to the decommissioning of facilities licensed under 180 NAC 3 and 12, as well as other facilities subject to the Department’s jurisdiction under the Act for low-level waste disposal facilities (180 NAC 12), the criteria apply only

to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities or to uranium solution extraction facilities.

4-015.02 The criteria in 180 NAC 4 do not apply to sites which:

1. Have been decommissioned prior to May 27, 2000 in accordance criteria identified in the Site Decommissioning Management Plan Action Plan of April 16, 1992 (57 FR 13389);
2. Have previously submitted and received Department approval on a decommissioning plan that is compatible with the Site Decommissioning Management Plan Action Plan criteria; or
3. Submit a sufficient decommissioning plan within one year after May 27, 2000 and such decommissioning plan is approved by the Department within two years after May 27, 2000 and in accordance with the criteria identified in the Site Decommissioning Management Plan, except that if an Environmental Impact Statement is required in the submittal, there will be a provision for day-for-day extension.

4-015.03 After a site has been decommissioned and the license terminated in accordance with the criteria in 180 NAC 4, the Department will require additional cleanup only if, based on new information, it determines that the criteria of 180 NAC 4 were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

4-015.04 When calculating TEDE to the average member of the critical group the license must determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

4-016 RADIOLOGICAL CRITERIA FOR UNRESTRICTED USE: A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.25 mSv ~~25 mrem~~ (25 mrem ~~0.25 mSv~~) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

4-017 CRITERIA FOR LICENSE TERMINATION UNDER RESTRICTED CONDITIONS

4-017.01 A site will be considered acceptable for license termination under restricted conditions if:

1. The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 180 NAC 4-016 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments,

such as traffic accidents, expected to potentially result from decontamination and waste disposal;

2. The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv ~~25 mrem~~ (25 mrem ~~0.25 mSv~~) per year;
3. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

    a. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent real rate of return on investment. ~~as described in 180 NAC 3-018.06, item 1;~~
    b. ~~Surety method, insurance, or other guarantee method as described in 180 NAC 3-018.06, item 2;~~
    ~~c.~~ A statement of intent in the case of Federal, State or local Government licensees, as described in 180 NAC 3-018.06, item 4; or
    ~~d.~~c. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

4. The licensee has submitted a decommissioning plan to the Department indicating the licensee's intent to decommission in accordance with 180 NAC 3-018.01, and specifying that the licensee intends to decommission by restricting use of the site. The licensee must document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

    a. Licensees proposing to decommission by restricting use of the site must seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

        (1) Whether provisions for institutional controls proposed by the licensee;

            (a) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 0.25 mSv ~~mrem~~ (25 mrem ~~0.25 mSv~~) TEDE per year;
            (b) Will be enforceable; and
            (c) Will not impose undue burdens on the local community or other affected parties.

(2) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

b. In seeking advice on the issues identified in 180 NAC 4-017.01, item 4.a., the licensee must provide for:

(1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
(2) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

5. Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either;

a. 1 mSv ~~100 mrem~~ (100 mrem ~~1 mSv~~) per year; or (1 mSv) per year; or
b. 5 mSv ~~500 mrem~~ (500 mrem ~~5 mSv~~) per year provided the licensee;

(1) Demonstrates that further reductions in residual radioactivity necessary to comply with the 1 mSv/y ~~100 mrem/y~~ (100 mrem/y ~~1 mSv/y~~) value of 180 NAC 4-017.01, item 5.a. are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;
(2) Makes provisions for durable institutional controls;
(3) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site both to carry out periodic rechecks of the site, no less frequently than every five years to assure that the institutional controls necessary to meet the criteria of 180 NAC 4-017.01, item 2 and to assume and carry out responsibilities for any necessary control and, maintenance of those controls. Acceptable financial assurance mechanisms are those in 180 NAC 4-017.01, item 3.

4-018 ALTERNATE CRITERIA FOR LICENSE TERMINATION

4-018.01 The Department may terminate a license using alternate criteria greater than the dose criterion of 180 NAC 4-016, 4-017.01, item 2 and 4-017.01, item 4.a.(1)(a), if the licensee:

1. Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit of 180 NAC 4-013.01, item 1, by submitting an analysis of possible sources of exposure;
2. Has employed to the extent practical restrictions on site use according to the provisions of 180 NAC 4-017 in minimizing exposures at the site; and
3. Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.
4. Has submitted a decommissioning plan to the Department indicating the licensee's intent to decommission in accordance with 180 NAC 3-019.04 and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee must document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee must provide for:

    a. Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning:
    b. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
    c. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

5. Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

4-018.02 The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Department staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to180 NAC 4-019.

4-019 PUBLIC NOTIFICATION AND PUBLIC PARTICIPATION

4-019.01 Upon the receipt of the decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to 180 NAC 4-017 and 4-018, or whenever the Department deems such notice to be in the public interest, the Department must:

1. Notify and solicit comments from:

    a. Local and State governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

b. The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to180 NAC 4-018.

4-019.02 Publish a notice in a forum, such as local newspapers, letters to the State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

4-020 MINIMIZATION OF CONTAMINATION:

4-020.01 Applicants for licenses, other than renewals, must describe in the application how the facility design and the procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

4-020.02 Licensees must, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 180 NAC 4-004 and radiological criteria for license termination in 180 NAC 4-015 thru 4-020.

SURVEYS AND MONITORING

4-021 GENERAL

4-021.01 Each licensee or registrant must make, or cause to be made, surveys of areas, including the subsurface, that:

1. Are necessary for the licensee or registrant to comply with 180 NAC 4; and
2. Are necessary under the circumstances to evaluate:

   a. The magnitude and extent of radiation levels; and
   b. Concentrations or quantities of residual radioactivity ~~radioactive material~~; and
   c. The potential radiological hazards of the radiation levels and residual radioactivity detected ~~that could be present~~.

4-021.02 Notwithstanding 180 NAC 4-048.01, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 180 NAC 3-018.07, as applicable.

4-021.0~~2~~3 The licensee or registrant must ensure that instruments and equipment used for quantitative radiation measurements for example, dose rate and effluent monitoring are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable chapter or a license condition.

4-021.0~~3~~4 All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity) that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 180 NAC 4-005, with other applicable provisions of these regulations, or with conditions specified in a license or registration must be processed and evaluated by a dosimetry processor:

1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

4-021.0~~4~~5 The licensee or registrant must ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

4-022 CONDITIONS REQUIRING INDIVIDUAL MONITORING OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE: Each licensee or registrant must monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 180 NAC 4. As a minimum:

4-022.01 Each licensee or registrant must monitor occupational exposures to radiation from registered, licensed and unlicensed radiation sources under the control of the licensee or registrant and must supply and require the use of individual monitoring devices by:

1. Adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 180 NAC 4-005.01; and
2. Minors likely to receive, in one year, from sources external to the body, a deep dose equivalent in excess of 1 mSv ~~0.1 rem~~ (0.1 rem ~~1 mSv~~), a lens dose equivalent in excess of 1.5 mSv ~~0.15 rem~~(0.15 rem ~~1.5 mSv~~), or a shallow dose equivalent to the skin or to the extremities in excess of 5 mSv ~~0.5 rem~~ (0.5 rem ~~5 mSv~~);
3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv ~~0.1 rem~~ (0.1 rem ~~1 mSv~~);[3] and
4. Individuals entering a high or very high radiation area.
5. Individuals working with medical fluoroscopic equipment.

    a. An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to 180 NAC 4-012.01, must be located under the protective apron at the waist.

[3] All of the occupational doses in 180 NAC 4-005 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

b. An individual monitoring device used for lense dose equivalent must be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron.
c. When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 180 NAC 4-005.03, it must be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used for the same purpose, it must be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

4-022.02 Each licensee or registrant must monitor, to determine compliance with 180 NAC 4-008, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

1. Adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Table I, Columns 1 and 2, of Appendix 180 NAC 4-B; and
2. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 1 mSv ~~0.1 rem~~ (0.1 rem ~~1 mSv~~).
3. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv ~~0.1 rem~~ (0.1 rem ~~1 mSv~~).

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

4-023 CONTROL OF ACCESS TO HIGH RADIATION AREAS

4-023.01 The licensee or registrant must ensure that each entrance or access point to a high radiation area has one or more of the following features:

1. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or
2. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
3. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

4-023.02 In place of the controls required by 180 NAC 4-023.01 for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

4-023.03 The licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

4-023.04 The licensee or registrant must establish the controls required by 180 NAC 4-023.01 and 4-023.03 in a way that does not prevent individuals from leaving a high radiation area.

4-023.05 The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

1. The packages do not remain in the area longer than 3 days; and
2. The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

4-023.06 The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in 180 NAC 4 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

4-023.07 The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 180 NAC 4-023 if the registrant has met all the specific requirements for access and control specified in other applicable 180 NAC Chapters, such as, 180 NAC 5 for industrial radiography, 180 NAC 6 for x-rays in the healing arts, and 180 NAC 9 for particle accelerators.

4-024 CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS

4-024.01 In addition to the requirements in 180 NAC 4-023, the licensee or registrant must institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

4-024.02 The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 180 NAC 4-024.01 if the registrant has met all the specific requirements for access and control specified in other applicable 180 NAC Chapters, such as, 180 NAC 5 for industrial radiography, 180 NAC 6 for x-rays in the healing arts, and 180 NAC 9 for particle accelerators.

4-025 CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS--IRRADIATORS

4-025.01 180 NAC 4-025 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. 180 NAC 4-025 does not apply to sources of radiation that

are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

4-025.02 Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials must meet the following requirements:

1. Each entrance or access point must be equipped with entry control devices which:

   a. Function automatically to prevent any individual from inadvertently entering a very high radiation area; and
   b. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
   c. Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

2. Additional control devices must be provided so that, upon failure of the entry control devices to function as required by 180 NAC 4-025.02, item 1:

   a. The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
   b. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

3. The licensee or registrant must provide control devices so that, upon failure or removal of physical radiation barriers:

   a. The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
   b. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

4. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 180 NAC 4-025.02, item 3.
5. Each area must be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.
6. Each area must be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.
7. Each area must be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.
8. The entry control devices required in 180 NAC 4-025.02, item 1 must have been tested for proper functioning. See 180 NAC 4-055 for record keeping requirements.

    a. Testing must be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and
    b. Testing must be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and
    c. The licensee or registrant must submit and adhere to a schedule for periodic tests of the entry control and warning systems.

9. The licensee or registrant must not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.
10. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, must be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals.

4-025.03 Registrants or applicants for registrations for sources of radiation within the purview of 180 NAC 4-025.02 which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 180 NAC 4-025.02, such as those for the automatic control of radiation levels, may apply to the Department for approval of alternative safety measures. Alternative safety measures must provide personnel protection at least equivalent to those specified in 180 NAC 4-025.02. At least one of the alternative measures must include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

4-025.04 The entry control devices required by 180 NAC 4-025.02 and 4-025.03 must be established in such a way that no individual will be prevented from leaving the area.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

4-026 USE OF PROCESS OR OTHER ENGINEERING CONTROLS: The licensee or registrant must use, to the extent practical, process or other engineering controls (for example, containment, decontamination, or ventilation) to control the concentrations of radioactive material in air.

4-027 USE OF OTHER CONTROLS

4-027.01 When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant must, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

1. Control of access; or
2. Limitation of exposure times; or
3. Use of respiratory protection equipment; or
4. Other controls.

4-027.02 If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

4-028 USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT

4-028.01 If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, pursuant to 180 NAC 4-027:

1. Except as provided in 180 NAC 4-028.01, item 2, the licensee must use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this part.

2. If the licensee wishes to use equipment that has not been tested or certified by the NIOSH, or for which there is no schedule for testing or certification, the licensee or registrant must submit an application for authorized use of this equipment, except as provided in 180 NAC 4-028.01. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

3. The licensee must implement and maintain a respiratory protection program that includes:

   a. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;
   b. Surveys and bioassays, as necessary, to evaluate actual intakes;
   c. Testing of respirators for operability (user seal check for face sealing devices and functional check for each other) immediately prior to each use; and
   d. Written procedures regarding--

      (1) Monitoring, including air sampling and bioassays;
      (2) Supervision and training of respiratory users;
      (3) Fit testing;
      (4) Respiratory selection
      (5) Breathing air quality;
      (6) Inventory and control
      (7) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;
      (8) Recordkeeping; and
      (9) Limitations on periods of respirator use and relief from respirator use;

   e. Determination by a physician that the individual user is medically fit to use the respiratory protection equipment; before

      (1) The initial fitting of a face sealing respiratory;
      (2) Before the first field use of non-face sealing respirators, and
      (3) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

   f. Fit testing, with fit factor $\geq$10 times the assigned protection factor (APF) for negative pressure devices, and a fit factor $\geq$500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepeice operating in the negative pressure mode.

4. The licensee must advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

5. The licensee must also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee must provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The

licensee must use equipment in such a way as not to interfere with the proper operation of the respirator.

6. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating him/herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons must observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

7. Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E) attached hereto as Attachment Number 4-1 and incorporated herein by this reference. Grade D quality air criteria include:

   (a) Oxygen content (v/v) of 19.5-23.5%;
   (b) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;
   (c) Carbon monoxide (CO) content of 10 ppm or less;
   (d) Carbon dioxide content of 1,000 ppm or less; and
   (e) Lack of noticeable odor.

8. The licensee must ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face--facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

9. In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

4-029 FURTHER RESTRICTIONS ON THE USE OF RESPIRATORY PROTECTION EQUIPMENT

The Department may impose restrictions in addition to the provisions of 180 NAC 4-027, 4-028,

and Appendix 4-A in order to:

4-029.01 Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

4-029.02 Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

4-030 APPLICATION FOR USE OF HIGHER ASSIGNED PROTECTION FACTORS

The licensee must obtain authorization from the Department before using assigned protection factors in excess of those specified in Appendix 4-A. The Department may authorize a licensee to use higher assigned protection factors on receipt of an application that:

4-030.01 Describes the situation for which a need exists for higher protection factors; and

4-030.02 Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

4-031 SECURITY AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION:

4-031.01 The licensee or registrant must secure licensed or registered radioactive material from unauthorized removal or access.

4-031.02 The licensee or registrant must maintain constant surveillance, use devices and/or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

4-031.03 The registrant must secure mobile or portable radiation machines that are capable of producing a high radiation area as defined in 180 NAC 1 from unauthorized removal.

4-031.04 The registrant must use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

4-031.05 Security requirements for portable gauges. Each portable gauge licensee must use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

4-032 RESERVED:

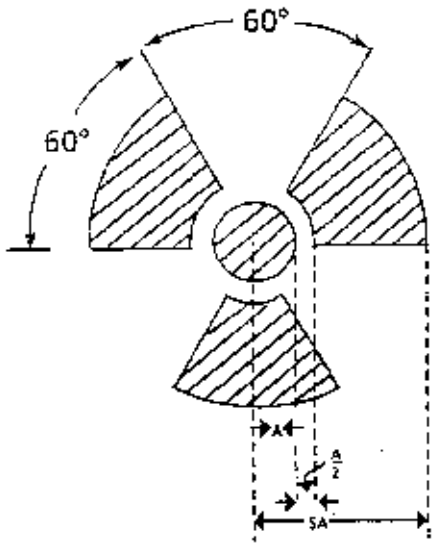
PRECAUTIONARY PROCEDURES

4-033 CAUTION SIGNS

4-033.01 Standard Radiation Symbol: Unless otherwise authorized by the Department, the symbol prescribed by 180 NAC 4-033 must use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



4-033.02 Exception to Color Requirements for Standard Radiation Symbol: Notwithstanding the requirements of 180 NAC 4-033.01, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

4-033.03 Additional Information on Signs and Labels: In addition to the contents of signs and labels prescribed in 180 NAC 4, the licensee or registrant must provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

4-034 POSTING REQUIREMENTS

4-034.01 Posting of Radiation Areas: The licensee or registrant must post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

4-034.02 Posting of High Radiation Areas: The licensee or registrant must post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

4-034.03 Posting of Very High Radiation Areas: The licensee or registrant must post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

4-034.04 Posting of Airborne Radioactivity Areas: The licensee or registrant must post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

4-034.05 Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored: The licensee or registrant must post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in Appendix 180 NAC 4-C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

4-035 EXCEPTIONS TO POSTING REQUIREMENT:

4-035.01 A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

1. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in 180 NAC 4; and
2. The area or room is subject to the licensee's or registrant's control.

4-035.02 Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 180 NAC 4-034 provided that the patient could be released from licensee control pursuant to 180 NAC 7-037.

4-035.03 A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

4-035.04 Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs in accordance with 180 NAC 4-034 if:

1. Access to the room is controlled in accordance with 180 NAC 7-071; and

2. Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in 180 NAC 4-035.

4-036 LABELING CONTAINERS AND RADIATION MACHINES

4-036.01 The licensee or registrant must ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

4-036.02 Each licensee or registrant must, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

4-036.03 Each registrant must ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

4-037 EXEMPTIONS TO LABELING REQUIREMENTS: A licensee or registrant is not required to label:

4-037.01 Containers holding licensed or registered material in quantities less than the quantities listed in Appendix 180 NAC 4-C; or

4-037.02 Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix 180 NAC 4-B; or

4-037.03 Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by 180 NAC 4;

4-037.04 Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation[4]; or

4-037.05 Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record must be retained as long as the containers are in use for the purpose indicated on the record; or

[4]Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

4-037.06 Installed manufacturing or process equipment, such as piping and tanks.

4-038 PROCEDURES FOR RECEIVING AND OPENING PACKAGES

4-038.01 Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 180 NAC 13-002 and Appendix A of 180 NAC 13, must make arrangements to receive:

1. The package when the carrier offers it for delivery; or
2. Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

4-038.02 Each licensee must:

1. Monitor the external surfaces of a labeled[5] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 180 NAC 1-002; and
2. Monitor the external surfaces of a labeled[6] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 180 NAC 13-002 and Appendix A to 180 NAC 13; and
3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

4-038.03 The licensee must perform the monitoring required by 180 NAC 4-038.02 as soon as practical after receipt of the package, but not later than three hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

4-038.04 The licensee must immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Department when:

1. Removable radioactive surface contamination exceeds the limits of 180 NAC 13-015.0~~8~~9; or
2. External radiation levels exceed the limits of 180 NAC 13-015.~~09~~10 and 13-015.~~10~~11

4-038.05 Each licensee must:

[5]Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

[6]Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

4-038.06 Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 180 NAC 4-038.02, but are not exempt from the monitoring requirement in 180 NAC 4-038.02 for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

4-039 GENERAL REQUIREMENTS

4-039.01 A licensee must dispose of licensed material only:

1. By transfer to an authorized recipient as provided in 180 NAC 4-044 or in 180 NAC 3, 12 or 19, or to the U.S. Department of Energy; or
2. By decay in storage in accordance with 180 NAC 4-039.03; or
3. By release in effluents within the limits in 180 NAC 4-013; or
4. As authorized pursuant to 180 NAC 4-040 through 4-043 or 4-039.05 and 4-039.06.

4-039.02 A person must be specifically licensed to receive waste containing licensed material from other persons for:

1. Treatment prior to disposal; or
2. Treatment or disposal by incineration; or
3. Decay in storage; or
4. Management at a facility licensed pursuant to 180 NAC 12; or
5. Storage until transferred to a storage or disposal facility authorized to receive the waste.

4-039.03 A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

1. Holds radioactive material for decay a minimum of ten half-lives;
2. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
3. Removes or obliterates all radiation labels; except for materials that will be handled as biomedical waste after released; and

4. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

4-039.04 For radioactive material disposed in accordance with 180 NAC 4-039.03, the licensee must retain a record of each disposal in accordance with 180 NAC 4-054.03.

4-039.05 Discrete sources of Radium 226 and discrete sources of naturally occurring radioactive material may be disposed of in accordance with 180 NAC 12, even though it is not defined as low-level radioactive waste. Therefore, any licensed radioactive material being disposed of at a facility, or transferred for ultimate disposal at a facility under 180 NAC 12 must meet the requirements of 180 NAC 4-044.02.

4-039.06 A licensee may dispose of discrete sources of Radium 226 and discrete sources of naturally occurring radioactive material, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law.

4-040 METHOD FOR OBTAINING APPROVAL OF PROPOSED DISPOSAL PROCEDURES:
A licensee or applicant for a license may apply to the Department for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed material generated in the licensee's operations. Each application must include:

1. A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and
2. An analysis and evaluation of pertinent information on the nature of the environment; and
3. The nature and location of other potentially affected facilities; and
4. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in 180 NAC 4.

4-041 DISPOSAL BY RELEASE INTO SANITARY SEWERAGE

4-041.01 A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

1. The material is readily soluble, or is readily dispersible biological material, in water; and
2. The quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix 180 NAC 4-B; and
3. If more than one radionuclide is released, the following conditions must also be satisfied:

    a. The licensee must determine the fraction of the limit in Table III of Appendix 180 NAC 4-B represented by discharges into sanitary sewerage

by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix 180 NAC 4-B; and

b. The sum of the fractions for each radionuclide required by 180 NAC 4-041.01, item 3.a. does not exceed unity; and

4. The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

4-041.02 Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 180 NAC 4-039.01.

4-042 TREATMENT OR DISPOSAL BY INCENERATION: A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in 180 NAC 4-043 or as specifically approved by the Department pursuant to 180 NAC 4-040.

4-043 DISPOSAL OF SPECIFIC WASTES

4-043.01 A licensee may dispose of the following licensed material as if it were not radioactive:

1. 1.85 kBq (0.05 μCi), or less, of Hydrogen-3, Carbon-14 or Iodine-125 per gram of medium used for liquid scintillation counting; and
2. 1.85 kBq (0.05 μCi), or less, of Hydrogen-3, or Carbon-14 or Iodine-125 per gram of animal tissue, averaged over the weight of the entire animal.

4-043.02 A licensee must not dispose of tissue pursuant to 180 NAC 4-041.01, item 2 in a manner that would permit its use either as food for humans or as animal feed.

4-043.03 The licensee must maintain records in accordance within 180 NAC 4-052.

4-043.04 Any licensee may, upon Department approval of procedures required in 180 NAC 4-043.06, dispose of radioactive material included in Appendix 180 NAC 4-G, provided that it does not exceed the concentration and total curie limits contained therein. Any radioactive material included in Appendix 180 NAC 4-G may be disposed of at a city or county landfill facility authorized to receive the radioactive material.

4-043.05 Each licensee who disposes of radioactive material described in 180 NAC 4-043.01 or 4-043.04 must:

1. Make surveys adequate to assure that the limits of 180 NAC 4-043.01 or 4-043.04 are not exceeded; and
2. Remove or otherwise obliterate all labels, tags, or other markings which would indicate that the material or its contents is radioactive.

4-043.06 Prior to the initiation of disposals authorized by 180 NAC 4-043.04, a licensee must submit procedures to the Department for:

1. The physical delivery of the material to the disposal site, the physical placing of the material in the disposal location and that the material is properly covered;
2. Surveys to be performed for compliance with 180 NAC 4-043.05, item 1;
3. Maintaining secure packaging during transportation to the site;
4. Maintaining records of disposals made under 180 NAC 4-043.04; and
5. Written authorization by the landfill operator agreeing to such disposal.

4-043.07 Nothing in 180 NAC 4, however, relieves the licensee of maintaining records showing the receipt, transfer, and disposal of such radioactive material as specified pursuant to 180 NAC 1-004.

4-043.08 Nothing in 180 NAC 4 relieves the licensee from complying with other applicable federal, state or local regulations governing any other toxic or hazardous property of these materials.

4-043.09 Radioactive material disposed of under 180 NAC 4 is not subject to the requirements of 180 NAC 13.

4-044 TRANSFER FOR DISPOSAL AND MANIFESTS

4-044.01 The requirements of 180 NAC 4 and Appendix 180 NAC 4-D are designed to:

1. Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor license, as defined in 180 NAC 4, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste disposal facility.
2. Establish a manifest tracking system; and
3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

4-044.02 All affected licensees must use Appendix 180 NAC 4-D and comply with 180 NAC 4-044.02, item 2.

1. Each shipment of radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility must be accompanied by a shipment manifest as specified in Section I of Appendix 180 NAC 4-D.
2. Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the Department's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix 180 NAC 4-D.

4-044.03 Each shipment manifest must include a certification by waste generator as specified in Section II of Appendix 180 NAC 4-D.

4-044.04 Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, must comply with the requirements specified in Section III of Appendix 180 NAC 4-D.

4-045 COMPLIANCE WITH ENVIRONMENTAL AND HEALTH PROTECTION REGULATIONS: Nothing in 180 NAC 4-039 through 4-044 relieves the licensee or registrant from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to 180 NAC 4-039 through 4-044.

RECORDS

4-046 GENERAL PROVISONS

4-046.01 Each licensee or registrant must use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and must clearly indicate the units of all quantities on records required by 180 NAC 4.

4-046.02 Not withstanding the requirements of 180 NAC 4-046.01, when recording information on shipment manifests, as required in 180 NAC 4-044.02, item 1, information must be recorded in the International System of Units (SI) or in SI and units as specified in 180 NAC 4-046.01.

4-046.03 The licensee or registrant must make a clear distinction among the quantities entered on the records required by 180 NAC 4, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

4-047 RECORDS OF RADIATION PROTECTION PROGRAMS

4-047.01 Each licensee or registrant must maintain records of the radiation protection program, including:

1. The provisions of the program; and
2. Audits and other reviews of program content and implementation.

4-047.02 The licensee or registrant must retain the records required by 180 NAC 4-047.01, item 1 until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant must retain the records required by 180 NAC 4-047.01, item 2 for three years after the record is made.

4-048 RECORDS OF SURVEYS

4-048.01 Each licensee or registrant must maintain records showing the results of surveys and calibrations required by 180 NAC 4-021 and 4-038.02. The licensee or registrant must retain these records for three years after the record is made.

4-048.02 The licensee or registrant must retain each of the following records until the Department terminates each pertinent license or registration requiring the record:

1. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. This includes those records of results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents required under the standards for protection against radiation in effect prior to May 30, 1994; and
2. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. This includes those records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to May 30, 1994.
3. Records showing the results of air sampling, surveys, and bioassays required pursuant to 180 NAC 4-028.01, item 3.a. This includes those records showing the results of air sampling, surveys and bioassays required under the standards for protection against radiation in effect prior to May 30, 1994; and
4. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to May 30, 1994.

4-049 RECORDS OF TESTS FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES: Records of tests for leakage or contamination of sealed sources required by 180 NAC 1-011 must be kept in units of becquerel or microcuries and maintained for inspection by the Department for five years after the records are made.

4-050 RECORDS OF PRIOR OCCUPATIONAL DOSE: For each individual who is likely to receive in a year, an occupational dose requiring monitoring pursuant to 180 NAC 4-022 the licensee or registrant must: Retain the records of prior occupational dose and exposure history as specified in 180 NAC 4-009 on Department Form NRH-1 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant must retain records used in preparing Department Form NRH-1 for three years after the record is made.

4-051 RECORDS OF PLANNED SPECIAL EXPOSURES

4-051.01 For each use of the provisions of 180 NAC 4-010 for planned special exposures, the licensee or registrant must maintain records that describe:

1. The exceptional circumstances requiring the use of a planned special exposure; and
2. The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

3. What actions were necessary; and
4. Why the actions were necessary; and
5. What precautions were taken to assure that doses were maintained ALARA; and
6. What individual and collective doses were expected to result; and
7. The doses actually received in the planned special exposure.

4-051.02 The licensee or registrant must retain the records until the Department terminates each pertinent license or registration requiring these records.

4-052 RECORDS OF INDIVIDUAL MONITORING RESULTS

4-052.01 Recordkeeping Requirement. Each licensee or registrant must maintain records of doses received by all individuals for whom monitoring was required pursuant to 180 NAC 4-022 and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before October 30, 1996 for 180 NAC 4 need not be changed. These records must include, when applicable:

1. The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
2. The estimated intake of radionuclides, see 180 NAC 4-006; and
3. The committed effective dose equivalent assigned to the intake of radionuclides;
4. The specific information used to calculate the committed effective dose equivalent pursuant to 180 NAC 4-008.03;
5. The total effective dose equivalent when required by 180 NAC 4-006; and
6. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

4-052.02 Recordkeeping Frequency. The licensee or registrant must make entries of the records specified in 180 NAC 4-052.01 at intervals not to exceed one year.

4-052.03 Recordkeeping Format. The licensee or registrant must maintain the records specified in 180 NAC 4-052.01 on Department Form NRH-2, in accordance with the instructions for Department Form NRH-2, or in clear and legible records containing all the information required by Department Form NRH-2.

4-052.04 The licensee or registrant must maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, must also be kept on file, but may be maintained separately from the dose records.

4-052.05 The licensee or registrant must retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

4-053 RECORDS OF DOSE TO INDIVIDUAL MEMBERS OF THE PUBLIC

4-053.01 Each licensee or registrant must maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 180 NAC 4-013.

4-053.02 The licensee or registrant must retain the records required by 180 NAC 4-053 until the Department terminates each pertinent license or registration requiring the record.

4-054 RECORDS OF WASTE DISPOSAL

4-054.01 Each licensee must maintain records of the disposal of licensed materials made pursuant to 180 NAC 4-040 through 4-043 and 180 NAC 12, and disposal by burial in soil, including burials authorized before August 22, 1982.[4]

4-054.02 The licensee must retain the records required by 180 NAC 4-054.01 until the Department terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in 180 NAC 3-030 for activities licensed under 180 NAC 4. This includes records required under the standards for protection against radiation in effect prior to May 30, 1994.

4-054.03 A licensee must maintain records of the disposal of licensed materials, as required by 180 NAC 4-039.03 for three years. The record must include the date of the disposal, the specific survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

4-055 RECORDS OF TESTING ENTRY CONTROL DEVICES FOR VERY HIGH RADIATION AREAS

4-055.01 Each licensee or registrant must maintain records of tests made pursuant to 180 NAC 4-025.02, item 8 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

4-055.02 The licensee or registrant must retain the records required by 180 NAC 4-055.01 for three years after the record is made.

4-056 FORM OF RECORDS: Each record required by 180 NAC 4 must be legible throughout the specified retention period. The record must be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant must maintain adequate safeguards against tampering with and loss of records.

[4]A previous 180 NAC 1-004.23, (January 1974) permitted burial of small quantities of licensed material in soil before August 22, 1982, without specific Department authorization.

REPORTS

4-057 REPORTS OF STOLEN, LOST, OR MISSING LICENSED OR REGISTERED SOURCES OF RADIATION

4-057.01 Telephone Reports. Each licensee or registrant must report to the Department by telephone as follows:

1. Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix 180 NAC 4-C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or
2. Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix 180 NAC 4-C that is still missing.
3. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

4-057.02 Written Reports. Each licensee or registrant required to make a report pursuant to 180 NAC 4-057.01 must, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
2. A description of the circumstances under which the loss or theft occurred; and
3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and
4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and
5. Actions that have been taken, or will be taken, to recover the source of radiation; and
6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

4-057.03 Subsequent to filing the written report, the licensee or registrant must also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

4-057.04 The licensee or registrant must prepare any report filed with the Department pursuant to 180 NAC 4-057 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

4-058 NOTIFICATION OF INCIDENTS

4-058.01 Immediate Notification: Notwithstanding other requirements for notification, each licensee or registrant must immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

1. An individual to receive:

   a. A total effective dose equivalent of 0.25 Sv (25 rem) or more; or
   b. A lens dose equivalent of 0.75 Sv (75 rem) or more; or
   c. A shallow dose equivalent to the skin or extremities of 2.5 Gy (250 rad) or more; or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

4-058.02 Twenty-Four Hour Notification: Each licensee or registrant must, within 24 hours of discovery of the event, report to the Department each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of 24 hours:

   a. A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
   b. A lens dose equivalent exceeding 0.15 Sv (15 rem); or
   c. A shallow dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem); or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

4-058.03 The licensee or registrant must prepare each report filed with the Department pursuant to 180 NAC 4-058 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

4-058.04 Licensees or registrants must make the reports required by 180 NAC 4-058.01 and 4-058.02 by initial contact by telephone to the Department and must confirm the initial contact by telegram, mailgram, or electronic media to the Department.

4-058.05 The provisions of 180 NAC 4-058 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to180 NAC 4-060.

4-059 REPORTS OF EXPOSURES, RADIATION LEVELS, AND CONCENTRATIONS OF RADIOACTIVE MATERIAL EXCEEDING THE CONSTRAINTS OR LIMITS

4-059.01 Reportable Events: In addition to the notification required by 180 NAC 4-058, each licensee or registrant must submit a written report within 30 days after learning of any of the following occurrences:

1. Any incident for which notification is required by 180 NAC 4-058; or
2. Doses in excess of any of the following:

    a. The occupational dose limits for adults in 180 NAC 4-005; or
    b. The occupational dose limits for a minor in 180 NAC 4-011; or
    c. The limits for an embryo/fetus of a declared pregnant woman in 180 NAC 4-012; or
    d. The limits for an individual member of the public in 180 NAC 4-013; or
    e. Any applicable limit in the license or registrant; or
    f. The ALARA constraints for air emissions established under 180 NAC 4-004.04; or

3. Levels of radiation or concentrations of radioactive material in:

    a. A restricted area in excess of applicable limits in the license; or
    b. An unrestricted area in excess of 10 times the applicable limit set forth in 180 NAC 4 or in the license, whether or not involving exposure of any individual in excess of the limits in 180 NAC 4-013; or

4. For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

4-059.02 Contents of Reports

1. Each report required by 180 NAC 4-059 must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

    a. Estimates of each individual's dose; and
    b. The levels of radiation and concentrations of radioactive material involved; and
    c. The cause of the elevated exposures, dose rates, or concentrations; and
    d. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards and associated license conditions.

2. Each report filed pursuant to 180 NAC 4-059.01 must include for each individual exposed: the name, Social Security account number, and date of birth. With

respect to the limit for the embryo fetus in 180 NAC 4-012, the identifiers should be those of the declared pregnant woman. The report must be prepared so that this information is stated in a separate and detachable portion of the report.

4-059.03 All licensees or registrants who make reports pursuant to 180 NAC 4-059.01 must submit the report in writing to the Department.

4-060 REPORTS OF PLANNED SPECIAL EXPOSURES: The licensee or registrant must submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with 180 NAC 4-010, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 180 NAC 4-051.

4-061 [Reserved]

4-062 REPORTS OF INDIVIDUAL MONITORING

4-062.01 180 NAC 4 applies to each person licensed by the Department to:

1. Possess or use sources of radiation for purposes of industrial radiography pursuant to 180 NAC 3 or 180 NAC 5; or
2. Receive radioactive waste from other persons for disposal pursuant to 180 NAC 12; or
3. Possess or use at any time, for processing or manufacturing for distribution pursuant to 180 NAC 3 or 180 NAC 7, radioactive material in quantities exceeding any one of the following quantities:

	Activity[a]	
Radionuclide	**Ci**	**GBq**
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

[a]The Department may require as a license condition, or by rule, regulation, or order pursuant to 180 NAC 1-007, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

4-062.02 Each licensee in a category listed in 180 NAC 4-062.01 must submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by 180 NAC 4-022 during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee must use Department Form NRH-2 or electronic media containing all the information required by Department Form NRH-2.

4-062.03 The licensee must file the report required by 180 NAC 4-060.02, covering the preceding year, on or before April 30 of each year. The licensee must submit the report to the Department.

4-063 NOTIFICATIONS AND REPORTS TO INDIVIDUALS

4-063.01 Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 180 NAC 10-004.

4-063.02 When a licensee or registrant is required, pursuant to the provisions of 180 NAC 4-059, 4-060, and 4-062, to report to the Department any exposure of identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant must also provide a copy of the report submitted to the Department to the individual. This report must be transmitted at a time no later than the transmittal to the Department.

4-064 REPORTS OF LEAKING OR CONTAMINATED SEALED SOURCES: The licensee must file a report within 5 days with the Department if the test for leakage or contamination required pursuant to 180 NAC 1-011 indicates a sealed source is leaking or contaminated. The report must include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

4-065 VACATING PREMISES: Each specific licensee must, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his/her activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee must decontaminate the premises in such a manner as the Department may specify.

4-066 REPORTS OF TRANSACTIONS INVOLVING NATIONALLY TRACKED SOURCES: Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source (Refer to Appendix 4-H) must complete and submit a National Source Tracking Transaction Report as specified in 180 NAC 4-066.01 through 4-066.05 for each type of transaction.

4-066.01 Each licensee who manufactures a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;
3. The manufacturer, model, and serial number of the source;
4. The radioactive material in the source;
5. The initial source strength in becquerels (curies) at the time of manufacture; and
6. The manufacture date of the source.

4-066.02 Each licensee that transfers a nationally tracked source to another person must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The name and license number of the recipient facility and the shipping address;
4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
5. The radioactive material in the source;
6. The initial or current source strength in becquerels (curies);
7. The date for which the source strength is reported;
8. The shipping date;
9. The estimated arrival date; and
10. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

4-066.03 Each licensee that receives a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The name, address, and license number of the person that provided the source;
4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
5. The radioactive material in the source;
6. The initial or current source strength in becquerels (curies);
7. The date for which the source strength is reported;
8. The date of receipt, and
9. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

4-066.04 Each licensee that disassembles a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
4. The radioactive material in the source;
5. The initial or current source strength in becquerels (curies);
6. The date for which the source strength is reported;
7. The disassemble date of the source.

4-066.05 Each licensee who disposes of a nationally tracked source must complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The waste manifest number;
4. The container identification with the nationally tracked source;
5. The date of disposal; and
6. The method of disposal.

4-066.06 The reports discussed in 180 NAC 4-066.01 through 4-066.05 must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

1. The on-line National Source Tracking System;
2. Electronically using a computer readable format;
3. By facsimile;
4. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or
5. By telephone with followup by facsimile or mail.

4-066.07 Each licensee must correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee must reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified in 180 NAC 4-066.01 through 4-066.05. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

4-066.08 Each licensee that possesses Category 1 nationally tracked sources must report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2

nationally tracked sources must report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified in 180 NAC 4-066.06, items 1 through 4. The initial inventory report must include the following information:

1. The name, address, and license number of the reporting licensee:
2. The name of the individual preparing the report;
3. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
4. The radioactive material in the sealed source;
5. The initial or current source strength in becquerels (curies); and
6. The date for which the source strength is reported.

APPENDIX 4-A

PROTECTION FACTORS FOR RESPIRATORS[a]

	Operating mode	Assigned Protection Factors
I. Air Purifying Respirators [Particulate1A[b] only]1A[c]:		
Filtering facepiece disposable[d]	Negative Pressure	([d])
Facepiece, half [e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere supplying respirators [particulate, gases and vapors1A[f]]:		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([g])
2. Self-contained breathing Apparatus (SCBA):		
Facepiece, full	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above.	

[a] These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Chapter. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with U.S. Department of Labor regulations.
Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix 4-B are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.
[b] Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95% efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99% efficient. Air purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97% efficient.

APPENDIX 4-A

[c] The licensee may apply to the Department for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).
[d] Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in 180 NAC 4-028 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.
[e] Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (that is, disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95% efficient and all other requirements of 180 NAC 4 are met.
[f] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.
[g] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (that is, 180 NAC 4-028).
[h] The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).
[i] This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption must be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

APPENDIX 4-B

ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

Introduction

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 μm, micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. The class (D,W, or Y) given in the column headed "Class" applies only to the inhalation ALIs and DACs given in Table I, columns 2 and 3. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600, and 6E+0 represents 6×10^{0} or 6.

Table I "Occupational Values"

Note that the columns in Table I of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 0.05 Sv (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in 180 NAC 4-02. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract -- stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;
St. wall = stomach wall;
Blad wall = bladder wall; and
Bone surf = bone surface.

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The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the nonstochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 Sv (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, $\sum$ (intake (in μCi) of each radionuclide/ALI_{ns}) $\leq$ 1.0. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than 1 - (H_d/50), instead of $\leq$1.0.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in μCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute) = [ALI/2.4 x 10^9] μCi/ml,

where 2 x 10^4 ml is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 180 NAC 4-06. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table II "Effluent Concentrations"

The columns in Table II of this appendix captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of 180 NAC 4-014. The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.5 mSv (0.05 rem).

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Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in Appendix 1 180 NAC 4.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9ml, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 1 mSv (0.1 rem) limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion (external dose) is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of Reference Man.

Note 2 at the end of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table III "Releases to Sewers"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 004.40. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by Reference Man, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a Reference Man during a year, would result in a committed effective dose equivalent of 0.5 mSv (0.5 rem).

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LIST OF ELEMENTS

Name	Atomic Symbol	Atomic Number	Name	Atomic Symbol	Atomic Number
Actinium	Ac	89	Neodymium	Nd	60
Aluminum	Al	13	Neptunium	Np	93
Americium	Am	95	Nickel	Ni	28
Antimony	Sb	51	Niobium	Nb	41
Argon	Ar	18	Nitrogen	N	7
Arsenic	As	33	Osmium	Os	76
Astatine	At	85	Oxygen	O	8
Barium	Ba	56	Palladium	Pd	46
Berkelium	Bk	97	Phosphorus	P	15
Beryllium	Be	4	Platinum	Pt	78
Bismuth	Bi	83	Plutonium	Pu	94
Bromine	Br	35	Polonium	Po	84
Cadmium	Cd	48	Potassium	K	19
Calcium	Ca	20	Praseodymium	Pr	59
Californium	Cf	98	Promethium	Pm	61
Carbon	C	6	Protactinium	Pa	91
Cerium	Ce	58	Radium	Ra	88
Cesium	Cs	55	Radon	Rn	86
Chlorine	Cl	17	Rhenium	Re	75
Chromium	Cr	24	Rhodium	Rh	45
Cobalt	Co	27	Rubidium	Rb	37
Copper	Cu	29	Ruthenium	Ru	44
Curium	Cm	96	Samarium	Sm	62
Dysprosium	Dy	66	Scandium	Sc	21
Einsteinium	Es	99	Selenium	Se	34
Erbium	Er	68	Silicon	Si	14
Europium	Eu	63	Silver	Ag	47
Fermium	Fm	100	Sodium	Na	11
Fluorine	F	9	Strontium	Sr	38
Francium	Fr	87	Sulfur	S	16
Gadolinium	Gd	64	Tantalum	Ta	73
Gallium	Ga	31	Technetium	Tc	43
Germanium	Ge	32	Tellurium	Te	52
Gold	Au	79	Terbium	Tb	65
Hafnium	Hf	72	Thallium	Tl	81
Holmium	Ho	67	Thorium	Th	90
Hydrogen	H	1	Thulium	Tm	69
Indium	In	49	Tin	Sn	50
Iodine	I	53	Titanium	Ti	22
Iridium	Ir	77	Tungsten	W	74
Iron	Fe	26	Uranium	U	92
Krypton	Kr	36	Vanadium	V	23
Lanthanum	La	57	Xenon	Xe	54
Lead	Pb	82	Ytterbium	Yb	70
Lutetium	Lu	71	Yttrium	Y	39
Magnesium	Mg	12	Zinc	Zn	30
Manganese	Mn	25	Zirconium	Zr	40
Mendelevium	Md	101			
Mercury	Hg	80			
Molybdenum	Mo	42			

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Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[1]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{7}Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13[2]	Submersion[1]			4E-6	2E-8		
8	Oxygen-15[2]	Submersion[1]			4E-6	2E-8		
9	Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	-	9E+4	4E-5	1E-7	-	-
		Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	9E+1	4E-8	1E-10	-	-
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3

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Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
		W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
		Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see ^{31}Si	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn^{2+}, S^{3+}, Mg^{2+}, Fe^{3+}, Bi^{3+}, and lanthanides	-	4E+2	2E-7	5E-10	-	-
15	Phosphorus-33	D, see ^{32}P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see ^{32}P	-	3E+3	1E-6	4E-9	-	-
16	Sulfur-35	Vapor	-	1E+4	6E-6	2E-8	-	-
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
			LLI wall (8E+3)	-	-	-	1E-4	1E-3
		W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3 -	2E+3	9E-7	3E-9	-	-
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-
17	Chlorine-38[2]	D, see ^{36}Cl	2E+4	4E+4	2E-5	6E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
		W, see ^{36}Cl	-	5E+4	2E-5	6E-8	-	-
17	Chlorine-39[2]	D, see ^{36}Cl	2E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{36}Cl	-	6E+4	2E-5	8E-8	-	-
18	Argon-37	Submersion[1]	-	-	1E+0	6E-3	-	-
18	Argon-39	Submersion[1]	-	-	2E-4	8E-7	-	-
18	Argon-41	Submersion[1]	-	-	3E-6	1E-8	-	-
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5

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Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19	Potassium-44[2]	D, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
19	Potassium-45[2]	D, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	-	-	-
			Bone surf (4E+3)	Bone surf (4E+3)	-	5E-9	6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Scandium-49[2]	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	3E+1	1E-8	4E-11	-	-
		Y, SrTi0	-	6E+0	2E-9	8E-12	-	-
22	Titanium-45	D, see ^{44}Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{44}Ti	-	4E+4	1E-5	5E-8	-	-
		Y, see ^{44}Ti	-	3E+4	1E-5	4E-8	-	-
23	Vanadium-47[2]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
23	Vanadium-48	D, see ^{47}V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
		W, see ^{47}V	-	6E+2	3E-7	9E-10	-	-
23	Vanadium-49	D, see ^{47}V	7E+4	3E+4	1E-5	-	-	-
			LLI wall	Bone surf				

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Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
			(9E+4)	(3E+4)	-	5E-8	1E-3	1E-2
		W, see ^{47}V	-	2E+4	8E-6	2E-8	-	-
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
		Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24	Chromium-49[2]	D, see ^{48}Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{48}Cr	-	1E+5	4E-5	1E-7	-	-
		Y, see ^{48}Cr	-	9E+4	4E-5	1E-7	-	-
24	Chromium-51	D, see ^{48}Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see ^{48}Cr	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{48}Cr	-	2E+4	8E-6	3E-8	-	-
25	Manganese-51[2]	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	8E-8	-	-
25	Manganese-52m[2]	D, see ^{51}Mn	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{51}Mn	-	1E+5	4E-5	1E-7	-	-
25	Manganese-52	D, see ^{51}Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see ^{51}Mn	-	9E+2	4E-7	1E-9	-	-
25	Manganese-53	D, see ^{51}Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
			-	Bone surf (2E+4)	-	3E-8	-	-
		W, see ^{51}Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see ^{51}Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see ^{51}Mn	-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see ^{51}Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{51}Mn	-	2E+4	9E-6	3E-8	-	-
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26	Iron-55	D, see ^{52}Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see ^{52}Fe	-	4E+3	2E-6	6E-9	-	-
26	Iron-59	D, see ^{52}Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see ^{52}Fe	-	5E+2	2E-7	7E-10	-	-
26	Iron-60	D, see ^{52}Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see ^{52}Fe	-	2E+1	8E-9	3E-11	-	-
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
27	Cobalt-56	W, see ^{55}Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see ^{55}Co	4E+2	2E+2	8E-8	3E-10	-	-
27	Cobalt-57	W, see ^{55}Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see ^{55}Co	4E+3	7E+2	3E-7	9E-10	-	-
27	Cobalt-58m	W, see ^{55}Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see ^{55}Co	-	6E+4	3E-5	9E-8	-	-
27	Cobalt-58	W, see ^{55}Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see ^{55}Co	1E+3	7E+2	3E-7	1E-9	-	-
27	Cobalt-60m[2]	W, see ^{55}Co	1E+6	4E+6	2E-3	6E-6	-	-
			St wall (1E+6)	-	-	-	2E-2	2E-1
		Y, see ^{55}Co	-	3E+6	1E-3	4E-6	-	-
27	Cobalt-60	W, see ^{55}Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see ^{55}Co	2E+2	3E+1	1E-8	5E-11	-	-
27	Cobalt-61[2]	W, see ^{55}Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{55}Co	2E+4	6E+4	2E-5	8E-8	-	-
27	Cobalt-62m[2]	W, see ^{55}Co	4E+4	2E+5	7E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{55}Co	-	2E+5	6E-5	2E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	-	1E+3	5E-7	2E-9	-	-
		Vapor	-	1E+3	5E-7	2E-9	-	-
28	Nickel-57	D, see ^{56}Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	6E+3	3E-6	9E-9	-	-
28	Nickel-59	D, see ^{56}Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see ^{56}Ni	-	7E+3	3E-6	1E-8	-	-
		Vapor	-	2E+3	8E-7	3E-9	-	-
28	Nickel-63	D, see ^{56}Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	8E+2	3E-7	1E-9	-	-
28	Nickel-65	D, see ^{56}Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{56}Ni	-	3E+4	1E-5	4E-8	-	-
		Vapor	-	2E+4	7E-6	2E-8	-	-
28	Nickel-66	D, see ^{56}Ni	4E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see ^{56}Ni	-	6E+2	3E-7	9E-10	-	-
		Vapor	-	3E+3	1E-6	4E-9	-	-
29	Copper-60[2]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-
29	Copper-61	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	-	4E+4	2E-5	6E-8	-	-
		Y, see ^{60}Cu	-	4E+4	1E-5	5E-8	-	-
29	Copper-64	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{60}Cu	-	2E+4	9E-6	3E-8	-	-
29	Copper-67	D, see ^{60}Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see ^{60}Cu	-	5E+3	2E-6	7E-9	-	-
		Y, see ^{60}Cu	-	5E+3	2E-6	6E-9	-	-
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63[2]	Y, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69[2]	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65[2]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31	Gallium-66	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see ^{65}Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ^{65}Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68[2]	D, see ^{65}Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{65}Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70[2]	D, see ^{65}Ga	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		W, see ^{65}Ga	-	2E+5	8E-5	3E-7	-	-
31	Gallium-72	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-73	D, see ^{65}Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{65}Ga	-	2E+4	6E-6	2E-8	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
		W, oxides, sulfides, and halides	-	2E+4	8E-6	3E-8	-	-
32	Germanium-67[2]	D, see ^{66}Ge	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, see ^{66}Ge	-	1E+5	4E-5	1E-7	-	-
32	Germanium-68	D, see ^{66}Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see ^{66}Ge	-	1E+2	4E-8	1E-10	-	-
32	Germanium-69	D, see ^{66}Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see ^{66}Ge	-	8E+3	3E-6	1E-8	-	-
32	Germanium-71	D, see ^{66}Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see ^{66}Ge	-	4E+4	2E-5	6E-8	-	-
32	Germanium-75[2]	D, see ^{66}Ge	4E+4	8E+4	3E-5	1E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see ^{66}Ge	-	8E+4	4E-5	1E-7	-	-
32	Germanium-77	D, see ^{66}Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see ^{66}Ge	-	6E+3	2E-6	8E-9	-	-
32	Germanium-78[2]	D, see ^{66}Ge	2E+4	2E+4	9E-6	3E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see ^{66}Ge	-	2E+4	9E-6	3E-8	-	-
33	Arsenic-69[2]	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
33	Arsenic-70[2]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	6E-5	6E-4
33	Arsenic-78[2]	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34	Selenium-70[2]	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
34	Selenium-73m[2]	D, see ^{70}Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	6E-5	2E-7	-	-
34	Selenium-73	D, see ^{70}Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see ^{70}Se	-	2E+4	7E-6	2E-8	-	-
34	Selenium-75	D, see ^{70}Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see ^{70}Se	-	6E+2	3E-7	8E-10	-	-
34	Selenium-79	D, see ^{70}Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see ^{70}Se	-	6E+2	2E-7	8E-10	-	-
34	Selenium-81m[2]	D, see ^{70}Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{70}Se	2E+4	7E+4	3E-5	1E-7	-	-
34	Selenium-81[2]	D, see ^{70}Se	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		W, see ^{70}Se	-	2E+5	1E-4	3E-7	-	-
34	Selenium-83[2]	D, see ^{70}Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	5E-5	2E-7	-	-
35	Bromine-74m[2]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, bromides of lantha-nides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-
35	Bromine-74[2]	D, see ^{74m}Br	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m}Br	-	8E+4	4E-5	1E-7	-	-
35	Bromine-75[2]	D, see ^{74m}Br	3E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m}Br	-	5E+4	2E-5	7E-8	-	-
35	Bromine-76	D, see ^{74m}Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see ^{74m}Br	-	4E+3	2E-6	6E-9	-	-
35	Bromine-77	D, see ^{74m}Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see ^{74m}Br	-	2E+4	8E-6	3E-8	-	-
35	Bromine-80m	D, see ^{74m}Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see ^{74m}Br	-	1E+4	6E-6	2E-8	-	-
35	Bromine-80[2]	D, see ^{74m}Br	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
		W, see ^{74m}Br	-	2E+5	9E-5	3E-7	-	-
35	Bromine-82	D, see ^{74m}Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{74m}Br	-	4E+3	2E-6	5E-9	-	-
35	Bromine-83	D, see ^{74m}Br	5E+4	6E+4	3E-5	9E-8	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see ^{74m}Br	-	6E+4	3E-5	9E-8	-	-
35	Bromine-84[2]	D, see ^{74m}Br	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see ^{74m}Br	-	6E+4	3E-5	9E-8	-	-
36	Krypton-74[2]	Submersion[1]	-	-	3E-6	1E-8	-	-
36	Krypton-76	Submersion[1]	-	-	9E-6	4E-8	-	-
36	Krypton-77[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
36	Krypton-79	Submersion[1]	-	-	2E-5	7E-8	-	-
36	Krypton-81	Submersion[1]	-	-	7E-4	3E-6	-	-
36	Krypton-83m[2]	Submersion[1]	-	-	1E-2	5E-5	-	-
36	Krypton-85m	Submersion[1]	-	-	2E-5	1E-7	-	-
36	Krypton-85	Submersion[1]	-	-	1E-4	7E-7	-	-
36	Krypton-87[2]	Submersion[1]	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion[1]	-	-	2E-6	9E-9	-	-
37	Rubidium-79[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
37	Rubidium-81m[2]	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88[2]	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
37	Rubidium-89[2]	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
			St wall (6E+4)	-	-	-	9E-4	9E-3
38	Strontium-80[2]	D, all soluble compounds except $SrTiO_3$	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and $SrTi0_3$	-	1E+4	5E-6	2E-8	-	-
38	Strontium-81[2]	D, see ^{80}Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{80}Sr	2E+4	8E+4	3E-5	1E-7	-	-
38	Strontium-82	D, see ^{80}Sr	3E+2	4E+2	2E-7	6E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		Y, see ^{80}Sr	2E+2	9E+1	4E-8	1E-10	-	-
38	Strontium-83	D, see ^{80}Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{80}Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m[2]	D, see ^{80}Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see ^{80}Sr	-	8E+5	4E-4	1E-6	-	-
38	Strontium-85	D, see ^{80}Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see ^{80}Sr	-	2E+3	6E-7	2E-9	-	-
38	Strontium-87m	D, see ^{80}Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{80}Sr	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see ^{80}Sr	6E+2	8E+2	4E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{80}Sr	5E+2	1E+2	6E-8	2E-10	-	-
38	Strontium-90	D, see ^{80}Sr	3E+1 Bone surf (4E+1)	2E+1 Bone surf (2E+1)	8E-9 -	- 3E-11	- 5E-7	- 5E-6
		Y, see ^{80}Sr	-	4E+0	2E-9	6E-12	-	-
38	Strontium-91	D, see ^{80}Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see ^{80}Sr	-	4E+3	1E-6	5E-9	-	-
38	Strontium-92	D, see ^{80}Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{80}Sr	-	7E+3	3E-6	9E-9	-	-
39	Yttrium-86m[2]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39	Yttrium-86	W, see ^{86m}Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-87	W, see ^{86m}Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-88	W, see ^{86m}Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see ^{86m}Y	-	2E+2	1E-7	3E-10	-	-
39	Yttrium-90m	W, see ^{86m}Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see ^{86m}Y	-	1E+4	5E-6	2E-8	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
39	Yttrium-90	W, see ^{86m}Y	4E+2	7E+2	3E-7	9E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see ^{86m}Y	-	6E+2	3E-7	9E-10	-	-
39	Yttrium-91m[2]	W, see ^{86m}Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see ^{86m}Y	-	2E+5	7E-5	2E-7	-	-
39	Yttrium-91	W, see ^{86m}Y	5E+2	2E+2	7E-8	2E-10	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{86m}Y	-	1E+2	5E-8	2E-10	-	-
39	Yttrium-92	W, see ^{86m}Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{86m}Y	-	8E+3	3E-6	1E-8	-	-
39	Yttrium-93	W, see ^{86m}Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{86m}Y	-	2E+3	1E-6	3E-9	-	-
39	Yttrium-94[2]	W, see ^{86m}Y	2E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, see ^{86m}Y	-	8E+4	3E-5	1E-7	-	-
39	Yttrium-95[2]	W, see ^{86m}Y	4E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{86m}Y	-	1E+5	6E-5	2E-7	-	-
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
		Y, carbide	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-88	D, see ^{86}Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see ^{86}Zr	-	5E+2	2E-7	7E-10	-	-
		Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-89	D, see ^{86}Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
		Y, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-93	D, see ^{86}Zr	1E+3	6E+0	3E-9	-	-	-
			Bone surf (3E+3)	Bone surf (2E+1)	-	2E-11	4E-5	4E-4
		W, see ^{86}Zr	-	2E+1	1E-8	-	-	-
			-	Bone surf (6E+1)	-	9E-11	-	-
		Y, see ^{86}Zr	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	9E-11	-	-
40	Zirconium-95	D, see ^{86}Zr	1E+3	1E+2	5E-8	-	2E-5	2E-4
			-	Bone surf (3E+2)	-	4E-10	-	-
		W, see ^{86}Zr	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
40	Zirconium-97	D, see ^{86}Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see ^{86}Zr	-	1E+3	6E-7	2E-9	-	-
		Y, see ^{86}Zr	-	1E+3	5E-7	2E-9	-	-
41	Niobium-88[2]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41	Niobium-89[2] (66 min)	W, see ^{88}Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see ^{88}Nb	-	4E+4	2E-5	5E-8	-	-
41	Niobium-89 (122 min)	W, see ^{88}Nb	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{88}Nb	-	2E+4	6E-6	2E-8	-	-
41	Niobium-90	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-93m	W, see ^{88}Nb	9E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+4)	-	-	-	2E-4	2E-3
		Y, see ^{88}Nb	-	2E+2	7E-8	2E-10	-	-
41	Niobium-94	W, see ^{88}Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see ^{88}Nb	-	2E+1	6E-9	2E-11	-	-
41	Niobium-95m	W, see ^{88}Nb	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{88}Nb	-	2E+3	9E-7	3E-9	-	-
41	Niobium-95	W, see ^{88}Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see ^{88}Nb	-	1E+3	5E-7	2E-9	-	-
41	Niobium-96	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-97[2]	W, see ^{88}Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{88}Nb	-	7E+4	3E-5	1E-7	-	-
41	Niobium-98[2]	W, see ^{88}Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see ^{88}Nb	-	5E+4	2E-5	7E-8	-	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS_2	2E+3	5E+3	2E-6	6E-9	-	-
42	Molybdenum-93m	D, see ^{90}Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see ^{90}Mo	4E+3	1E+4	6E-6	2E-8	-	-
42	Molybdenum-93	D, see ^{90}Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see ^{90}Mo	2E+4	2E+2	8E-8	2E-10	-	-
42	Molybdenum-99	D, see ^{90}Mo	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
		Y, see ^{90}Mo	1E+3	1E+3	6E-7	2E-9	-	-
42	Molybdenum-101[2]	D, see ^{90}Mo	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{90}Mo	-	1E+5	6E-5	2E-7	-	-
43	Technetium-93m[2]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43	Technetium-93	D, see ^{93m}Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see ^{93m}Tc	-	1E+5	4E-5	1E-7	-	-
43	Technetium-94m[2]	D, see ^{93m}Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{93m}Tc	-	6E+4	2E-5	8E-8	-	-
43	Technetium-94	D, see ^{93m}Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	-	2E+4	1E-5	3E-8	-	-
43	Technetium-95m	D, see ^{93m}Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see ^{93m}Tc	-	2E+3	8E-7	3E-9	-	-
43	Technetium-95	D, see ^{93m}Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	-	2E+4	8E-6	3E-8	-	-
43	Technetium-96m[2]	D, see ^{93m}Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-96	D, see ^{93m}Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{93m}Tc	-	2E+3	9E-7	3E-9	-	-
43	Technetium-97m	D, see ^{93m}Tc	5E+3	7E+3	3E-6	-	6E-5	6E-4
			-	St wall (7E+3)	-	1E-8	-	-
		W, see ^{93m}Tc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see ^{93m}Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m}Tc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see ^{93m}Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m}Tc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see ^{93m}Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see ^{93m}Tc	4E+3	5E+3	2E-6	-	6E-5	6E-4
			-	St wall (6E+3)	-	8E-9	-	-
		W, see ^{93m}Tc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101[2]	D, see ^{93m}Tc	9E+4	3E+5	1E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, see ^{93m}Tc	-	4E+5	2E-4	5E-7	-	-
43	Technetium-104[2]	D, see ^{93m}Tc	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
		W, see ^{93m}Tc	-	9E+4	4E-5	1E-7	-	-
44	Ruthenium-94[2]	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	-	6E+4	3E-5	9E-8	-	-
		Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-
44	Ruthenium-97	D, see ^{94}Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
		Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-103	D, see ^{94}Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see ^{94}Ru	-	1E+3	4E-7	1E-9	-	-
		Y, see ^{94}Ru	-	6E+2	3E-7	9E-10	-	-
44	Ruthenium-105	D, see ^{94}Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{94}Ru	-	1E+4	6E-6	2E-8	-	-
		Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-106	D, see ^{94}Ru	2E+2	9E+1	4E-8	1E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		W, see ^{94}Ru	-	5E+1	2E-8	8E-11	-	-
		Y, see ^{94}Ru	-	1E+1	5E-9	2E-11	-	-
45	Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	-	8E+4	3E-5	1E-7	-	-
		Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
45	Rhodium-99	D, see ^{99m}Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{99m}Rh	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{99m}Rh	-	2E+3	8E-7	3E-9	-	-
45	Rhodium-100	D, see ^{99m}Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{99m}Rh	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{99m}Rh	-	4E+3	2E-6	5E-9	-	-
45	Rhodium-101m	D, see ^{99m}Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{99m}Rh	-	8E+3	4E-6	1E-8	-	-
		Y, see ^{99m}Rh	-	8E+3	3E-6	1E-8	-	-
45	Rhodium-101	D, see ^{99m}Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{99m}Rh	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{99m}Rh	-	2E+2	6E-8	2E-10	-	-
45	Rhodium-102m	D, see ^{99m}Rh	1E+3	5E+2	2E-7	7E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		W, see ^{99m}Rh	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{99m}Rh	-	1E+2	5E-8	2E-10	-	-
45	Rhodium-102	D, see ^{99m}Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see ^{99m}Rh	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{99m}Rh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m[2]	D, see ^{99m}Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
		Y, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
45	Rhodium-105	D, see ^{99m}Rh	4E+3	1E+4	5E-6	2E-8	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see ^{99m}Rh	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{99m}Rh	-	6E+3	2E-6	8E-9	-	-
45	Rhodium-106m	D, see ^{99m}Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{99m}Rh	-	4E+4	2E-5	5E-8	-	-
		Y, see ^{99m}Rh	-	4E+4	1E-5	5E-8	-	-
45	Rhodium-107[2]	D, see ^{99m}Rh	7E+4	2E+5	1E-4	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{99m}Rh	-	3E+5	1E-4	4E-7	-	-
		Y, see ^{99m}Rh	-	3E+5	1E-4	3E-7	-	-
46	Palladium-100	D, all compounds except						
		those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	-	1E+3	5E-7	2E-9	-	-
		Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46	Palladium-101	D, see ^{100}Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{100}Pd	-	3E+4	1E-5	5E-8	-	-
		Y, see ^{100}Pd	-	3E+4	1E-5	4E-8	-	-
46	Palladium-103	D, see ^{100}Pd	6E+3	6E+3	3E-6	9E-9	-	-
			LLI wall (7E+3)	-	-	-	1E-4	1E-3
		W, see ^{100}Pd	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{100}Pd	-	4E+3	1E-6	5E-9	-	-
46	Palladium-107	D, see ^{100}Pd	3E+4	2E+4	9E-6	-	-	-
			LLI wall (4E+4)	Kidneys (2E+4)	-	3E-8	5E-4	5E-3
		W, see ^{100}Pd	-	7E+3	3E-6	1E-8	-	-
		Y, see ^{100}Pd	-	4E+2	2E-7	6E-10	-	-
46	Palladium-109	D, see ^{100}Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		W, see ^{100}Pd	-	5E+3	2E-6	8E-9	-	-
		Y, see ^{100}Pd	-	5E+3	2E-6	6E-9	-	-
47	Silver-102[2]	D, all compounds except						
		those given for W and Y	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, nitrates and sulfides	-	2E+5	9E-5	3E-7	-	-
		Y, oxides and hydroxides	-	2E+5	8E-5	3E-7	-	-
47	Silver-103[2]	D, see ^{102}Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104m[2]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104[2]	D, see ^{102}Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-
		Y, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
47	Silver-105	D, see ^{102}Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
		W, see ^{102}Ag	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{102}Ag	-	2E+3	7E-7	2E-9	-	-
47	Silver-106m	D, see ^{102}Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
		W, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-106[2]	D, see ^{102}Ag	6E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	9E-4	9E-3
		W, see ^{102}Ag	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{102}Ag	-	2E+5	8E-5	3E-7	-	-
47	Silver-108m	D, see ^{102}Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
		W, see ^{102}Ag	-	3E+2	1E-7	4E-10	-	-
		Y, see ^{102}Ag	-	2E+1	1E-8	3E-11	-	-
47	Silver-110m	D, see ^{102}Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
		W, see ^{102}Ag	-	2E+2	8E-8	3E-10	-	-
		Y, see ^{102}Ag	-	9E+1	4E-8	1E-10	-	-
47	Silver-111	D, see ^{102}Ag	9E+2	2E+3	6E-7	-	-	-
			LLI wall (1E+3)	Liver (2E+3)	-	2E-9	2E-5	2E-4
		W, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-112	D, see ^{102}Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{102}Ag	-	1E+4	4E-6	1E-8	-	-
		Y, see ^{102}Ag	-	9E+3	4E-6	1E-8	-	-
47	Silver-115[2]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see ^{102}Ag	-	9E+4	4E-5	1E-7	-	-
		Y, see ^{102}Ag	-	8E+4	3E-5	1E-7	-	-
48	Cadmium-104[2]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
48	Cadmium-107	D, see ^{104}Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{104}Cd	-	6E+4	2E-5	8E-8	-	-
		Y, see ^{104}Cd	-	5E+4	2E-5	7E-8	-	-
48	Cadmium-109	D, see ^{104}Cd	3E+2	4E+1	1E-8	-	-	-
			Kidneys (4E+2)	Kidneys (5E+1)	-	7E-11	6E-6	6E-5
		W, see ^{104}Cd	-	1E+2	5E-8	-	-	-
			-	Kidneys (1E+2)	-	2E-10	-	-
		Y, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
48	Cadmium-113m	D, see ^{104}Cd	2E+1	2E+0	1E-9	-	-	-
			Kidneys	Kidneys				

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
			(4E+1)	(4E+0)	-	5E-12	5E-7	5E-6
		W, see ^{104}Cd	-	8E+0 Kidneys	4E-9	-	-	-
			-	(1E+1)	-	2E-11	-	-
		Y, see ^{104}Cd	-	1E+1	5E-9	2E-11	-	-
48	Cadmium-113	D, see ^{104}Cd	2E+1 Kidneys	2E+0 Kidneys	9E-10	-	-	-
			(3E+1)	(3E+0)	-	5E-12	4E-7	4E-6
		W, see ^{104}Cd	-	8E+0 Kidneys	3E-9	-	-	-
			-	(1E+1)	-	2E-11	-	-
		Y, see ^{104}Cd	-	1E+1	6E-9	2E-11	-	-
48	Cadmium-115m	D, see ^{104}Cd	3E+2	5E+1 Kidneys	2E-8	-	4E-6	4E-5
			-	(8E+1)	-	1E-10	-	-
		W, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{104}Cd	-	1E+2	6E-8	2E-10	-	-
48	Cadmium-115	D, see ^{104}Cd	9E+2 LLI wall	1E+3	6E-7	2E-9	-	-
			(1E+3)	-	-	-	1E-5	1E-4
		W, see ^{104}Cd	-	1E+3	5E-7	2E-9	-	-
		Y, see ^{104}Cd	-	1E+3	6E-7	2E-9	-	-
48	Cadmium-117m	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-
48	Cadmium-117	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	9E-8	-	-
49	Indium-110[2] (69.1 min)	D, see ^{109}In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	-	6E+4	2E-5	8E-8	-	-
49	Indium-110 (4.9 h)	D, see ^{109}In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		W, see ^{109}In	-	2E+4	8E-6	3E-8	-	-
49	Indium-111	D, see ^{109}In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see ^{109}In	-	6E+3	3E-6	9E-9	-	-
49	Indium-112[2]	D, see ^{109}In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see ^{109}In	-	7E+5	3E-4	1E-6	-	-
49	Indium-113m[2]	D, see ^{109}In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see ^{109}In	-	2E+5	8E-5	3E-7	-	-
49	Indium-114m	D, see ^{109}In	3E+2 LLI wall	6E+1	3E-8	9E-11	-	-
			(4E+2)	-	-	-	5E-6	5E-5
		W, see ^{109}In	-	1E+2	4E-8	1E-10	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
49	Indium-115m	D, see ^{109}In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	-	5E+4	2E-5	7E-8	-	-
49	Indium-115	D, see ^{109}In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see ^{109}In	-	5E+0	2E-9	8E-12	-	-
49	Indium-116m[2]	D, see ^{109}In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{109}In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m[2]	D, see ^{109}In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{109}In	-	4E+4	2E-5	6E-8	-	-
49	Indium-117[2]	D, see ^{109}In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see ^{109}In	-	2E+5	9E-5	3E-7	-	-
49	Indium-119m[2]	D, see ^{109}In	4E+4 St wall (5E+4)	1E+5	5E-5	2E-7	-	-
				-	-	-	7E-4	7E-3
		W, see ^{109}In	-	1E+5	6E-5	2E-7	-	-
50	Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	-	1E+4	5E-6	2E-8	-	-
50	Tin-111[2]	D, see ^{110}Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
		W, see ^{110}Sn	-	3E+5	1E-4	4E-7	-	-
50	Tin-113	D, see ^{110}Sn	2E+3 LLI wall (2E+3)	1E+3	5E-7	2E-9	-	-
				-	-	-	3E-5	3E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-117m	D, see ^{110}Sn	2E+3 LLI wall (2E+3)	1E+3 Bone surf (2E+3)	5E-7	-	-	-
					-	3E-9	3E-5	3E-4
		W, see ^{110}Sn	-	1E+3	6E-7	2E-9	-	-
50	Tin-119m	D, see ^{110}Sn	3E+3 LLI wall (4E+3)	2E+3	1E-6	3E-9	-	-
				-	-	-	6E-5	6E-4
		W, see ^{110}Sn	-	1E+3	4E-7	1E-9	-	-
50	Tin-121m	D, see ^{110}Sn	3E+3 LLI wall (4E+3)	9E+2	4E-7	1E-9	-	-
				-	-	-	5E-5	5E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-121	D, see ^{110}Sn	6E+3 LLI wall (6E+3)	2E+4	6E-6	2E-8	-	-
				-	-	-	8E-5	8E-4
		W, see ^{110}Sn	-	1E+4	5E-6	2E-8	-	-
50	Tin-123m[2]	D, see ^{110}Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
		W, see ^{110}Sn	-	1E+5	6E-5	2E-7	-	-
50	Tin-123	D, see ^{110}Sn	5E+2 LLI wall	6E+2	3E-7	9E-10	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
			(6E+2)	-	-	-	9E-6	9E-5
		W, see ^{110}Sn	-	2E+2	7E-8	2E-10	-	-
50	Tin-125	D, see ^{110}Sn	4E+2	9E+2	4E-7	1E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see ^{110}Sn	-	4E+2	1E-7	5E-10	-	-
50	Tin-126	D, see ^{110}Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
		W, see ^{110}Sn	-	7E+1	3E-8	9E-11	-	-
50	Tin-127	D, see ^{110}Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see ^{110}Sn	-	2E+4	8E-6	3E-8	-	-
50	Tin-128[2]	D, see ^{110}Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{110}Sn	-	4E+4	1E-5	5E-8	-	-
51	Antimony-115[2]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51	Antimony-116m[2]	D, see ^{115}Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{115}Sb	-	1E+5	6E-5	2E-7	-	-
51	Antimony-116[2]	D, see ^{115}Sb	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{115}Sb	-	3E+5	1E-4	5E-7	-	-
51	Antimony-117	D, see ^{115}Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see ^{115}Sb	-	3E+5	1E-4	4E-7	-	-
51	Antimony-118m	D, see ^{115}Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see ^{115}Sb	5E+3	2E+4	9E-6	3E-8	-	-
51	Antimony-119	D, see ^{115}Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{115}Sb	2E+4	3E+4	1E-5	4E-8	-	-
51	Antimony-120[2] (16 min)	D, see ^{115}Sb	1E+5	4E+5	2E-4	6E-7	-	-
			St wall (2E+5)	-	-	-	2E-3	2E-2
		W, see ^{115}Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120 (5.76 d)	D, see ^{115}Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see ^{115}Sb	9E+2	1E+3	5E-7	2E-9	-	-
51	Antimony-122	D, see ^{115}Sb	8E+2	2E+3	1E-6	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see ^{115}Sb	7E+2	1E+3	4E-7	2E-9	-	-
51	Antimony-124m[2]	D, see ^{115}Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see ^{115}Sb	2E+5	6E+5	2E-4	8E-7	-	-
51	Antimony-124	D, see ^{115}Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	2E+2	1E-7	3E-10	-	-
51	Antimony-125	D, see ^{115}Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
		W, see ^{115}Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m[2]	D, see ^{115}Sb	5E+4 St wall (7E+4)	2E+5 -	8E-5 -	3E-7 -	- 9E-4	- 9E-3
		W, see ^{115}Sb	-	2E+5	8E-5	3E-7	-	-
51	Antimony-126	D, see ^{115}Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	5E+2	2E-7	7E-10	-	-
51	Antimony-127	D, see ^{115}Sb	8E+2 LLI wall (8E+2)	2E+3 -	9E-7 -	3E-9 -	- 1E-5	- 1E-4
		W, see ^{115}Sb	7E+2	9E+2	4E-7	1E-9	-	-
51	Antimony-128[2] (10.4 min)	D, see ^{115}Sb	8E+4 St wall (1E+5)	4E+5 -	2E-4 -	5E-7 -	- 1E-3	- 1E-2
		W, see ^{115}Sb	-	4E+5	2E-4	6E-7	-	-
51	Antimony-128 (9.01 h)	D, see ^{115}Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see ^{115}Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see ^{115}Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see ^{115}Sb	-	9E+3	4E-6	1E-8	-	-
51	Antimony-130[2]	D, see ^{115}Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{115}Sb	-	8E+4	3E-5	1E-7	-	-
51	Antimony-131[2]	D, see ^{115}Sb	1E+4 Thyroid (2E+4)	2E+4 Thyroid (4E+4)	1E-5 -	- 6E-8	- 2E-4	- 2E-3
		W, see ^{115}Sb	- -	2E+4 Thyroid (4E+4)	1E-5 -	6E-8	- -	- -
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	-	-
52	Tellurium-121m	D, see ^{116}Te	5E+2 Bone surf (7E+2)	2E+2 Bone surf (4E+2)	8E-8 -	- 5E-10	- 1E-5	- 1E-4
		W, see ^{116}Te	-	4E+2	2E-7	6E-10	-	-
52	Tellurium-121	D, see ^{116}Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{116}Te	-	3E+3	1E-6	4E-9	-	-
52	Tellurium-123m	D, see ^{116}Te	6E+2 Bone surf (1E+3)	2E+2 Bone surf (5E+2)	9E-8 -	- 8E-10	- 1E-5	- 1E-4
		W, see ^{116}Te	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-123	D, see ^{116}Te	5E+2 Bone surf (1E+3)	2E+2 Bone surf (5E+2)	8E-8 -	- 7E-10	- 2E-5	- 2E-4
		W, see ^{116}Te	- -	4E+2 Bone surf (1E+3)	2E-7 -	- 2E-9	- -	- -

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
52	Tellurium-125m	D, see ^{116}Te	1E+3	4E+2	2E-7	-	-	-
			Bone surf (1E+3)	Bone surf (1E+3)	-	1E-9	2E-5	2E-4
		W, see ^{116}Te	-	7E+2	3E-7	1E-9	-	-
52	Tellurium-127m	D, see ^{116}Te	6E+2	3E+2	1E-7	-	9E-6	9E-5
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see ^{116}Te	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{116}Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ^{116}Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129[2]	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{116}Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see ^{116}Te	3E+2	4E+2	2E-7	-	-	-
			Thyroid (6E+2)	Thyroid (1E+3)	-	2E-9	8E-6	8E-5
		W, see ^{116}Te	-	4E+2	2E-7	-	-	-
				Thyroid				
			-	(9E+2)	-	1E-9	-	-
52	Tellurium-131[2]	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	8E-5	8E-4
		W, see ^{116}Te	-	5E+3	2E-6	-	-	-
				Thyroid				
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-132	D, see ^{116}Te	2E+2	2E+2	9E-8	-	-	-
			Thyroid (7E+2)	Thyroid (8E+2)	-	1E-9	9E-6	9E-5
		W, see ^{116}Te	-	2E+2	9E-8	-	-	-
				Thyroid				
			-	(6E+2)	-	9E-10	-	-
52	Tellurium-133m[2]	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	9E-5	9E-4
		W, see ^{116}Te	-	5E+3	2E-6	-	-	-
				Thyroid				
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-133[2]	D, see ^{116}Te	1E+4	2E+4	9E-6	-	-	-
			Thyroid (3E+4)	Thyroid (6E+4)	-	8E-8	4E-4	4E-3
		W, see ^{116}Te	-	2E+4	9E-6	-	-	-
				Thyroid				
			-	(6E+4)	-	8E-8	-	-
52	Tellurium-134[2]	D, see ^{116}Te	2E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (5E+4)	-	7E-8	3E-4	3E-3
		W, see ^{116}Te	-	2E+4	1E-5	-	-	-
				Thyroid				

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
			-	(5E+4)	-	7E-8	-	-
53	Iodine-120m[2]	D, all compounds	1E+4 Thyroid (1E+4)	2E+4 -	9E-6 -	3E-8 -	- 2E-4	- 2E-3
53	Iodine-120[2]	D, all compounds	4E+3 Thyroid (8E+3)	9E+3 Thyroid (1E+4)	4E-6 -	- 2E-8	- 1E-4	- 1E-3
53	Iodine-121	D, all compounds	1E+4 Thyroid (3E+4)	2E+4 Thyroid (5E+4)	8E-6 -	- 7E-8	- 4E-4	- 4E-3
53	Iodine-123	D, all compounds	3E+3 Thyroid (1E+4)	6E+3 Thyroid (2E+4)	3E-6 -	- 2E-8	- 1E-4	- 1E-3
53	Iodine-124	D, all compounds	5E+1 Thyroid (2E+2)	8E+1 Thyroid (3E+2)	3E-8 -	- 4E-10	- 2E-6	- 2E-5
53	Iodine-125	D, all compounds	4E+1 Thyroid (1E+2)	6E+1 Thyroid (2E+2)	3E-8 -	- 3E-10	- 2E-6	- 2E-5
53	Iodine-126	D, all compounds	2E+1 Thyroid (7E+1)	4E+1 Thyroid (1E+2)	1E-8 -	- 2E-10	- 1E-6	- 1E-5
53	Iodine-128[2]	D, all compounds	4E+4 St wall (6E+4)	1E+5 -	5E-5 -	2E-7 -	- 8E-4	- 8E-3
53	Iodine-129	D, all compounds	5E+0 Thyroid (2E+1)	9E+0 Thyroid (3E+1)	4E-9 -	- 4E-11	- 2E-7	- 2E-6
53	Iodine-130	D, all compounds	4E+2 Thyroid (1E+3)	7E+2 Thyroid (2E+3)	3E-7 -	- 3E-9	- 2E-5	- 2E-4
53	Iodine-131	D, all compounds	3E+1 Thyroid (9E+1)	5E+1 Thyroid (2E+2)	2E-8 -	- 2E-10	- 1E-6	- 1E-5
53	Iodine-132m[2]	D, all compounds	4E+3 Thyroid (1E+4)	8E+3 Thyroid (2E+4)	4E-6 -	- 3E-8	- 1E-4	- 1E-3
53	Iodine-132	D, all compounds	4E+3 Thyroid (9E+3)	8E+3 Thyroid (1E+4)	3E-6 -	- 2E-8	- 1E-4	- 1E-3
53	Iodine-133	D, all compounds	1E+2 Thyroid (5E+2)	3E+2 Thyroid (9E+2)	1E-7 -	- 1E-9	- 7E-6	- 7E-5
53	Iodine-134[2]	D, all compounds	2E+4	5E+4	2E-5	6E-8	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
			Thyroid (3E+4)	-	-	-	4E-4	4E-3
53	Iodine-135	D, all compounds	8E+2 Thyroid (3E+3)	2E+3 Thyroid (4E+3)	7E-7 -	- 6E-9	- 3E-5	- 3E-4
54	Xenon-120[2]	Submersion[1]	-	-	1E-5	4E-8	-	-
54	Xenon-121[2]	Submersion[1]	-	-	2E-6	1E-8	-	-
54	Xenon-122	Submersion[1]	-	-	7E-5	3E-7	-	-
54	Xenon-123	Submersion[1]	-	-	6E-6	3E-8	-	-
54	Xenon-125	Submersion[1]	-	-	2E-5	7E-8	-	-
54	Xenon-127	Submersion[1]	-	-	1E-5	6E-8	-	-
54	Xenon-129m	Submersion[1]	-	-	2E-4	9E-7	-	-
54	Xenon-131m	Submersion[1]	-	-	4E-4	2E-6	-	-
54	Xenon-133m	Submersion[1]	-	-	1E-4	6E-7	-	-
54	Xenon-133	Submersion[1]	-	-	1E-4	5E-7	-	-
54	Xenon-135m[2]	Submersion[1]	-	-	9E-6	4E-8	-	-
54	Xenon-135	Submersion[1]	-	-	1E-5	7E-8	-	-
54	Xenon-138[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
55	Cesium-125[2]	D, all compounds	5E+4 St wall (9E+4)	1E+5 -	6E-5 -	2E-7 -	- 1E-3	- 1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130[2]	D, all compounds	6E+4 St wall (1E+5)	2E+5 -	8E-5 -	3E-7 -	- 1E-3	- 1E-2
55	Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cesium-134m	D, all compounds	1E+5 St wall (1E+5)	1E+5 -	6E-5 -	2E-7 -	- 2E-3	- 2E-2
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cesium-135m[2]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138[2]	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
56	Barium-126[2]	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m[2]	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
			St wall (5E+5)	-	-	-	7E-3	7E-2
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139[2]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
56	Barium-141[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131[2]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57	Lanthanum-132	D, see ^{131}La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-135	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
57	Lanthanum-137	D, see ^{131}La	1E+4	6E+1	3E-8	-	2E-4	2E-3
			-	Liver (7E+1)	-	1E-10	-	-
		W, see ^{131}La	-	3E+2	1E-7	-	-	-
			-	Liver (3E+2)	-	4E-10	-	-
57	Lanthanum-138	D, see ^{131}La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see ^{131}La	-	1E+1	6E-9	2E-11	-	-
57	Lanthanum-140	D, see ^{131}La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{131}La	-	1E+3	5E-7	2E-9	-	-
57	Lanthanum-141	D, see ^{131}La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
57	Lanthanum-142[2]	D, see ^{131}La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{131}La	-	3E+4	1E-5	5E-8	-	-
57	Lanthanum-143[2]	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see ^{134}Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ^{134}Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see ^{134}Ce	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	4E+3	2E-6	5E-9	-	-
58	Cerium-137	W, see ^{134}Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ^{134}Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see ^{134}Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ^{134}Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see ^{134}Ce	2E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see ^{134}Ce	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{134}Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see ^{134}Ce	2E+2	3E+1	1E-8	4E-11	-	-
			LLI wall (3E+2)	-	-	-	3E-6	3E-5
		Y, see ^{134}Ce	-	1E+1	6E-9	2E-11	-	-
59	Praseodymium-136[2]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-
59	Praseodymium-137[2]	W, see ^{136}Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-138m	W, see ^{136}Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see ^{136}Pr	-	4E+4	2E-5	6E-8	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
59	Praseodymium-139	W, see ^{136}Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-142m[2]	W, see ^{136}Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-142	W, see ^{136}Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see ^{136}Pr	-	2E+3	8E-7	3E-9	-	-
59	Praseodymium-143	W, see ^{136}Pr	9E+2	8E+2	3E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{136}Pr	-	7E+2	3E-7	9E-10	-	-
59	Praseodymium-144[2]	W, see ^{136}Pr	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-145	W, see ^{136}Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{136}Pr	-	8E+3	3E-6	1E-8	-	-
59	Praseodymium-147[2]	W, see ^{136}Pr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		Y, see ^{136}Pr	-	2E+5	8E-5	3E-7	-	-
60	Neodymium-136[2]	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60	Neodymium-138	W, see ^{136}Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see ^{136}Nd	-	5E+3	2E-6	7E-9	-	-
60	Neodymium-139m	W, see ^{136}Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see ^{136}Nd	-	1E+4	6E-6	2E-8	-	-
60	Neodymium-139[2]	W, see ^{136}Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see ^{136}Nd	-	3E+5	1E-4	4E-7	-	-
60	Neodymium-141	W, see ^{136}Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see ^{136}Nd	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see ^{136}Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{136}Nd	-	8E+2	4E-7	1E-9	-	-
60	Neodymium-149[2]	W, see ^{136}Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see ^{136}Nd	-	2E+4	1E-5	3E-8	-	-
60	Neodymium-151[2]	W, see ^{136}Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see ^{136}Nd	-	2E+5	8E-5	3E-7	-	-
61	Promethium-141[2]	W, all compounds except those given for Y	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
		Y, oxides, hydroxides,						

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
		carbides, and fluorides	-	2E+5	7E-5	2E-7	-	-
61	Promethium-143	W, see ^{141}Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see ^{141}Pm	-	7E+2	3E-7	1E-9	-	-
61	Promethium-144	W, see ^{141}Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see ^{141}Pm	-	1E+2	5E-8	2E-10	-	-
61	Promethium-145	W, see ^{141}Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see ^{141}Pm	-	2E+2	8E-8	3E-10	-	-
61	Promethium-146	W, see ^{141}Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see ^{141}Pm	-	4E+1	2E-8	6E-11	-	-
61	Promethium-147	W, see ^{141}Pm	4E+3	1E+2	5E-8	-	-	-
			LLI wall (5E+3)	Bone surf (2E+2)	-	3E-10	7E-5	7E-4
		Y, see ^{141}Pm	-	1E+2	6E-8	2E-10	-	-
61	Promethium-148m	W, see ^{141}Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see ^{141}Pm	-	3E+2	1E-7	5E-10	-	-
61	Promethium-148	W, see ^{141}Pm	4E+2	5E+2	2E-7	8E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see ^{141}Pm	-	5E+2	2E-7	7E-10	-	-
61	Promethium-149	W, see ^{141}Pm	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{141}Pm	-	2E+3	8E-7	2E-9	-	-
61	Promethium-150	W, see ^{141}Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{141}Pm	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see ^{141}Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{141}Pm	-	3E+3	1E-6	4E-9	-	-
62	Samarium-141m[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141[2]	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
62	Samarium-142[2]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E-2	1E-11	-	-	-
			Bone surf (3E+1)	Bone surf (6E-2)	-	9E-14	3E-7	3E-6
62	Samarium-147	W, all compounds	2E+1	4E-2	2E-11	-	-	-
			Bone surf (3E+1)	Bone surf (7E-2)	-	1E-13	4E-7	4E-6
62	Samarium-151	W, all compounds	1E+4	1E+2	4E-8	-	-	-
			LLI wall	Bone surf				

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
			(1E+4)	(2E+2)	-	2E-10	2E-4	2E-3
62	Samarium-153	W, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
62	Samarium-155[2]	W, all compounds	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[2]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[2]	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64	Gadolinium-146	D, see ^{145}Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see ^{145}Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see ^{145}Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{145}Gd	-	4E+3	1E-6	5E-9	-	-
64	Gadolinium-148	D, see ^{145}Gd	1E+1 Bone surf	8E+3 Bone surf	3E-12	-	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
			(2E+1)	(2E-2)	-	2E-14	3E-7	3E-6
		W, see ^{145}Gd	-	3E-2	1E-11	-	-	-
			-	Bone surf (6E-2)	-	8E-14	-	-
64	Gadolinium-149	D, see ^{145}Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see ^{145}Gd	-	2E+3	1E-6	3E-9	-	-
64	Gadolinium-151	D, see ^{145}Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4
			-	Bone surf (6E+2)	-	9E-10	-	-
		W, see ^{145}Gd	-	1E+3	5E-7	2E-9	-	-
64	Gadolinium-152	D, see ^{145}Gd	2E+1 Bone surf	1E-2 Bone surf	4E-12	-	-	-
			(3E+1)	(2E-2)	-	3E-14	4E-7	4E-6
		W, see ^{145}Gd	-	4E-2	2E-11	-	-	-
			-	Bone surf (8E-2)	-	1E-13	-	-
64	Gadolinium-153	D, see ^{145}Gd	5E+3	1E+2	6E-8	-	6E-5	6E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		W, see ^{145}Gd	-	6E+2	2E-7	8E-10	-	-
64	Gadolinium-159	D, see ^{145}Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{145}Gd	-	6E+3	2E-6	8E-9	-	-
65	Terbium-147[2]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65	Terbium-157	W, all compounds	5E+4 LLI wall	3E+2 Bone surf	1E-7	-	-	-
			(5E+4)	(6E+2)	-	8E-10	7E-4	7E-3
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3 LLI wall	2E+3	7E-7	2E-9	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
			(2E+3)	-	-	-	3E-5	3E-4
66	Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dysprosium-166	W, all compounds	6E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
67	Holmium-155[2]	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Holmium-157[2]	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159[2]	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m[2]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162[2]	W, all compounds	5E+5	2E+6	1E-3	3E-6	-	-
			St wall (8E+5)	-	-	-	1E-2	1E-1
67	Holmium-164m[2]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164[2]	W, all compounds	2E+5	6E+5	3E-4	9E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (9E+2)	-	-	-	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
69	Thulium-162[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-
			LLI wall (1E+4)	Bone surf (6E+2)	-	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
70	Ytterbium-162[2]	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		Y, oxides, hydroxides, and fluorides	-	3E+5	1E-4	4E-7	-	-
70	Ytterbium-166	W, see ^{162}Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		Y, see ^{162}Yb	-	2E+3	8E-7	3E-9	-	-
70	Ytterbium-167[2]	W, see ^{162}Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
		Y, see ^{162}Yb	-	7E+5	3E-4	1E-6	-	-
70	Ytterbium-169	W, see ^{162}Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
		Y, see ^{162}Yb	-	7E+2	3E-7	1E-9	-	-
70	Ytterbium-175	W, see ^{162}Yb	3E+3	4E+3	1E-6	5E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see ^{162}Yb	-	3E+3	1E-6	5E-9	-	-
70	Ytterbium-177[2]	W, see ^{162}Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
		Y, see ^{162}Yb	-	5E+4	2E-5	6E-8	-	-
70	Ytterbium-178[2]	W, see ^{162}Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		Y, see ^{162}Yb	-	4E+4	2E-5	5E-8	-	-
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		Y, oxides, hydroxides, and fluorides	-	4E+3	2E-6	6E-9	-	-
71	Lutetium-170	W, see ^{169}Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
		Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-171	W, see ^{169}Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
		Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
71	Lutetium-172	W, see ^{169}Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
		Y, see ^{169}Lu	-	1E+3	5E-7	2E-9	-	-
71	Lutetium-173	W, see ^{169}Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
			-	Bone surf (5E+2)	-	6E-10	-	-
		Y, see ^{169}Lu	-	3E+2	1E-7	4E-10	-	-
71	Lutetium-174m	W, see ^{169}Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall (3E+3)	Bone surf (3E+2)	-	5E-10	4E-5	4E-4
		Y, see ^{169}Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see ^{169}Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see ^{169}Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see ^{169}Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ^{169}Lu	-	2E+4	9E-6	3E-8	-	-
71	Lutetium-176	W, see ^{169}Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
			-	Bone surf (1E+1)	-	2E-11	-	-
		Y, see ^{169}Lu	-	8E+0	3E-9	1E-11	-	-
71	Lutetium-177m	W, see ^{169}Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
		Y, see ^{169}Lu	-	8E+1	3E-8	1E-10	-	-
71	Lutetium-177	W, see ^{169}Lu	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see ^{169}Lu	-	2E+3	9E-7	3E-9	-	-
71	Lutetium-178m[2]	W, see ^{169}Lu	5E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	8E-4	8E-3
		Y, see ^{169}Lu	-	2E+5	7E-5	2E-7	-	-
71	Lutetium-178[2]	W, see ^{169}Lu	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see ^{169}Lu	-	1E+5	5E-5	2E-7	-	-
71	Lutetium-179	W, see ^{169}Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{169}Lu	-	2E+4	6E-6	3E-8	-	-
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
72	Hafnium-172	D, see ^{170}Hf	1E+3	9E+0 Bone surf	4E-9	-	2E-5	2E-4
			-	(2E+1)	-	3E-11	-	-
		W, see ^{170}Hf	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
72	Hafnium-173	D, see ^{170}Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{170}Hf	-	1E+4	5E-6	2E-8	-	-
72	Hafnium-175	D, see ^{170}Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
			-	Bone surf (1E+3)	-	1E-9	-	-
		W, see ^{170}Hf	-	1E+3	5E-7	2E-9	-	-
72	Hafnium-177m[2]	D, see ^{170}Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{170}Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see ^{170}Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
			-	Bone surf (2E+0)	-	3E-12	-	-
		W, see ^{170}Hf	-	5E+0	2E-9	-	-	-
			-	Bone surf (9E+0)	-	1E-11	-	-
72	Hafnium-179m	D, see ^{170}Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
			-	Bone surf (6E+2)	-	8E-10	-	-
		W, see ^{170}Hf	-	6E+2	3E-7	8E-10	-	-
72	Hafnium-180m	D, see ^{170}Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{170}Hf	-	3E+4	1E-5	4E-8	-	-
72	Hafnium-181	D, see ^{170}Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see ^{170}Hf	-	4E+2	2E-7	6E-10	-	-
72	Hafnium-182m[2]	D, see ^{170}Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see ^{170}Hf	-	1E+5	6E-5	2E-7	-	-
72	Hafnium-182	D, see ^{170}Hf	2E+2 Bone surf (4E+2)	8E-1 Bone surf (2E+0)	3E-10 -	- 2E-12	- 5E-6	- 5E-5
		W, see ^{170}Hf	-	3E+0	1E-9	-	-	-
			-	Bone surf (7E+0)	-	1E-11	-	-
72	Hafnium-183[2]	D, see ^{170}Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{170}Hf	-	6E+4	2E-5	8E-8	-	-
72	Hafnium-184	D, see ^{170}Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{170}Hf	-	6E+3	3E-6	9E-9	-	-
73	Tantalum-172[2]	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
73	Tantalum-173	W, see ^{172}Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-174[2]	W, see ^{172}Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	-	9E+4	4E-5	1E-7	-	-
73	Tantalum-175	W, see ^{172}Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see ^{172}Ta	-	1E+4	6E-6	2E-8	-	-
73	Tantalum-176	W, see ^{172}Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see ^{172}Ta	-	1E+4	5E-6	2E-8	-	-
73	Tantalum-177	W, see ^{172}Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-178	W, see ^{172}Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see ^{172}Ta	-	7E+4	3E-5	1E-7	-	-
73	Tantalum-179	W, see ^{172}Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ^{172}Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see ^{172}Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{172}Ta	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-180	W, see ^{172}Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ^{172}Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m[2]	W, see ^{172}Ta	2E+5 St wall (2E+5)	5E+5	2E-4	8E-7	-	-
				-	-	-	3E-3	3E-2
		Y, see ^{172}Ta	-	4E+5	2E-4	6E-7	-	-
73	Tantalum-182	W, see ^{172}Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see ^{172}Ta	-	1E+2	6E-8	2E-10	-	-
73	Tantalum-183	W, see ^{172}Ta	9E+2 LLI wall (1E+3)	1E+3	5E-7	2E-9	-	-
				-	-	-	2E-5	2E-4
		Y, see ^{172}Ta	-	1E+3	4E-7	1E-9	-	-
73	Tantalum-184	W, see ^{172}Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see ^{172}Ta	-	5E+3	2E-6	7E-9	-	-
73	Tantalum-185[2]	W, see ^{172}Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	-	6E+4	3E-5	9E-8	-	-
73	Tantalum-186[2]	W, see ^{172}Ta	5E+4 St wall (7E+4)	2E+5	1E-4	3E-7	-	-
				-	-	-	1E-3	1E-2
		Y, see ^{172}Ta	-	2E+5	9E-5	3E-7	-	-
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74	Tungsten-179[2]	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
74	Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
74	Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
75	Rhenium-177[2]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-
75	Rhenium-178[2]	D, see ^{177}Re	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ^{177}Re	-	3E+5	1E-4	4E-7	-	-
75	Rhenium-181	D, see ^{177}Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see ^{177}Re	-	9E+3	4E-6	1E-8	-	-
75	Rhenium-182 (12.7 h)	D, see ^{177}Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
		W, see ^{177}Re	-	2E+4	6E-6	2E-8	-	-
75	Rhenium-182 (64.0 h)	D, see ^{177}Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{177}Re	-	2E+3	9E-7	3E-9	-	-
75	Rhenium-184m	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	4E+2	2E-7	6E-10	-	-
75	Rhenium-184	D, see ^{177}Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{177}Re	-	1E+3	6E-7	2E-9	-	-
75	Rhenium-186m	D, see ^{177}Re	1E+3	2E+3	7E-7	-	-	-
			St wall (2E+3)	St wall (2E+3)	-	3E-9	2E-5	2E-4
		W, see ^{177}Re	-	2E+2	6E-8	2E-10	-	-
75	Rhenium-186	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	2E+3	7E-7	2E-9	-	-
75	Rhenium-187	D, see ^{177}Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
			-	St wall (9E+5)	-	1E-6	-	-
		W, see ^{177}Re	-	1E+5	4E-5	1E-7	-	-
75	Rhenium-188m[2]	D, see ^{177}Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{177}Re	-	1E+5	6E-5	2E-7	-	-
75	Rhenium-188	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see ^{177}Re	-	3E+3	1E-6	4E-9	-	-
75	Rhenium-189	D, see ^{177}Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see ^{177}Re	-	4E+3	2E-6	6E-9	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
76	Osmium-180[2]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	-	5E+5	2E-4	7E-7	-	-
		Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-	-
76	Osmium-181[2]	D, see ^{180}Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{180}Os	-	5E+4	2E-5	6E-8	-	-
		Y, see ^{180}Os	-	4E+4	2E-5	6E-8	-	-
76	Osmium-182	D, see ^{180}Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
76	Osmium-185	D, see ^{180}Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
76	Osmium-189m	D, see ^{180}Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see ^{180}Os	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{180}Os	-	2E+5	7E-5	2E-7	-	-
76	Osmium-191m	D, see ^{180}Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{180}Os	-	2E+4	8E-6	3E-8	-	-
		Y, see ^{180}Os	-	2E+4	7E-6	2E-8	-	-
76	Osmium-191	D, see ^{180}Os	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	3E-5	3E-4
		W, see ^{180}Os	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{180}Os	-	1E+3	6E-7	2E-9	-	-
76	Osmium-193	D, see ^{180}Os	2E+3	5E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		W, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
76	Osmium-194	D, see ^{180}Os	4E+2	4E+1	2E-8	6E-11	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		W, see ^{180}Os	-	6E+1	2E-8	8E-11	-	-
		Y, see ^{180}Os	-	8E+0	3E-9	1E-11	-	-
77	Iridium-182[2]	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
77	Iridium-184	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	5E-8	-	-
		Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-185	D, see ^{182}Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{182}Ir	-	1E+4	5E-6	2E-8	-	-
		Y, see ^{182}Ir	-	1E+4	4E-6	1E-8	-	-
77	Iridium-186	D, see ^{182}Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
		W, see ^{182}Ir	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{182}Ir	-	6E+3	2E-6	8E-9	-	-
77	Iridium-187	D, see ^{182}Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-188	D, see ^{182}Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-
		Y, see ^{182}Ir	-	3E+3	1E-6	5E-9	-	-
77	Iridium-189	D, see ^{182}Ir	5E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	7E-5	7E-4
		W, see ^{182}Ir	-	4E+3	2E-6	5E-9	-	-
		Y, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-
77	Iridium-190m[2]	D, see ^{182}Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see ^{182}Ir	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{182}Ir	-	2E+5	8E-5	3E-7	-	-
77	Iridium-190	D, see ^{182}Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see ^{182}Ir	-	1E+3	4E-7	1E-9	-	-
		Y, see ^{182}Ir	-	9E+2	4E-7	1E-9	-	-
77	Iridium-192m	D, see ^{182}Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
		Y, see ^{182}Ir	-	2E+1	6E-9	2E-11	-	-
77	Iridium-192	D, see ^{182}Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see ^{182}Ir	-	4E+2	2E-7	6E-10	-	-
		Y, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
77	Iridium-194m	D, see ^{182}Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
		W, see ^{182}Ir	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{182}Ir	-	1E+2	4E-8	1E-10	-	-
77	Iridium-194	D, see ^{182}Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{182}Ir	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{182}Ir	-	2E+3	8E-7	3E-9	-	-
77	Iridium-195m	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see ^{182}Ir	-	2E+4	9E-6	3E-8	-	-
77	Iridium-195	D, see ^{182}Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{182}Ir	-	5E+4	2E-5	7E-8	-	-
		Y, see ^{182}Ir	-	4E+4	2E-5	6E-8	-	-
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	-	-
			LLI wall (3E+4)	-	-	-	4E-5	4E-4

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
78	Platinum-193	D, all compounds	4E+4	2E+4	1E-5	3E-8	-	-
			LLI wall (5E+4)	-	-	-	6E-4	6E-3
78	Platinum-195m	D, all compounds	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
78	Platinum-197m[2]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Platinum-199[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
		Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79	Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193}Au	-	5E+3	2E-6	8E-9	-	-
		Y, see ^{193}Au	-	5E+3	2E-6	7E-9	-	-
79	Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{193}Au	-	1E+3	6E-7	2E-9	-	-
		Y, see ^{193}Au	-	4E+2	2E-7	6E-10	-	-
79	Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
		Y, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
79	Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	-	2E+3	8E-7	3E-9	-	-
		Y, see ^{193}Au	-	2E+3	7E-7	2E-9	-	-
79	Gold-199	D, see ^{193}Au	3E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see ^{193}Au	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{193}Au	-	4E+3	2E-6	5E-9	-	-
79	Gold-200m	D, see ^{193}Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{193}Au	-	2E+4	1E-6	3E-9	-	-
79	Gold-200[2]	D, see ^{193}Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{193}Au	-	8E+4	3E-5	1E-7	-	-
		Y, see ^{193}Au	-	7E+4	3E-5	1E-7	-	-
79	Gold-201[2]	D, see ^{193}Au	7E+4	2E+5	9E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{193}Au	-	2E+5	1E-4	3E-7	-	-
		Y, see ^{193}Au	-	2E+5	9E-5	3E-7	-	-
80	Mercury-193m	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
		D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-
80	Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		D, see ^{193m}Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{193m}Hg	-	4E+4	2E-5	6E-8	-	-
80	Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
		Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
		D, see ^{193m}Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
		W, see ^{193m}Hg	-	1E+2	5E-8	2E-10	-	-
80	Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
		Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
		D, see ^{193m}Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
		W, see ^{193m}Hg	-	4E+3	2E-6	5E-9	-	-
80	Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		D, see ^{193m}Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{193m}Hg	-	3E+4	1E-5	5E-8	-	-
80	Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
		Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		D, see ^{193m}Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193m}Hg	-	5E+3	2E-6	7E-9	-	-
80	Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
		D, see ^{193m}Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{193m}Hg	-	9E+3	4E-6	1E-8	-	-
80	Mercury-199m[2]	Vapor	-	8E+4	3E-5	1E-7	-	-
		Organic D	6E+4	2E+5	7E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		D, see ^{193m}Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
		W, see ^{193m}Hg	-	2E+5	7E-5	2E-7	-	-
80	Mercury-203	Vapor	-	8E+2	4E-7	1E-9	-	-
		Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
		D, see ^{193m}Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		W, see ^{193m}Hg	-	1E+3	5E-7	2E-9	-	-
81	Thallium-194m[2]	D, all compounds	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
81	Thallium-194[2]	D, all compounds	3E+5	6E+5	2E-4	8E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
81	Thallium-195[2]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198m[2]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
81	Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Lead-195m[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-199[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E-1 Bone surf (1E+0)	2E-1 Bone surf (4E-1)	1E-10 -	- 6E-13	- 1E-8	- 1E-7
82	Lead-211[2]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1 Bone surf (1E+2)	3E+1 -	1E-8 -	5E-11 -	- 2E-6	- 2E-5
82	Lead-214[2]	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bismuth-200[2]	D, nitrates W, all other compounds	3E+4 -	8E+4 1E+5	4E-5 4E-5	1E-7 1E-7	4E-4 -	4E-3 -
83	Bismuth-201[2]	D, see ^{200}Bi W, see ^{200}Bi	1E+4 -	3E+4 4E+4	1E-5 2E-5	4E-8 5E-8	2E-4 -	2E-3 -
83	Bismuth-202[2]	D, see ^{200}Bi W, see ^{200}Bi	1E+4 -	4E+4 8E+4	2E-5 3E-5	6E-8 1E-7	2E-4 -	2E-3 -
83	Bismuth-203	D, see ^{200}Bi W, see ^{200}Bi	2E+3 -	7E+3 6E+3	3E-6 3E-6	9E-9 9E-9	3E-5 -	3E-4 -
83	Bismuth-205	D, see ^{200}Bi W, see ^{200}Bi	1E+3 -	3E+3 1E+3	1E-6 5E-7	3E-9 2E-9	2E-5 -	2E-4 -

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
83	Bismuth-206	D, see ^{200}Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{200}Bi	-	9E+2	4E-7	1E-9	-	-
83	Bismuth-207	D, see ^{200}Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{200}Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-210m	D, see ^{200}Bi	4E+1 Kidneys (6E+1)	5E+0 Kidneys (6E+0)	2E-9 -	- 9E-12	- 8E-7	- 8E-6
		W, see ^{200}Bi	-	7E-1	3E-10	9E-13	-	-
83	Bismuth-210	D, see ^{200}Bi	8E+2 -	2E+2 Kidneys (4E+2)	1E-7 -	- 5E-10	1E-5 -	1E-4 -
		W, see ^{200}Bi	-	3E+1	1E-8	4E-11	-	-
83	Bismuth-212[2]	D, see ^{200}Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see ^{200}Bi	-	3E+2	1E-7	4E-10	-	-
83	Bismuth-213[2]	D, see ^{200}Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see ^{200}Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-214[2]	D, see ^{200}Bi	2E+4 St wall (2E+4)	8E+2 -	3E-7 -	1E-9 -	- 3E-4	- 3E-3
		W, see ^{200}Bi	-	9E-2	4E-7	1E-9	-	-
84	Polonium-203[2]	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-	-
84	Polonium-205[2]	D, see ^{203}Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see ^{203}Po	-	7E+4	3E-5	1E-7	-	-
84	Polonium-207	D, see ^{203}Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{203}Po	-	3E+4	1E-5	4E-8	-	-
84	Polonium-210	D, see ^{203}Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see ^{203}Po	-	6E-1	3E-10	9E-13	-	-
85	Astatine-207[2]	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	-	2E+3	9E-7	3E-9	-	-
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	-	5E+1	2E-8	8E-11	-	-
86	Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
		With daughters present	-	2E+1 (or 12 working level months)	9E-9 (or 1.0 working level)	3E-11	-	-
86	Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
		With daughters present	-	1E+2 (or 4 working level months)	3E-8 (or 0.33 working level)	1E-10	-	-
87	Francium-222[2]	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
87	Francium-223[2]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0	7E-1	3E-10	9E-13	-	-
			Bone surf (9E+0)	-	-	-	1E-7	1E-6
88	Radium-224	W, all compounds	8E+0	2E+0	7E-10	2E-12	-	-
			Bone surf (2E+1)	-	-	-	2E-7	2E-6
88	Radium-225	W, all compounds	8E+0	7E-1	3E-10	9E-13	-	-
			Bone surf (2E+1)	-	-	-	2E-7	2E-6
88	Radium-226	W, all compounds	2E+0	6E-1	3E-10	9E-13	-	-
			Bone surf (5E+0)	-	-	-	6E-8	6E-7
88	Radium-227[2]	W, all compounds	2E+4	1E+4	6E-6	-	-	-
			Bone surf (2E+4)	Bone surf (2E+4)	-	3E-8	3E-4	3E-3
88	Radium-228	W, all compounds	2E+0	1E+0	5E-10	2E-12	-	-
			Bone surf (4E+0)	-	-	-	6E-8	6E-7
89	Actinium-224	D, all compounds except those given for W and Y	2E+3	3E+1	1E-8	-	-	-
			LLI wall (2E+3)	Bone surf (4E+1)	-	5E-11	3E-5	3E-4
		W, halides and nitrates	-	5E+1	2E-8	7E-11	-	-
		Y, oxides and hydroxides	-	5E+1	2E-8	6E-11	-	-
89	Actinium-225	D, see ^{224}Ac	5E+1	3E-1	1E-10	-	-	-
			LLI wall (5E+1)	Bone surf (5E-1)	-	7E-13	7E-7	7E-6
		W, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
		Y, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
89	Actinium-226	D, see ^{224}Ac	1E+2	3E+0	1E-9	-	-	-
			LLI wall (1E+2)	Bone surf (4E+0)	-	5E-12	2E-6	2E-5
		W, see ^{224}Ac	-	5E+0	2E-9	7E-12	-	-
		Y, see ^{224}Ac	-	5E+0	2E-9	6E-12	-	-
89	Actinium-227	D, see ^{224}Ac	2E-1	4E-4	2E-13	-	-	-
			Bone surf (4E-1)	Bone surf (8E-4)	-	1E-15	5E-9	5E-8
		W, see ^{224}Ac	-	2E-3	7E-13	-	-	-
				Bone surf				
			-	(3E-3)	-	4E-15	-	-
		Y, see ^{224}Ac	-	4E-3	2E-12	6E-15	-	-
89	Actinium-228	D, see ^{224}Ac	2E+3	9E+0	4E-9	-	3E-5	3E-4
				Bone surf				
			-	(2E+1)	-	2E-11	-	-
		W, see ^{224}Ac	-	4E+1	2E-8	-	-	-
				Bone surf				

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
			-	(6E+1)	-	8E-11	-	-
		Y, see ^{224}Ac	-	4E+1	2E-8	6E-11	-	-
90	Thorium-226[2]	W, all compounds except those given for Y	5E+3	2E+2	6E-8	2E-10	-	-
			St wall (5E+3)	-	-	-	7E-5	7E-4
		Y, oxides and hydroxides	-	1E+2	6E-8	2E-10	-	-
90	Thorium-227	W, see ^{226}Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
		Y, see ^{226}Th	-	3E-1	1E-10	5E-13	-	-
90	Thorium-228	W, see ^{226}Th	6E+0	1E-2	4E-12	-	-	-
			Bone surf (1E+1)	Bone surf (2E-2)	-	3E-14	2E-7	2E-6
		Y, see ^{226}Th	-	2E-2	7E-12	2E-14	-	-
90	Thorium-229	W, see ^{226}Th	6E-1	9E-4	4E-13	-	-	-
			Bone surf (1E+0)	Bone surf (2E-3)	-	3E-15	2E-8	2E-7
		Y, see ^{226}Th	-	2E-3	1E-12	-	-	-
			-	Bone surf (3E-3)	-	4E-15	-	-
90	Thorium-230	W, see ^{226}Th	4E+0	6E-3	3E-12	-	-	-
			Bone surf (9E+0)	Bone surf (2E-2)	-	2E-14	1E-7	1E-6
		Y, see ^{226}Th	-	2E-2	6E-12	-	-	-
			-	Bone surf (2E-2)	-	3E-14	-	-
90	Thorium-231	W, see ^{226}Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see ^{226}Th	-	6E+3	3E-6	9E-9	-	-
90	Thorium-232	W, see ^{226}Th	7E-1	1E-3	5E-13	-	-	-
			Bone surf (2E+0)	Bone surf (3E-3)	-	4E-15	3E-8	3E-7
		Y, see ^{226}Th	-	3E-3	1E-12	-	-	-
			-	Bone surf (4E-3)	-	6E-15	-	-
90	Thorium-234	W, see ^{226}Th	3E+2	2E+2	8E-8	3E-10	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		Y, see ^{226}Th	-	2E+2	6E-8	2E-10	-	-
91	Protactinium-227[2]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91	Protactinium-228	W, see ^{227}Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
		Y, see ^{227}Pa	-	1E+1	5E-9	2E-11	-	-
91	Protactinium-230	W, see ^{227}Pa	6E+2	5E+0	2E-9	7E-12	-	-
			Bone surf (9E+2)	-	-	-	1E-5	1E-4
		Y, see ^{227}Pa	-	4E+0	1E-9	5E-12	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
91	Protactinium-231	W, see ^{227}Pa	2E-1	2E-3	6E-13	-	-	-
			Bone surf (5E-1)	Bone surf (4E-3)	-	6E-15	6E-9	6E-8
		Y, see ^{227}Pa	-	4E-3	2E-12	-	-	-
			-	Bone surf (6E-3)	-	8E-15	-	-
91	Protactinium-232	W, see ^{227}Pa	1E+3	2E+1	9E-9	-	2E-5	2E-4
			-	Bone surf (6E+1)	-	8E-11	-	-
		Y, see ^{227}Pa	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	1E-10	-	-
91	Protactinium-233	W, see ^{227}Pa	1E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		Y, see ^{227}Pa	-	6E+2	2E-7	8E-10	-	-
91	Protactinium-234	W, see ^{227}Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{227}Pa	-	7E+3	3E-6	9E-9	-	-
92	Uranium-230	D, UF_6, UO_2F_2, $UO_2(NO_3)_2$	4E+0	4E-1	2E-10	-	-	-
			Bone surf (6E+0)	Bone surf (6E-1)	-	8E-13	8E-8	8E-7
		W, UO_3, UF_4, UCl_4	-	4E-1	1E-10	5E-13	-	-
		Y, UO_2, U_3O_8	-	3E-1	1E-10	4E-13	-	-
92	Uranium-231	D, see ^{230}U	5E+3	8E+3	3E-6	1E-8	-	-
			LLI wall (4E+3)	-	-	-	6E-5	6E-4
		W, see ^{230}U	-	6E+3	2E-6	8E-9	-	-
		Y, see ^{230}U	-	5E+3	2E-6	6E-9	-	-
92	Uranium-232	D, see ^{230}U	2E+0	2E-1	9E-11	-	-	-
			Bone surf (4E+0)	Bone surf (4E-1)	-	6E-13	6E-8	6E-7
		W, see ^{230}U	-	4E-1	2E-10	5E-13	-	-
		Y, see ^{230}U	-	8E-3	3E-12	1E-14	-	-
92	Uranium-233	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-234[3]	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-235[3]	D, see ^{230}U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
92	Uranium-236	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	5E-10	-	-	-
			(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-237	D, see ^{230}U	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see ^{230}U	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{230}U	-	2E+3	6E-7	2E-9	-	-
92	Uranium-238[3]	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	6E-10	-	-	-
			(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-239[2]	D, see ^{230}U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		W, see ^{230}U	-	2E+5	7E-5	2E-7	-	-
		Y, see ^{230}U	-	2E+5	6E-5	2E-7	-	-
92	Uranium-240	D, see ^{230}U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{230}U	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{230}U	-	2E+3	1E-6	3E-9	-	-
92	Uranium-natural[3]	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	5E-10	-	-	-
			(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	9E-13	-	-
		Y, see ^{230}U	-	5E-2	2E-11	9E-14	-	-
93	Neptunium-232[2]	W, all compounds	1E+5	2E+3	7E-7	-	2E-3	2E-2
			-	Bone surf (5E+2)	-	6E-9	-	-
93	Neptunium-233[2]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Neptunium-235	W, all compounds	2E+4	8E+2	3E-7	-	-	-
			LLI wall (2E+4)	Bone surf (1E+3)	-	2E-9	3E-4	3E-3
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0 Bone surf	2E-2 Bone surf	9E-12	-	-	-
			(6E+0)	(5E-2)	-	8E-14	9E-8	9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3 Bone surf	3E+1 Bone surf	1E-8	-	-	-
			(4E+3)	(7E+1)	-	1E-10	5E-5	5E-4
93	Neptunium-237	W, all compounds	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
			(1E+0)	(1E-2)	-	1E-14	2E-8	2E-7
93	Neptunium-238	W, all compounds	1E+3	6E+1	3E-8	-	2E-5	2E-4
			-	Bone surf (2E+2)	-	2E-10	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
93	Neptunium-239	W, all compounds	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
93	Neptunium-240[2]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO_2	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO_2	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235[2]	W, see ^{234}Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ^{234}Pu	-	3E+6	1E-3	3E-6	-	-
94	Plutonium-236	W, see ^{234}Pu	2E+0 Bone surf (4E+0)	2E-2 Bone surf (4E-2)	8E-12 -	- 5E-14	- 6E-8	- 6E-7
		Y, see ^{234}Pu	-	4E-2	2E-11	6E-14	-	-
94	Plutonium-237	W, see ^{234}Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see ^{234}Pu	-	3E+3	1E-6	4E-9	-	-
94	Plutonium-238	W, see ^{234}Pu	9E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	-	2E-2	8E-12	2E-14	-	-
94	Plutonium-239	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-240	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-241	W, see ^{234}Pu	4E+1 Bone surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 -	- 8E-13	- 1E-6	- 1E-5
		Y, see ^{234}Pu	- -	8E-1 Bone surf (1E+0)	3E-10 -	- 1E-12	- -	- -
94	Plutonium-242	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-243	W, see ^{234}Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see ^{234}Pu	-	4E+4	2E-5	5E-8	-	-
94	Plutonium-244	W, see ^{234}Pu	8E-1 Bone surf	7E-3 Bone surf	3E-12	-	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
			(2E+0)	(1E-2)	-	2E-14	2E-8	2E-7
		Y, see ^{234}Pu	-	2E-2 Bone surf	7E-12	-	-	-
			-	(2E-2)	-	2E-14	-	-
94	Plutonium-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see ^{234}Pu	-	4E+3	2E-6	6E-9	-	-
94	Plutonium-246	W, see ^{234}Pu	4E+2	3E+2	1E-7	4E-10	-	-
			(4E+2) LLI wall	-	-	-	6E-6	6E-5
		Y, see ^{234}Pu	-	3E+2	1E-7	4E-10	-	-
95	Americium-237[2]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238[2]	W, all compounds	4E+4	3E+3	1E-6	-	5E-4	5E-3
			-	(6E+3) Bone surf	-	9E-9	-	-
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1 Bone surf	6E-3 Bone surf	3E-12	-	-	-
			(1E+0)	(1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242m	W, all compounds	8E-1 Bone surf	6E-3 Bone surf	3E-12	-	-	-
			(1E+0)	(1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
			-	(9E+1) Bone surf	-	1E-10	-	-
95	Americium-243	W, all compounds	8E-1 Bone surf	6E-3 Bone surf	3E-12	-	-	-
			(1E+0)	(1E-2)	-	2E-14	2E-8	2E-7
95	Americium-244m[2]	W, all compounds	6E+4 St wall	4E+3	2E-6	-	-	-
			(8E+4)	(7E+3) Bone surf	-	1E-8	1E-3	1E-2
95	Americium-244	W, all compounds	3E+3	2E+2	8E-8	-	4E-5	4E-4
			-	(3E+2) Bone surf	-	4E-10	-	-
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m[2]	W, all compounds	5E+4 St wall	2E+5	8E-5	3E-7	-	-
			(6E+4)	-	-	-	8E-4	8E-3
95	Americium-246[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1 Bone surf	6E-1 Bone surf	2E-10	-	-	-
			(8E+1)	(6E-1)	-	9E-13	1E-6	1E-5

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
96	Curium-241	W, all compounds	1E+3	3E+1	1E-8	-	2E-5	2E-4
			-	Bone surf (4E+1)	-	5E-11	-	-
96	Curium-242	W, all compounds	3E+1 Bone surf (5E+1)	3E-1 Bone surf (3E-1)	1E-10 -	- 4E-13	- 7E-7	- 7E-6
96	Curium-243	W, all compounds	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 -	- 2E-14	- 3E-8	- 3E-7
96	Curium-244	W, all compounds	1E+0 Bone surf (3E+0)	1E-2 Bone surf (2E-2)	5E-12 -	- 3E-14	- 3E-8	- 3E-7
96	Curium-245	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96	Curium-246	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96	Curium-247	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96	Curium-248	W, all compounds	2E-1 Bone surf (4E-1)	2E-3 Bone surf (3E-3)	7E-13 -	- 4E-15	- 5E-9	- 5E-8
96	Curium-249[2]	W, all compounds	5E+4	2E+4	7E-6	-	7E-4	7E-3
			-	Bone surf (3E+4)	-	4E-8	-	-
96	Curium-250	W, all compounds	4E-2 Bone surf (6E-2)	3E-4 Bone surf (5E-4)	1E-13 -	- 8E-16	- 9E-10	- 9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 -	- 1E-14	- 2E-8	- 2E-7
97	Berkelium-249	W, all compounds	2E+2 Bone surf (5E+2)	2E+0 Bone surf (4E+0)	7E-10 -	- 5E-12	- 6E-6	- 6E-5
97	Berkelium-250	W, all compounds	9E+3	3E+2	1E-7	-	1E-4	1E-3
			-	Bone surf (7E+2)	-	1E-9	-	-
98	Californium-244[2]	W, all compounds except those given for Y	3E+4	6E+2	2E-7	8E-10	-	-

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-
98	Californium-246	W, see ^{244}Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see ^{244}Cf	-	9E+0	4E-9	1E-11	-	-
98	Californium-248	W, see ^{244}Cf	8E+0	6E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
		Y, see ^{244}Cf	-	1E-1	4E-11	1E-13	-	-
98	Californium-249	W, see ^{244}Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	-	1E-2	4E-12	-	-	-
			-	Bone surf (1E-2)	-	2E-14	-	-
98	Californium-250	W, see ^{244}Cf	1E+0	9E-3	4E-12	-	-	-
			Bone surf (2E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	-	3E-2	1E-11	4E-14	-	-
98	Californium-251	W, see ^{244}Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	-	1E-2	4E-12	-	-	-
			-	Bone surf (1E-2)	-	2E-14	-	-
98	Californium-252	W, see ^{244}Cf	2E+0	2E-2	8E-12	-	-	-
			Bone surf (5E+0)	Bone surf (4E-2)	-	5E-14	7E-8	7E-7
		Y, see ^{244}Cf	-	3E-2	1E-11	5E-14	-	-
98	Californium-253	W, see ^{244}Cf	2E+2	2E+0	8E-10	3E-12	-	-
			Bone surf (4E+2)	-	-	-	5E-6	5E-5
		Y, see ^{244}Cf	-	2E+0	7E-10	2E-12	-	-
98	Californium-254	W, see ^{244}Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	-	2E-2	7E-12	2E-14	-	-
99	Einsteinium-250	W, all compounds	4E+4	5E+2	2E-7	-	6E-4	6E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-251	W, all compounds	7E+3	9E+2	4E-7	-	1E-4	1E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99	Einsteinium-254m	W, all compounds	3E+2	1E+1	4E-9	1E-11	-	-
			LLI wall (3E+2)	-	-	-	4E-6	4E-5

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values Col. 2 Inhalation ALI (μCi)	Table 1 Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III release to Sewers Monthly Average Concentration (μCi/ml)
99	Einsteinium-254	W, all compounds	8E+0	7E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1	2E-1	7E-11	-	-	-
			Bone surf (4E+1)	Bone surf (2E-1)	-	3E-13	5E-7	5E-6
101	Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	-	1E-4	1E-3
			-	Bone surf (9E+1)	-	1E-10	-	-
101	Mendelevium-258	W, all compounds	3E+1	2E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	5E-13	6E-7	6E-6
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours	Submersion[1]	-	2E+2	1E-7	1E-9	-	-
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours		-	2E-1	1E-10	1E-12	1E-8	1E-7
-	Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known		-	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:

[1]"Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2]These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See180 NAC 4-007.)

[3]For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see180 NAC 4-004, item 5). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1 Occupational Values: Inhalation Col. 2 ALI (μCi)	Table 1 Occupational Values: Inhalation Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II Effluent Concentrations: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)

SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

SA = 3.6E-7 curies/gram U U-depleted

SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)^2] E-6 , enrichment $\geq$ 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

NOTE:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

+If it is known that Ac-227-D and Cm-250-W are not present	-	7E-4	3E-13	-	-	-
If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present	-	7E-3	3E-12	-	-	-
If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present	-	7E-2	3E-11	-	-	-
If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present	-	7E-1	3E-10	-	-	-
If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present	-	7E+0	3E-9	-	-	-
If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present-	-	-	1E-14	-	-	
If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y,						

Appendix 4-B

Atomic No.	Radionuclide	Class	Table 1 Occupational Values: Col. 1 Oral Ingestion ALI (μCi)	Table 1: Col. 2 Inhalation ALI (μCi)	Table 1: Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations: Col. 1 Air (μCi/ml)	Table II: Col. 2 Water (μCi/ml)	Table III release to Sewers: Monthly Average Concentration (μCi/ml)
	U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present		-	-	-	1E-13	-	-
	If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present		-	-	-	1E-12	-	-
	If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present		-	-	-	-	1E-6	1E-5

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 μm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 μCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 μCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in 180 NAC Appendix 4-B for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

   Example: If radionuclides "A," "B," and "C" are present in concentrations CA, CB, and CC, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Hydrogen-3	1,000	Manganese-54	100
Beryllium-7	1,000	Manganese-56	1,000
Beryllium-10	1	Iron-52	100
Carbon-11	1,000	Iron-55	100
Carbon-14	100	Iron-59	10
Fluorine-18	1,000	Iron-60	1
Sodium-22	10	Cobalt-55	100
Sodium-24	100	Cobalt-56	10
Magnesium-28	100	Cobalt-57	100
Aluminum-26	10	Cobalt-58m	1,000
Silicon-31	1,000	Cobalt-58	100
Silicon-32	1	Cobalt-60m	1,000
Phosphorus-32	10	Cobalt-60	1
Phosphorus-33	100	Cobalt-61	1,000
Sulfur-35	100	Cobalt-62m	1,000
Chlorine-36	10	Nickel-56	100
Chlorine-38	1,000	Nickel-57	100
Chlorine-39	1,000	Nickel-59	100
Argon-39	1,000	Nickel-63	100
Argon-41	1,000	Nickel-65	1,000
Potassium-40	100	Nickel-66	10
Potassium-42	1,000	Copper-60	1,000
Potassium-43	1,000	Copper-61	1,000
Potassium-44	1,000	Copper-64	1,000
Potassium-45	1,000	Copper-67	1,000
Calcium-41	100	Zinc-62	100
Calcium-45	100	Zinc-63	1,000
Calcium-47	100	Zinc-65	10
Scandium-43	1,000	Zinc-69m	100
Scandium-44m	100	Zinc-69	1,000
Scandium-44	100	Zinc-71m	1,000
Scandium-46	10	Zinc-72	100
Scandium-47	100	Gallium-65	1,000
Scandium-48	100	Gallium-66	100
Scandium-49	1,000	Gallium-67	1,000
Titanium-44	1	Gallium-68	1,000
Titanium-45	1,000	Gallium-70	1,000
Vanadium-47	1,000	Gallium-72	100
Vanadium-48	100	Gallium-73	1,000
Vanadium-49	1,000	Germanium-66	1,000
Chromium-48	1,000	Germanium-67	1,000
Chromium-49	1,000	Germanium-68	10
Chromium-51	1,000	Germanium-69	1,000
Manganese-51	1,000	Germanium-71	1,000
Manganese-52m	1,000	Germanium-75	1,000
Manganese-52	100	Germanium-77	1,000
Manganese-53	1,000	Germanium-78	1,000

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Arsenic-69	1,000	Strontium-80	100
Arsenic-70	1,000	Strontium-81	1,000
Arsenic-71	100	Strontium-83	100
Arsenic-72	100	Strontium-85m	1,000
Arsenic-73	100	Strontium-85	100
Arsenic-74	100	Strontium-87m	1,000
Arsenic-76	100	Strontium-89	10
Arsenic-77	100	Strontium-90	0.1
Arsenic-78	1,000	Strontium-91	100
Selenium-70	1,000	Strontium-92	100
Selenium-73m	1,000	Yttrium-86m	1,000
Selenium-73	100	Yttrium-86	100
Selenium-75	100	Yttrium-87	100
Selenium-79	100	Yttrium-88	10
Selenium-81m	1,000	Yttrium-90m	1,000
Selenium-81	1,000	Yttrium-90	10
Selenium-83	1,000	Yttrium-91m	1,000
Bromine-74m	1,000	Yttrium-91	10
Bromine-74	1,000	Yttrium-92	100
Bromine-75	1,000	Yttrium-93	100
Bromine-76	100	Yttrium-94	1,000
Bromine-77	1,000	Yttrium-95	1,000
Bromine-80m	1,000	Zirconium-86	100
Bromine-80	1,000	Zirconium-88	10
Bromine-82	100	Zirconium-89	10
Bromine-83	1,000	Zirconium-93	1
Bromine-84	1,000	Zirconium-95	10
Krypton-74	1,000	Zirconium-97	100
Krypton-76	1,000	Niobium-88	1,000
Krypton-77	1,000	Niobium-89 (66 min)	1,000
Krypton-79	1,000	Niobium-89 (122 min)	1,000
Krypton-81	1,000	Niobium-90	100
Krypton-83m	1,000	Niobium-93m	10
Krypton-85m	1,000	Niobium-94	1
Krypton-85	1,000	Niobium-95m	100
Krypton-87	1,000	Niobium-95	100
Krypton-88	1,000	Niobium-96	100
Rubidium-79	1,000	Niobium-97	1,000
Rubidium-81m	1,000	Niobium-98	1,000
Rubidium-81	1,000	Molybdenum-90	100
Rubidium-82m	1,000	Molybdenum-93m	100
Rubidium-83	100	Molybdenum-93	10
Rubidium-84	100	Molybdenum-99	100
Rubidium-86	100	Molybdenum-101	1,000
Rubidium-87	100	Technetium-93m	1,000
Rubidium-88	1,000	Technetium-93	1,000
Rubidium-89	1,000	Technetium-94m	1,000

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Technetium-94	1,000	Cadmium-113	100
Technetium-96m	1,000	Cadmium-115m	10
Technetium-96	100	Cadmium-115	100
Technetium-97m	100	Cadmium-117m	1,000
Technetium-97	1,000	Cadmium-117	1,000
Technetium-98	10	Indium-109	1,000
Technetium-99m	1,000	Indium-110 (69.1m)	1,000
Technetium-99	100	Indium-110 (4.9h)	1,000
Technetium-101	1,000	Indium-111	100
Technetium-104	1,000	Indium-112	1,000
Ruthenium-94	1,000	Indium-113m	1,000
Ruthenium-97	1,000	Indium-114m	10
Ruthenium-103	100	Indium-115m	1,000
Ruthenium-105	1,000	Indium-115	100
Ruthenium-106	1	Indium-116m	1,000
Rhodium-99m	1,000	Indium-117m	1,000
Rhodium-99	100	Indium-117	1,000
Rhodium-100	100	Indium-119m	1,000
Rhodium-101m	1,000	Tin-110	100
Rhodium-101	10	Tin-111	1,000
Rhodium-102m	10	Tin-113	100
Rhodium-102	10	Tin-117m	100
Rhodium-103m	1,000	Tin-119m	100
Rhodium-105	100	Tin-121m	100
Rhodium-106m	1,000	Tin-121	1,000
Rhodium-107	1,000	Tin-123m	1,000
Palladium-100	100	Tin-123	10
Palladium-101	1,000	Tin-125	10
Palladium-103	100	Tin-126	10
Palladium-107	10	Tin-127	1,000
Palladium-109	100	Tin-128	1,000
Silver-102	1,000	Antimony-115	1,000
Silver-103	1,000	Antimony-116m	1,000
Silver-104m	1,000	Antimony-116	1,000
Silver-104	1,000	Antimony-117	1,000
Silver-105	100	Antimony-118m	1,000
Silver-106m	100	Antimony-119	1,000
Silver-106	1,000	Antimony-120 (16min.)	1,000
Silver-108m	1	Antimony-120 (5.76d)	100
Silver-110m	10	Antimony-122	100
Silver-111	100	Antimony-124m	1,000
Silver-112	100	Antimony-124	10
Silver-115	1,000	Antimony-125	100
Cadmium-104	1,000	Antimony-126m	1,000
Cadmium-107	1,000	Antimony-126	100
Cadmium-109	1	Antimony-127	100
Cadmium-113m	0.1	Antimony-128 (10.4min.)	1,000

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Antimony-128 (9.01h)	100	Xenon-135	1,000
Antimony-129	100	Xenon-138	1,000
Antimony-130	1,000	Cesium-125	1,000
Antimony-131	1,000	Cesium-127	1,000
Tellurium-116	1,000	Cesium-129	1,000
Tellurium-121m	10	Cesium-130	1,000
Tellurium-121	100	Cesium-131	1,000
Tellurium-123m	10	Cesium-132	100
Tellurium-123	100	Cesium-134m	1,000
Tellurium-125m	10	Cesium-134	10
Tellurium-127m	10	Cesium-135m	1,000
Tellurium-127	1,000	Cesium-135	100
Tellurium-129m	10	Cesium-136	10
Tellurium-129	1,000	Cesium-137	10
Tellurium-131m	10	Cesium-138	1,000
Tellurium-131	100	Barium-126	1,000
Tellurium-132	10	Barium-128	100
Tellurium-133m	100	Barium-131m	1,000
Tellurium-133	1,000	Barium-131	100
Tellurium-134	1,000	Barium-133m	100
Iodine-120m	1,000	Barium-133	100
Iodine-120	100	Barium-135m	100
Iodine-121	1,000	Barium-139	1,000
Iodine-123	100	Barium-140	100
Iodine-124	10	Barium-141	1,000
Iodine-125	1	Barium-142	1,000
Iodine-126	1	Lanthanum-131	1,000
Iodine-128	1,000	Lanthanum-132	100
Iodine-129	1	Lanthanum-135	1,000
Iodine-130	10	Lanthanum-137	10
Iodine-131	1	Lanthanum-138	100
Iodine-132m	100	Lanthanum-140	100
Iodine-132	100	Lanthanum-141	100
Iodine-133	10	Lanthanum-142	1,000
Iodine-134	1,000	Lanthanum-143	1,000
Iodine-135	100	Cerium-134	100
Xenon-120	1,000	Cerium-135	100
Xenon-121	1,000	Cerium-137m	100
Xenon-122	1,000	Cerium-137	1,000
Xenon-123	1,000	Cerium-139	100
Xenon-125	1,000	Cerium-141	100
Xenon-127	1,000	Cerium-143	100
Xenon-129m	1,000	Cerium-144	1
Xenon-131m	1,000	Praseodymium-136	1,000
Xenon-133m	1,000	Praseodymium-137	1,000
Xenon-133	1,000	Praseodymium-138m	1,000
Xenon-135m	1,000	Praseodymium-139	1,000

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Praseodymium-142m	1,000	Europium-157	100
Praseodymium-142	100	Europium-158	1,000
Praseodymium-143	100	Gadolinium-145	1,000
Praseodymium-144	1,000	Gadolinium-146	10
Praseodymium-145	100	Gadolinium-147	100
Praseodymium-147	1,000	Gadolinium-148	0.001
Neodymium-136	1,000	Gadolinium-149	100
Neodymium-138	100	Gadolinium-151	10
Neodymium-139m	1,000	Gadolinium-152	100
Neodymium-139	1,000	Gadolinium-153	10
Neodymium-141	1,000	Gadolinium-159	100
Neodymium-147	100	Terbium-147	1,000
Neodymium-149	1,000	Terbium-149	100
Neodymium-151	1,000	Terbium-150	1,000
Promethium-141	1,000	Terbium-151	100
Promethium-143	100	Terbium-153	1,000
Promethium-144	10	Terbium-154	100
Promethium-145	10	Terbium-155	1,000
Promethium-146	1	Terbium-156m (5.0h)	1,000
Promethium-147	10	Terbium-156m (24.4h)	1,000
Promethium-148m	10	Terbium-156	100
Promethium-148	10	Terbium-157	10
Promethium-149	100	Terbium-158	1
Promethium-150	1,000	Terbium-160	10
Promethium-151	100	Terbium-161	100
Samarium-141m	1,000	Dysprosium-155	1,000
Samarium-141	1,000	Dysprosium-157	1,000
Samarium-142	1,000	Dysprosium-159	100
Samarium-145	100	Dysprosium-165	1,000
Samarium-146	1	Dysprosium-166	100
Samarium-147	100	Holmium-155	1,000
Samarium-151	10	Holmium-157	1,000
Samarium-153	100	Holmium-159	1,000
Samarium-155	1,000	Holmium-161	1,000
Samarium-156	1,000	Holmium-162m	1,000
Europium-145	100	Holmium-162	1,000
Europium-146	100	Holmium-164m	1,000
Europium-147	100	Holmium-164	1,000
Europium-148	10	Holmium-166m	1
Europium-149	100	Holmium-166	100
Europium-150 (12.62h)	100	Holmium-167	1,000
Europium-150 (34.2y)	1	Erbium-161	1,000
Europium-152m	100	Erbium-165	1,000
Europium-152	1	Erbium-169	100
Europium-154	1	Erbium-171	100
Europium-155	10	Erbium-172	100
Europium-156	100	Thulium-162	1,000

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Thulium-166	100	Tantalum-178	1,000
Thulium-167	100	Tantalum-179	100
Thulium-170	10	Tantalum-180m	1,000
Thulium-171	10	Tantalum-180	100
Thulium-172	100	Tantalum-182m	1,000
Thulium-173	100	Tantalum-182	10
Thulium-175	1,000	Tantalum-183	100
Ytterbium-162	1,000	Tantalum-184	100
Ytterbium-166	100	Tantalum-185	1,000
Ytterbium-167	1,000	Tantalum-186	1,000
Ytterbium-169	100	Tungsten-176	1,000
Ytterbium-175	100	Tungsten-177	1,000
Ytterbium-177	1,000	Tungsten-178	1,000
Ytterbium-178	1,000	Tungsten-179	1,000
Lutetium-169	100	Tungsten-181	1,000
Lutetium-170	100	Tungsten-185	100
Lutetium-171	100	Tungsten-187	100
Lutetium-172	100	Tungsten-188	10
Lutetium-173	10	Rhenium-177	1,000
Lutetium-174m	10	Rhenium-178	1,000
Lutetium-174	10	Rhenium-181	1,000
Lutetium-176m	1,000	Rhenium-182 (12.7h)	1,000
Lutetium-176	100	Rhenium-182 (64.0h)	100
Lutetium-177m	10	Rhenium-184m	10
Lutetium-177	100	Rhenium-184	100
Lutetium-178m	1,000	Rhenium-186m	10
Lutetium-178	1,000	Rhenium-186	100
Lutetium-179	1,000	Rhenium-187	1,000
Hafnium-170	100	Rhenium-188m	1,000
Hafnium-172	1	Rhenium-188	100
Hafnium-173	1,000	Rhenium-189	100
Hafnium-175	100	Osmium-180	1,000
Hafnium-177m	1,000	Osmium-181	1,000
Hafnium-178m	0.1	Osmium-182	100
Hafnium-179m	10	Osmium-185	100
Hafnium-180m	1,000	Osmium-189m	1,000
Hafnium-181	10	Osmium-191m	1,000
Hafnium-182m	1,000	Osmium-191	100
Hafnium-182	0.1	Osmium-193	100
Hafnium-183	1,000	Osmium-194	1
Hafnium-184	100	Iridium-182	1,000
Tantalum-172	1,000	Iridium-184	1,000
Tantalum-173	1,000	Iridium-185	1,000
Tantalum-174	1,000	Iridium-186	100
Tantalum-175	1,000	Iridium-187	1,000
Tantalum-176	100	Iridium-188	100
Tantalum-177	1,000	Iridium-189	100

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Iridium-190m	1,000	Thallium-204	100
Iridium-190	100	Lead-195m	1,000
Iridium-192 (73.8d)	1	Lead-198	1,000
Iridium-192m (1.4min.)	10	Lead-199	1,000
Iridium-194m	10	Lead-200	100
Iridium-194	100	Lead-201	1,000
Iridium-195m	1,000	Lead-202m	1,000
Iridium-195	1,000	Lead-202	10
Platinum-186	1,000	Lead-203	1,000
Platinum-188	100	Lead-205	100
Platinum-189	1,000	Lead-209	1,000
Platinum-191	100	Lead-210	0.01
Platinum-193m	100	Lead-211	100
Platinum-193	1,000	Lead-212	1
Platinum-195m	100	Lead-214	100
Platinum-197m	1,000	Bismuth-200	1,000
Platinum-197	100	Bismuth-201	1,000
Platinum-199	1,000	Bismuth-202	1,000
Platinum-200	100	Bismuth-203	100
Gold-193	1,000	Bismuth-205	100
Gold-194	100	Bismuth-206	100
Gold-195	10	Bismuth-207	10
Gold-198m	100	Bismuth-210m	0.1
Gold-198	100	Bismuth-210	1
Gold-199	100	Bismuth-212	10
Gold-200m	100	Bismuth-213	10
Gold-200	1,000	Bismuth-214	100
Gold-201	1,000	Polonium-203	1,000
Mercury-193m	100	Polonium-205	1,000
Mercury-193	1,000	Polonium-207	1,000
Mercury-194	1	Polonium-210	0.1
Mercury-195m	100	Astatine-207	100
Mercury-195	1,000	Astatine-211	10
Mercury-197m	100	Radon-220	1
Mercury-197	1,000	Radon-222	1
Mercury-199m	1,000	Francium-222	100
Mercury-203	100	Francium-223	100
Thallium-194m	1,000	Radium-223	0.1
Thallium-194	1,000	Radium-224	0.1
Thallium-195	1,000	Radium-225	0.1
Thallium-197	1,000	Radium-226	0.1
Thallium-198m	1,000	Radium-227	1,000
Thallium-198	1,000	Radium-228	0.1
Thallium-199	1,000	Actinium-224	1
Thallium-200	1,000	Actinium-225	0.01
Thallium-201	1,000	Actinium-226	0.1
Thallium-202	100	Actinium-227	0.001

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Actinium-228	1	Plutonium-242	0.001
Thorium-226	10	Plutonium-243	1,000
Thorium-227	0.01	Plutonium-244	0.001
Thorium-228	0.001	Plutonium-245	100
Thorium-229	0.001	Americium-237	1,000
Thorium-230	0.001	Americium-238	100
Thorium-231	100	Americium-239	1,000
Thorium-232	100	Americium-240	100
Thorium-234	10	Americium-241	0.001
Thorium-natural	100	Americium-242m	0.001
Protactinium-227	10	Americium-242	10
Protactinium-228	1	Americium-243	0.001
Protactinium-230	0.1	Americium-244m	100
Protactinium-231	0.001	Americium-244	10
Protactinium-232	1	Americium-245	1,000
Protactinium-233	100	Americium-246m	1,000
Protactinium-234	100	Americium-246	1,000
Uranium-230	0.01	Curium-238	100
Uranium-231	100	Curium-240	0.1
Uranium-232	0.001	Curium-241	1
Uranium-233	0.001	Curium-242	0.01
Uranium-234	0.001	Curium-243	0.001
Uranium-235	0.001	Curium-244	0.001
Uranium-236	0.001	Curium-245	0.001
Uranium-237	100	Curium-246	0.001
Uranium-238	100	Curium-247	0.001
Uranium-239	1,000	Curium-248	0.001
Uranium-240	100	Curium-249	1,000
Uranium-natural	100	Berkelium-245	100
Neptunium-232	100	Berkelium-246	100
Neptunium-233	1,000	Berkelium-247	0.001
Neptunium-234	100	Berkelium-249	0.1
Neptunium-235	100	Berkelium-250	10
Neptunium-236 (1.15×10^5y)	0.001	Californium-244	100
Neptunium-236 (22.5h)	1	Californium-246	1
Neptunium-237	0.001	Californium-248	0.01
Neptunium-238	10	Californium-249	0.001
Neptunium-239	100	Californium-250	0.001
Neptunium-240	1,000	Californium-251	0.001
Plutonium-234	10	Californium-252	0.001
Plutonium-235	1,000	Californium-253	0.1
Plutonium-236	0.001	Californium-254	0.001
Plutonium-237	100	Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001
Plutonium-238	0.001		
Plutonium-239	0.001		
Plutonium-240	0.001		
Plutonium-241	0.01	Einsteinium-250	100

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-C

QUANTITIES[1] MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Einsteinium-251	100		
Einsteinium-253	0.1		
Einsteinium-254m	1		
Einsteinium-254	0.01		
Fermium-252	1		
Fermium-253	1		
Fermium-254	10		
Fermium-255	1		
Fermium-257	0.01		
Mendelevium-257	10		
Mendelevium-258	0.01		
Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta- emitters of unknown composition	0.01		

[1]The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix 004-B to Section 004, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 μCi). Values of 3.7 MBq (100 μCi) have been assigned for radionuclides having a radioactive half-life in excess of 10^9 years, except rhenium, 37 MBq (1,000 μCi), to take into account their low specific activity.

NOTE: For purposes of 180 NAC 4-32.05, 4-035.01 and 4-055.01, item 1 where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX 4-D

REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED DISPOSAL FACILITIES AND MANIFESTS

Section I. - Manifest.

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste disposal facility must prepare a Manifest reflecting information requested on the following forms, U.S. Nuclear Regulatory Commission (U.S. NRC) U.S. NRC 540, (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and U.S. Form NRC 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description) and if necessary, on Agency Form NRC 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation). U.S. NRC 540 and U.S. NRC 540A must be completed and must physically accompany the pertinent low-level radioactive waste shipment. Upon agreement between shipper and consignee, U.S. Forms U.S. NRC 541 and U.S. NRC 541A and U.S. NRC 542 and U.S. NRC 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the Agency to comply with the manifesting requirements of this section when they ship:

(a) Low-Level Waste for processing and expect its return (that is, for storage under their license) prior to disposal at a licensed land disposal facility;

(b) Low-Level Waste that is being returned to the licensee who is the “waste generator” or “generator,” as defined in this section; or

(c) Radioactively contaminated material to a “waste processor” that becomes the processor’s “residual waste”.

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

Forms U.S. NRC 540, U.S. NRC 541, U.S. NRC 541A and U.S. NRC 542 and U.S. NRC 542A and the accompanying instructions, in hard copy, may be obtained from

Department of Health and Human Services
Division of Public Health, Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, Nebraska 68509-5026

This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this section.

As used in this appendix, the following definitions apply:

“Chelating agent” has the same meaning as that given in 180 NAC 1-002.

“Chemical description” means a description of the principal chemical characteristics of a low-level radioactive waste.

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"Computer-readable medium" means that the Agency's computer can transfer the information from the medium into its memory.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste.

"Decontamination facility" means a facility operating under an Agency, U.S. Nuclear Regulatory Commission or Agreement State or license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this section, is not considered to be a consignee for low-level waste shipments.

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"EPA identification number" means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

"Generator" means a licensee operating under a Department, U.S. Nuclear Regulatory Commission or Agreement State license who (1) is a waste generator as defined in this part, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

"High integrity container (HIC)" means a container commonly designed to meet the structural stability requirements of Appendix 180 NAC 4-E, Section II, and to meet Department of Transportation requirements for a Type A package.

U.S. NRC Forms 540, 540A, 541, 541A, 542, and 542A are Forms referenced in this appendix. Licensees need not use originals of these U.S. NRC Forms as long as any substitute forms are equivalent to the original document in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, U.S. NRC Forms 541 (and 541A) and U.S. NRC Forms 542 and (542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Package" means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

"Physical description" means the items called for on Form U.S. NRC 541 to describe a low-level radioactive waste.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means U.S. NRC 540 and, if required Form U.S. NRC 540A, which includes the information required by DOT in 49 CFR part 172.

"Source material" has the same meaning as that given in180 NAC 1-002.

"Special nuclear material" has the same meaning as that given in180 NAC 1-002.

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"Uniform Low-Level Radioactive Waste Manifest" or "Uniform Manifest" means the combination of U.S. NRC Forms 540, 541, and if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Waste collector" means an entity, operating under a Department, U.S. Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on Form U.S. NRC 541.

"Waste generator" means an entity, operating under a Department, U.S. Nuclear Regulatory Commission or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

"Waste processor" means an entity, operating under a Department, U.S. Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description that is, a specific waste descriptor code or description; or a waste absorbed on or solidified in a specifically defined media).

INFORMATION REQUIREMENTS

A. General Information

The shipper of the low-level radioactive waste must provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;
2. An explicit declaration indicting whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and
3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste must provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;
2. The total number of packages/disposal containers;
3. The total disposal volume and disposal weight in the shipment;
4. The total radionuclide activity in the shipment.
5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

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6. The total masses of U-233, U-235, and plutonium in the form of special nuclear material, and the total mass of uranium and thorium in the form of source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste must provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;
2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;
3. The volume displaced by the disposal container;
4. The gross weight of the disposal container, including the waste;
5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;
6. A physical and chemical description of the waste;
7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;
8. The approximate volume of waste within a container;
9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;
10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in the form of special nuclear material, and the masses of uranium and thorium in the form of source material. For discrete waste types (that is, activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with a disposal container must be reported;
11. The total radioactivity within each container; and
12. For wastes consigned to a disposal facility, the classification of the waste pursuant to Appendix 4-E, Section I. Waste not meeting the structural stability requirements of Appendix 4-E, Section II(b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste must provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;
2. A physical and chemical description of the waste;
3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;
4. For waste consigned to a disposal facility, the classification of the waste pursuant to Appendix 180 NAC 4-E, Section I. Waste not meeting the structural stability requirements of Appendix 180 NAC 4-E, Section II(b) must be identified.
5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in the form of special nuclear material, and the masses of uranium and thorium in the form of source material; and
6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

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This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the low-level waste resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this section). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (that is activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

   (a) The volume of waste within the disposal container;

   (b) A physical and chemical description of the waste, including the solidification agent, if any;

   (c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

   (d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Appendix 180 NAC 4-E, Section II(b); and

   (e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in the form of special nuclear material, and the masses of uranium and thorium in the form of source material if contained in the waste.

Section II - Certification

An authorized representative of the waste generator, processor, or collector must certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Department. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

Section III - Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector must comply with the requirements in A.1 through 9 of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging of A.4 through 9 of this section. A licensee shall:

   1. Prepare all wastes so that the waste is classified according to Appendix 180 NAC 4-E, Section I and meets waste characteristics requirements in, Appendix 180 NAC 4-E, Section II.
   2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with Appendix 180 NAC 4-E, Section I.
   3. Conduct a quality assurance program to assure compliance with Appendix 180 NAC 4-E, Section I and Section II (the program must include management evaluation of audits);

4. Prepare the Department Uniform Low-Level Radioactive Waste Manifest as required by this appendix;
5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (i) receipt of the manifest precedes the low-level waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

6. Include Forms U.S. NRC 540 and U.S. NRC 540A, if required, with the shipment regardless of the option in Paragraph A.5 of this section;.
7. Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 180 NAC 3. This includes those manifests and documents required under the standards for protection against radiation in effect prior to May 30, 1994; and
8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by Appendix 180 NAC 4-D.
9. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste must:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form U.S. NRC 540.
2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector must ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;
3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the low-level waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;
4. Include Forms U.S. NRC 540 and NRC 540A, if required, with the shipment regardless of the option chosen in Paragraph B.3 of this section;
5. Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by180 NAC 3, and retain information from generator manifest until the license is terminated. This includes those manifests and documents of acknowledgment of receipt required under the standards for protection against radiation in effect prior to May 30, 1994; and
6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt;
7. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Paragraph E of this appendix; and
8. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste must:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form U.S. NRC 540;
2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each

container of waste in the shipment, the manifest must identify the waste generators, the preprocessed waste volume, and other information as required in Section I.E. of this appendix;

3. Prepare all wastes so that the waste is classified according to Appendix 18- NAC 4-E, Section I, of Appendix 180 NAC 4-D and meets the waste characteristics requirements in Appendix 180 NAC 4-E, Section II;
4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Appendix 180 NAC 4-E, Section I and Section III;

5. Conduct a quality assurance program to assure compliance with Appendix 180 NAC 4- E, Section I and II (the program must include management evaluation of audits);
6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) receipt of the manifest precedes the low-level waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;
7. Include Forms U.S. NRC 540 and NRC 540A, if required, with the shipment regardless of the option chosen in Paragraph C.6 of this section;
8. Retain copies of the original manifests and new manifests and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 180 NAC 3. This includes those manifests and documents of acknowledgment of receipt required under the standards for protection against radiation in effect prior to May 30, 1994; and
9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 180 NAC 3;
10. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Paragraph E of this appendix; and
11. Notify the shipper and the Department when any shipment, or any part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator must:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of Form U.S. NRC 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating that discrepancy.
2. Maintain copies of all completed manifests or equivalent documentation until the license is terminated. This includes those manifests or equivalent documents required under the standards for protection against radiation in effect prior to May 30, 1994.
3. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipments or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and
2. Be traced and reported. The investigation must include tracing the shipment and filing a report with the Department. Each licensee who conducts a trace investigation must file a written report with the Department within two weeks of completion of the investigation.

APPENDIX 4-E

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

I. Classification of Radioactive Waste for Land Disposal

a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

b) Classes of waste.

1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II. (a). If Class A waste also meets the stability requirements set forth in Section II. (b), it is not necessary to segregate the waste for disposal.

2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification must be determined as follows:

1) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

2) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

3) If the concentration exceeds the value in Table I, the waste is not generally acceptable for near surface disposal.

4) For wastes containing mixtures of radionuclides listed in Table I, the total concentration must be determined by the sum of fractions rule described in Section I. (g).

APPENDIX 4-E

Table I		
	Concentration	
Radionuclide	curie/cubic meter[a]	nanocurie/gram[b]
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100
[a]To convert the Ci/m^3 values to gigabecquerel (Gbq) per cubic meter, multiply the Ci/m^3 value by 37.		
[b]To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.		

d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I classification must be determined based on the concentrations shown in Table II. However, as specified in Section I. (f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

1) If the concentration does not exceed the value in Column 1, the waste is Class A.

2) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

3) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

5) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration must be determined by the sum of fractions rule described in Section I. (g).

APPENDIX 4-E

Table II			
	Concentration, curie/cubic meter*		
Radionuclide	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	-----	-----
H-3	40	-----	-----
Co-60	700	-----	-----
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

*DEPARTMENT NOTE: To convert the Ci/m^3 value to gigabecquerel (Gbq) per cubic meter, multiply the Ci/m^3 value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification must be determined as follows:

1) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class must be that determined by the concentration of radionuclides listed in Table II.

2) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste must be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

g) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m^3 (50 Ci/m^3) and Cs-137 in a concentration of 814 GBq/m^3 (22 Ci/m^3). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33., for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

APPENDIX 4-E

h) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

II. Radioactive Waste Characteristics

a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

1) Wastes must be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of 180 NAC 4, the site license conditions shall govern.

2) Wastes must not be packaged for disposal in cardboard or fiberboard boxes.

3) Liquid waste must be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

4) Solid waste containing liquid must contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

5) Waste must not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

6) Waste must not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.(a)(8).

7) Waste must not be pyrophoric. Pyrophoric materials contained in wastes must be treated, prepared, and packaged to be nonflammable.[1]

8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity must not exceed 3.7 TBq (100 Ci) per container.

9) Wastes containing hazardous, biological, pathogenic, or infectious material must be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1) Waste must have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be

[1]See 180 NAC 1-002 for definition of pyrophoric.

APPENDIX 4-E

provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2) Notwithstanding the provisions in Section II. (a)(3) and (4), liquid wastes, or wastes containing liquid, must be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3) Void spaces within the waste and between the waste and its package must be reduced to the extent practicable.

III. Labeling

Each package of waste must be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

APPENDIX 4-F

QUANTITIES FOR USE WITH DECOMMISSIONING

(To convert μCi to kBq, multiply the μCi value by 37.)

Material	Microcurie
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1
Europium-155	10
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10

APPENDIX 4-F

QUANTITIES FOR USE WITH DECOMMISSIONING

(To convert μCi to kBq, multiply the μCi value by 37.)

Material	Microcurie
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1

APPENDIX 4-F

QUANTITIES FOR USE WITH DECOMMISSIONING

(To convert μCi to kBq, multiply the μCi value by 37.)

Material	Microcurie
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100

APPENDIX 4-F

QUANTITIES FOR USE WITH DECOMMISSIONING

(To convert μCi to kBq, multiply the μCi value by 37.)

Material	Microcurie
Thallium-204	10
Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2]	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or Mixtures of alpha emitters of unknown composition	0.1
Any radionuclide other than alpha emitting Radionuclides, not listed above or mixtures of Beta emitters of unknown composition	0.1

NOTE:Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" -- that is, unity.

[1]Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2]Based on alpha disintegration rate of U-238, U-234 and U-235.

APPENDIX 4-G
CONCENTRATION AND ACTIVITY LIMITS OF NUCLIDES FOR DISPOSAL IN A CITY OR COUNTY LANDFILL DISPOSAL FACILITY
(For use in 180 NAC 4-038)

Nuclides	Concentration Limits (Ci/m^3)	Annual Generator Disposal Limit (Ci/yr)
F-18	3E-1	8
Si-31	1E-2	3E+3
Na-24	9E-4	2E-2
P-32	2	5E+1
P-33	10	3E+2
S-35	9	2E+2
Ar-41	3E-1	8
K-42	2E-2	5E-1
Ca-45	4	1E+2
Ca-47	2E-2	5E-1
Sc-46	2E-3	5E-2
Cr-51	6E-1	2E+1
Fe-59	5E-3	1E-1
Co-57	6E-2	2
Co-58	1E-2	3E-1
Zn-65	7E-3	2E-1
Ga-67	3E-1	8
Se-75	5E-2	1
Br-82	2E-3	5E-2
Rb-86	4E-2	1
Sr-85	2E-2	5E-1
Sr-89	8	2E+2
Y-90	4	1E+2
Y-91	4E-1	10
Zr-95	8E-3	2E-1
Nb-95	8E-3	2E-1
Mo-99	5E-2	1

APPENDIX 4-G
CONCENTRATION AND ACTIVITY LIMITS OF NUCLIDES FOR DISPOSAL IN A CITY OR COUNTY LANDFILL DISPOSAL FACILITY
(For use in 180 NAC 4-038)

Nuclides	Concentration Limits (Ci/m^3)	Annual Generator Disposal Limit (Ci/yr)
Tc-99m	1	3E+1
Rh-106	1	3E+1
Ag-110m	2E-3	5E-2
Cd-115m	2E-1	5
In-111	9E-2	2
In-113m	9	2E+2
Sn-113	6E-2	2
Sn-119	2E+1	5E+2
Sb-124	2E-3	5E-2
Te-129	2E-1	5
I-123	4E-1	1E+1
I-125	7E-1	2E+1
I-131	4E-2	1
I-133	2E-2	5E-1
Xe-127	8E-2	2
Xe-133	1	3E+1
Ba-140	2E-3	5E-2
La-140	2E-3	5E-2
Ce-141	4E-1	1E+1
Ce-144	1E-3	3E-2
Pr-143	6	2E+2
Nd-147	7E-2	2
Yb-169	6E-2	2
Ir-192	1E-2	3E-1
Au-198	3E-2	8E-1
Hg-197	8E-1	2E+1
TI-201	4E-1	1E+1

APPENDIX 4-G
CONCENTRATION AND ACTIVITY LIMITS OF NUCLIDES FOR DISPOSAL IN A CITY OR COUNTY LANDFILL DISPOSAL FACILITY
(For use in 180 NAC 4-038)

Nuclides	Concentration Limits (Ci/m^3)	Annual Generator Disposal Limit (Ci/yr)
Hg-203	1E-1	3

NOTE: In any case where there is a mixture in waste of more than one radionuclide, the limiting values for purposes of this Appendix must be determined as follows:

For each radionuclide in the mixture, calculate the ratio between the quantity present in the mixture and the limit established in Appendix 004-G for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Examples: If radionuclides a, b, and c are present in concentrations C_a, C_b, and C_c, and if the applicable concentrations are CL_a, CL_b, and CL_c respectively, then the concentrations shall be limited so that the following relationship exists:

$$(C_a/CL_a) + (C_b/CL_b) + (C_c/CL_c) \leq 1$$

If the total curies for radionuclides a, b, and c are represented A_a, A_b, and A_c, and the annual curie limit for each radionuclide is AL_a, AL_b, and AL_c, then the generator is limited to the following:

$$(A_a/AL_a) + (A_b/AL_b) + (A_c/AL_c) \leq 1$$

APPENDIX 4-H
NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1.0	27
Gadolinium-153	1,000	27,000	10	270
Iridum-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

Nebraska Department of Health and Human Services, Radiological Health

CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY

NRH-1
DRAFT DATE

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX: MALE ☐ FEMALE ☐	5. DATE OF BIRTH

6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

19. SIGNATURE OF MONITORED INDIVIDUAL	20. DATE SIGNED	21. CERTIFYING ORGANIZATION	22. SIGNATURE OF DESIGNEE	23. DATE SIGNED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF NRH-1
(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee, registrant, or facility not licensed by the Department that provided monitoring.

8. Enter the Department license or registration number or numbers.

9. Place an "X" in Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee or registrant intends to assign the record dose on the basis of TLD results that are not yet available.

10. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all PSEs.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).

15. Enter the committed effective dose equivalent (CEDE).

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ.

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.

20. Enter the date this form was signed by the monitored individual.

21. [OPTIONAL] Enter the name of the licensee, registrant or facility not licensed by the Department, providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is not employed by the licensee or registrant and the employer chooses to maintain exposure records for its employees.

22. [OPTIONAL] Signature of the person designated to represent the licensee, registrant or employer entered in item 21. The licensee, registrant or employer who chooses to countersign the form should have on file documentation of all the information on the Department Form Y being signed.

23. [OPTIONAL] Enter the date this form was signed by the designated representative.

Nebraska Department of Health and Human Services, Radiological Health

OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD

NRH-2
DRAFT DATE

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX MALE_____ FEMALE_____	5. DATE OF BIRTH

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER(S)	9A.		9B.	
				RECORD		ROUTINE
				ESTIMATE		PSE

INTAKES

10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN ΦCi

DOSES (in rem)	
DEEP DOSE EQUIVALENT (DDE)	11.
EYE DOSE EQUIVALENT TO THE LENS OF THE EYE (LDE)	12.
SHALLOW DOSE EQUIVALENT, WHOLE BODY (SDE,WB)	13.
SHALLOW DOSE EQUIVALENT, MAX EXTREMITY (SDE,ME)	14.
COMMITTED EFFECTIVE DOSE EQUIVALENT(CEDE)	15.
COMMITTED DOSE EQUIVALENT, MAXIMALLY EXPOSED ORGAN (CDE)	16.
TOTAL EFFECTIVE DOSE EQUIVALENT (BLOCKS 11+15) (TEDE)	17.
TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN (BLOCKS 11+16) (TODE)	18.
19. COMMENTS	

20. SIGNATURE -- LICENSEE OR REGISTRANT	21. DATE PREPARED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF NRH-2
(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee or registrant.

8. Enter the Department license or registration number or numbers.

9A. Place an "X" in Record or Estimate. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

9B. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSEs.

10A. Enter the symbol for each radionuclide that resulted in an internal exposure recorded for the individual, using the format "Xx-###x," for instance, Cs-137 or Tc-99m.

10B. Enter the lung clearance class as listed in Appendix B to Part D (D, W, Y, V, or O for other) for all intakes by inhalation.

10C. Enter the mode of intake. For inhalation, enter "H." For absorption through the skin, enter "B." For oral ingestion, enter "G." For injection, enter "J."

10D. Enter the intake of each radionuclide in ΦCi.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).

15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated".

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the person designated to represent the licensee or registrant.

20. Enter the date this form was prepared.

21. COMMENTS.
In the space provided, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE,ME was the result of exposure from a discrete hot particle. Another possibility would be to indicate that an overexposed report has been sent to the Department in reference to the exposure report.

ATTACHMENT 4-1

29 CFR 1910.134(i)(1)(ii)(A-E)

(i) Compressed and liquid oxygen shall meet the United States Pharmacopoeia requirements for medical or breathing oxygen; and

(ii) Compressed breathing air shall meet at least the requirements for Grade D breathing air described in ANSI/Compressed Gas Association Commodity Specification for Air, G–7.1–1989, to include:

(A) Oxygen content (v/v) of 19.5–23.5%;

(B) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(C) Carbon monoxide (CO) content of 10 ppm or less;

(D) Carbon dioxide content of 1,000 ppm or less; and

(E) Lack of noticeable odor.

(2) The employer shall ensure that compressed oxygen is not used in atmosphere-supplying respirators that have previously used compressed air.

(3) The employer shall ensure that oxygen concentrations greater than 23.5% are used only in equipment designed for oxygen service or distribution.

(4) The employer shall ensure that cylinders used to supply breathing air to respirators meet the following requirements:

(i) Cylinders are tested and maintained as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR part 180);

(ii) Cylinders of purchased breathing air have a certificate of analysis from the supplier that the breathing air meets the requirements for Grade D breathing air; and

(iii) The moisture content in the cylinder does not exceed a dew point of −50 °F (−45.6 °C) at 1 atmosphere pressure.

(5) The employer shall ensure that compressors used to supply breathing air to respirators are constructed and situated so as to:

(i) Prevent entry of contaminated air into the air-supply system;

(ii) Minimize moisture content so that the dew point at 1 atmosphere pressure is 10 degrees F (5.56 °C) below the ambient temperature;

(iii) Have suitable in-line air-purifying sorbent beds and filters to further ensure breathing air quality. Sorbent beds and filters shall be maintained and replaced or refurbished periodically following the manufacturer's instructions.

(iv) Have a tag containing the most recent change date and the signature of the person authorized by the employer to perform the change. The tag shall be maintained at the compressor.

(6) For compressors that are not oil-lubricated, the employer shall ensure that carbon monoxide levels in the breathing air do not exceed 10 ppm.

(7) For oil-lubricated compressors, the employer shall use a high-temperature or carbon monoxide alarm, or both, to monitor carbon monoxide levels. If only high-temperature alarms are used, the air supply shall be monitored at intervals sufficient to prevent carbon monoxide in the breathing air from exceeding 10 ppm.

(8) The employer shall ensure that breathing air couplings are incompatible with outlets for nonrespirable worksite air or other gas systems. No asphyxiating substance shall be introduced into breathing air lines.

(9) The employer shall use only the respirator manufacturer's NIOSH-approved breathing-gas containers, marked and maintained in accordance with the Quality Assurance provisions of the NIOSH approval for the SCBA as issued in accordance with the NIOSH respirator-certification standard at 42 CFR part 84.

(j) *Identification of filters, cartridges, and canisters.* The employer shall ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible.

(k) *Training and information.* This paragraph requires the employer to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in appendix D of this section to employees who wear respirators when not required by this section or by the employer to do so.

TITLE 180 CONTROL OF RADIATION

CHAPTER 5 RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

NOTIFICATIONS

APPENDIXES

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

TITLE 180 CONTROL OF RADIATION

CHAPTER 5 RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

5-001 SCOPE AND AUTHORITY

5-001.01 180 NAC 5 prescribes requirements for the issuance of licenses or registrations for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

5-001.02 The provisions and requirements of 180 NAC 5 are in addition to, and not in substitution for, other requirements of Title 180. In particular, the general requirements and provisions of 180 NAC 1, 2, 3, 4, 10, 13, 17 and 18 apply to applicants, licensees and registrants subject to 180 NAC 5. 180 NAC 3 and 13 apply to licensing and transportation of radioactive material and 180 NAC 2 applies to registration of radiation machines. Except for chapters which are applicable only to sealed radioactive source, radiation machines and sealed radioactive sources are both covered by 180 NAC 5. 180 NAC 5 does not apply to medical uses of sources of radiation which are addressed in 180 NAC 6, 7 and 9.

5-001.03 21 CFR as published on April 1, 20~~02~~14 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

5-001.04 National Bureau of Standards Handbook 136 issued 1-1981 as referred to in this Chapter is herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

5-002 DEFINITIONS: As used in 180 NAC 5, the following definitions apply:
Annual refresher safety training means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review must

include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review must also provide opportunities for employees to ask safety questions.

ANSI means the American National Standards Institute.

Associated equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source.[1]

Cabinet radiography means industrial radiography conducted in an enclosure or cabinet so shielded that radiation levels at every location on the exterior meet the limitations specified in 180 NAC 4-013.01, 4-013.02, and 4-013.03.

Cabinet x-ray system means an x-ray system with the x-ray tube installed in an enclosure that is independent of existing architectural structures except the floor. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. A x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

Camera see Radiographic exposure device.

Certifiable cabinet x-ray system means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

Certified cabinet x-ray system means an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

Certifying entity means an independent certifying organization meeting the requirements in Appendix A of 180 NAC 5 or a state regulatory program meeting the requirements in Appendix A, Parts II and III of 180 NAC 5.

Collimator means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

Control cable (Drive cable) means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

Control drive mechanism means a device that enables the source assembly to be moved into and out of the exposure device.

[1]For example, guide tube, control tube, control (drive) cable, removable stop, “J” tube and collimator when used as an exposure head.

Control tube means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

Drive cable see Control cable.

Exposure head means a device that locates the gamma radiography sealed source in the selected working position.[2]

Field station means a facility where sources of radiation may be stored or used and from which equipment is dispatched.

Guide tube (Projection sheath) means a flexible or rigid tube or "J" tube for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

Hands-on experience means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2000 hours of hands-on experience required for an Radiation Safety Officer in 180 NAC 5-015.01, item 2 or the hands-on experience for a radiographer as required by 180 NAC 5-016.01.

Independent certifying organization means an independent organization that meets all of the criteria of Appendix A to 180 NAC 5.

Industrial radiography (Radiography) means the examination of the structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

Permanent radiographic installation means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

Pigtail see Source assembly.

~~Pill see Sealed source.~~

Practical examination means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

~~Projection sheath see Guide tube.~~

[2]An exposure head is also known as a source stop.

Projector see Radiographic exposure device.

Radiation Safety Officer for "industrial radiography" means an individual with the responsibility for the overall radiation safety protection program on behalf of the licensee or registrant and who meets the requirements of 180 NAC 5-015.

Radiographer means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Department's regulations and the conditions of the license or registration.

Radiographer's assistant means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

Radiographer certification means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 180 NAC 15-016.

Radiographic exposure device (Camera or Projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

Radiographic operations means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting (except by common or contract carriers), or storing a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

Radiography see Industrial radiography.

S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

Sealed source see 180 NAC 1-002.

Shielded position means the location within the radiographic exposure device, source changer or storage container that, by manufacturer's design, is the proper location for storage of the sealed source.

Source assembly (Pigtail) means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

Source changer means a device designed and used for replacement of sealed sources in radiographic exposure devices. They may also be used for transporting and storing sealed source.

Storage area means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, sealed source, or a storage container, when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

Storage container means a device in which sealed sources or radiation machines are secured or stored.

Temporary job site means a location where radiographic operations are performed and where sources of radiation may be stored other than the location(s) of use authorized on the license or registration.

Underwater radiography means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

5-003 EXEMPTIONS

5-003.01 Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of 180 NAC 5 except for the following:

1. For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

a. No registrant may permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with 180 NAC 5-003.01, item 1 must be maintained for Department inspection until disposal is authorized by the Department.

b. Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests must be maintained for Department inspection until disposal is authorized by the Department.

c. The registrant must perform an evaluation of the radiation dose limits to determine compliance with 180 NAC 4-013.01, 4-013.02, and 4-013.03, and 21 CFR 1020.40, Cabinet X-ray Systems, at intervals not to exceed one year. Records of these evaluations must be maintained for Department inspection for two years after the evaluation.

5-003.02 Industrial uses of hand-held light intensified imaging devices are exempt from the requirements in 180 NAC 5 if the dose rate 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour. Devices which exceed this limit must

meet the applicable requirements of 180 NAC 5 and the licensing or registration requirements of 180 NAC 2 or 180 NAC 3, as applicable.

5-004 LICENSING AND REGISTRATION REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS

5-004.01 The Department will approve an application for specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements and pays applicable fees specified in 180 NAC 18:

1. The applicant satisfies the general requirements specified in 180 NAC 2 for radiation machine facilities or 180 NAC 3 for radioactive material, as applicable, and any special requirements contained in 180 NAC 5;
2. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of 180 NAC 5-016:
3. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;
4. The applicant submits written operating and emergency procedures as described in 180 NAC 5-017;
5. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six months as described in 180 NAC 5-016.05;
6. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;
7. The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 180 NAC 5-015.01;
8. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test and the qualifications of the persons(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the:

    a. Methods of collecting the samples;
    b. Qualifications of the individual who analyzes the samples;
    c. Instruments to be used; and
    d. Methods of analyzing the samples

9. If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 180 NAC 5-008 and 180 NAC 5-019.07, item 4.
10. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

11. The applicant identifies the location(s) where all records required by this and other Chapters of Title 180 will be maintained.
12. If an application includes underwater radiography, a description of:

    a. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
    b. Radiographic equipment and radiation safety equipment unique to underwater radiography; and
    c. Methods for gas-tight encapsulation of equipment.

5-005 PERFORMANCE REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY EQUIPMENT: Equipment used in industrial radiographic operations must meet the following minimum criteria:

5-005.01 Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in ~~American National Standard Institute (~~ANSI), N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). This publication has been incorporated herein by reference and is available for viewing at the Department of Health and Human Services, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

5-005.02 In addition to the requirements specified in 180 NAC 5-005.01, the following requirements apply to radiographic exposure devices, source chargers, source assemblies and sealed sources:

1. The licensee must ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

    a. Chemical symbol and mass number of the radionuclide in the device;
    b. Activity and the date on which this activity was last measured;
    c. Model or product code and serial number of the sealed source;
    d. Name of the manufacturer of the sealed source; and
    e. Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of 180 NAC 13.
3. Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

5-005.03 In addition to the requirements specified in 180 NAC 5-005.01 and 5-005.02, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
2. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.
3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
4. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

   "DANGER -- RADIOACTIVE"

   The label may not interfere with the safe operation of the exposure device or associated equipment.
5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.
6. Guide tubes must be used when moving the source out of the device.
7. An exposure head or similar device designed to prevent the source of assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during the industrial radiography operations.
8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.
9. Source changes must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

5-005.04 All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of 180 NAC 5; and

5-005.05 As an exception to 180 NAC 5-005.01, equipment used in industrial radiographic operations need not comply with Section 8.9.2 (c) of the Endurance Test in ~~American National Standards Institute (~~ANSI) N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

5-006 LIMITS ON EXTERNAL RADIATION LEVELS FROM STORAGE CONTAINERS AND SOURCE CHANGERS: The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10

mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

5-007 LOCKING OF SOURCES OF RADIATION, STORAGE CONTAINERS AND SOURCE CHANGERS

5-007.01 Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 180 NAC 5-021. In addition, during radiographic operations the sealed source assembly must be secured in a shielded position each time the source is returned to that position.

5-007.02 Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

5-007.03 The control panel of each radiation machine must be equipped with a lock that will prevent the unauthorized use of a x-ray system or the accidental production of radiation. The radiation machine must be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

5-008 RADIATION SURVEY INSTRUMENTS

5-008.01 The licensee or registrant must keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by 180 NAC 4 and 180 NAC 5 . Instrumentation required by 180 NAC 5 must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

5-008.02 The licensee or registrant must have each radiation survey instrument required under 180 NAC 5-008.01 calibrated:

1. At energies appropriate for use and at intervals not to exceed six months or after instrument servicing, except for battery changes;
2. For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and
3. So that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.

5-008.03 The licensee or registrant must maintain records of the results of the instrument calibrations in accordance with 180 NAC 5-025.

5-009 LEAK TESTING AND REPLACEMENT OF SEALED SOURCES

5-009.01 The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State.

5-009.02 The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State.

5-009.03 Testing and recordkeeping requirements.

1. Each licensee who uses a sealed source must have the source tested for leakage at intervals not to exceed six months. The leak testing of the sources must be performed using a method approved by the Department, the U.S. Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 μCi) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis.
2. The licensee must maintain records of the leak tests in accordance with 180 NAC 5-026.
3. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.

5-009.04 Any test conducted pursuant to 180 NAC 5-009.02 and 180 NAC 5-009.03 that reveals the presence of 185 becquerel (0.005 μCi) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee must immediately withdraw the equipment involved from use and must have it decontaminated and repaired or disposed of in accordance with Department regulations. A report must be filed with the Department within five days of any test with results that exceed the threshold in 180 NAC 5-009.04, describing the equipment involved, the test results, and the corrective action taken.

5-009.05 Each exposure device using depleted uranium (DU) shielding and an S-tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerel (0.005μCi) of

radioactive material on the test sample and must be performed by a person specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform the analysis. Should such testing reveal the presence of 185 becquerel (0.005μCi) or more of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with 180 NAC 5-026.

5-010 QUARTERLY INVENTORY

5-010.01 Each licensee or registrant must conduct a quarterly physical inventory to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license.

5-010.02 The licensee or registrant must maintain records of the quarterly inventory in accordance with 180 NAC 5-027.

5-011 INSPECTION AND MAINTENANCE OF RADIATION MACHINES, RADIOGRAPHIC EXPOSURE DEVICES, TRANSPORT, AND STORAGE CONTAINERS, ASSOCIATED EQUIPMENT, SOURCE CHANGERS, AND SURVEY INSTRUMENTS

5-011.01 The licensee or registrant must perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

1. The equipment is in good working condition;
2. The sources are adequately shielded; and
3. Required labeling is present.

5-011.02 Survey instrument operability must be performed using check sources or other appropriate means.

5-011.03 If equipment problems are found, the equipment must be removed from service until repaired.

5-011.04 Each licensee or registrant must have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

5-011.05 The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

5-011.06 Records of equipment problems and of any maintenance performed under 180 NAC 5-011 must be made in accordance with 180 NAC 5-029.

5-011.07 A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 180 NAC 5-011 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirement, is deemed to satisfy the requirements of 180 NAC 13-007 and 180 NAC 13-021.

5-012 PERMANENT RADIOGRAPHIC INSTALLATIONS

5-012.01 Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

1. An entrance control of the type described in 180 NAC 4-023.01, item 1 that causes the radiation level upon entry into the area to be reduced; or

2. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible sign must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

5-012.02 The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in 180 NAC 5-012.01, item 1 must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this seven day period, provided the licensee or registrant implements the continuous surveillance requirements of 180 NAC 5-021 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 180 NAC 5-030.

5-013 LABELING, STORAGE, AND TRANSPORTATION

5-013.01 The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, that is, magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION*
RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")
* or "DANGER"

5-013.02 The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with 180 NAC 13.

5-013.03 Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee must store radioactive material in a manner that will minimize danger from explosion or fire.

5-013.04 The licensee must lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

5-013.05 The licensee's or registrant's name and city or town where the main business office is located must be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

RADIATION SAFETY REQUIREMENTS

5-014 CONDUCTING INDUSTRIAL RADIOGRAPHIC OPERATIONS

5-014.01 Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 180 NAC 5-016.03. The additional qualified individual must observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

5-014.02 All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Department.

5-014.03 Except when physically impossible, collimators must be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

5-014.04 A licensee or registrant may conduct lay-barge, offshore platform or underwater radiography only if procedures have been approved by the Department, the U.S. Nuclear Regulatory Commission, or by another Agreement State.

5-015 RADIATION SAFETY OFFICER FOR INDUSTRIAL RADIOGRAPHY: The Radiation Safety Officer must ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

5-015.01 The minimum qualifications, training, and experience for Radiation Safety Officers for industrial radiography are as follows:

1. Completion of the training and testing requirements of 180 NAC 5-016.01
2. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and
3. Formal training in the establishment and maintenance of a radiation safety protection program.

5-015.02 The Department will consider alternatives when the Radiation Safety Officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

5-015.03 The specific duties and authorities of the Radiation Safety Officer include:

1. Establishing and overseeing all operating, emergency, and ALARA procedures as required by 180 NAC 4 and reviewing them regularly to ensure that they conform to Department regulations and the license or registration conditions;
2. Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;
3. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;
4. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by 180 NAC 4; and
5. Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

5-016 TRAINING

5-016.01 The licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received at least 40 hours of training in the subjects outlined in 5-016.07, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of 180 NAC 5. The on the job training must include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (three months or 480 hours).

5-016.02 In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received copies and instruction in the requirements described in the regulations contained in 180 NAC 5, and applicable chapters of 180 NAC 4, 10, and 13, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;
2. Has demonstrated an understanding of items in 180 NAC 5-016.02, item 1 by successful completion of a written or oral examination;
3. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and
4. Has demonstrated understanding of the use of the equipment described in 180 NAC 5-016.02, item 3 by successful completion of a practical examination.

5-016.03 The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in the requirements described in the regulations contained in 180 NAC 5, and applicable 180 NAC 4, 10, and 13, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;
2. Has demonstrated an understanding of items 180 NAC 5-016.03, item 1 by successful completion of a written or oral examination;
3. Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and
4. Has demonstrated understanding of the use of the equipment described in 180 NAC 5-016.03, item 3 by successful completion of a practical examination.

5-016.04 The licensee or registrant must provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

5-016.05 Except as provided in 180 NAC 5-016.05, item 4, the Radiation Safety Officer or designee must conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Department's regulations, license or registration requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and
2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last

inspection, the radiographer must demonstrate knowledge of the training requirements of 180 NAC 5-016.02, item 3 and the radiographer's assistant must demonstrate knowledge of the training requirement of 180 NAC 5-016.03, item 3, by a practical examination before these individuals can next participate in a radiographic operation.

3. The Department may consider alternatives in those situations where the individual serves as both radiographer and Radiation Safety Officer.
4. In those operations where a single individual serves as both radiographer and Radiation Safety Officer, and performs all radiography operations, an inspection program is not required.

5-016.06 The licensee or registrant must maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with 180 NAC 5-031.

5-016.07 The licensee or registrant must include the following subjects required in 180 NAC 5-016.01:

1. Fundamentals of radiation safety including:

    a. Characteristics of gamma and x-radiation;
    b. Units of radiation dose and quantity of radioactivity;
    c. Hazards of exposure to radiation;
    d. Levels of radiation from sources of radiation; and
    e. Methods of controlling radiation dose (time, distance, and shielding);

2. Radiation detection instruments including:

    a. Use, operation, calibration, and limitations of radiation survey instruments;
    b. Survey techniques; and
    c. Use of personnel monitoring equipment;

3. Equipment to be used including:

    a. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);
    b. Operation and control of radiation machines;
    c. Storage, control, and disposal of sources of radiation; and
    d. Inspection and maintenance of equipment.

4. The requirements of pertinent state and federal regulations; and
5. Case histories of accidents in radiography.

5-016.08 Records of radiographer certification maintained in accordance with 180 NAC 5-031.01 provide appropriate affirmation of certification requirements specified in180 NAC 005-016.01, item 1.

5-017 OPERATING AND EMERGENCY PROCEDURES

5-017.01 Operating and emergency procedures must include, as a minimum, instructions in the following:

1. Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in 180 NAC 4.;
2. Methods and occasions for conducting radiation surveys;
3. Methods of posting and controlling access to radiographic areas;
4. Methods and occasions for locking and securing sources of radiation;
5. Personnel monitoring and the use of personnel monitoring equipment;
6. Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the equipment during transportation as described in 180 NAC 13;
7. The inspection, maintenance, and operability checks of radiographic exposure , devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;
8. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;
9. The procedure(s) for identifying and reporting defects and noncompliance, as required by 180 NAC 5-037;
10. The procedure for notifying proper persons in the event of an accident or incident;
11. Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;
12. Source recovery procedure if licensee will perform source recoveries; and
13. Maintenance of records.

5-017.02 The licensee or registrant must maintain copies of current operating and emergency procedures in accordance with 180 NAC 5-032 and180 NAC 5-036.

5-018 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS

5-018.01 The radiographer's assistant must be under the personal supervision of a radiographer when using sources of radiation or conducting radiation surveys required by 180 NAC 5-020.02 to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

1. The radiographer's physical presence at the site where the sources of radiation are being used;
2. The availability of the radiographer to give immediate assistance if required; and

3. The radiographer's direct observation of the assistant's performance of the operations referred to in 180 NAC 5-018.01.

5-019 PERSONNEL MONITORING

5-019.01 The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarming ratemeter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the use of an alarming ratemeter is not required.

1. Pocket dosimeters must have a range from zero to 2 millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.
2. Each personnel dosimeter must be assigned to and worn by only one individual;
3. Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months.
4. After replacement, each personnel dosimeter must be processed as soon as possible.

5-019.02 Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with180 NAC 5-033.

5-019.03 Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 180 NAC 5-033. Acceptable dosimeters must read within plus or minus 20% of the true radiation exposure.

5-019.04 If an individual's pocket dosimeter is found to be off-scale, or if his/her electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the Radiation Safety Officer or the Radiation Safety Officer's designee. The results of this determination must be included in the records maintained in accordance with180 NAC 5-033.

5-019.05 If the personnel dosimeter that is required by 180 NAC 5-019 is lost or damaged, the worker must cease work immediately until a replacement personnel dosimeter meeting the requirements of 180 NAC 5-019 is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with 180 NAC 5-033.

5-019.06 Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with 180 NAC 5-033.

5-019.07 Each alarming ratemeter must:

1. Be checked to ensure that the alarm functions properly before using at the start of each shift;
2. Be set to give an alarm signal at a preset dose rate of 5 millisieverts per hour (500 mrem/hr); with an accuracy of plus or minus 20% of the true radiation dose rate;
3. Require special means to change the preset alarm function; and
4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee must maintain records of alarming ratemeter calibrations in accordance with 180 NAC 5-033.

5-020 RADIATION SURVEYS: The licensee or registrant must:

5-020.01 Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 180 NAC 5-008;

5-020.02 Conduct a survey of the radiographic exposure device and guide tube after each exposure when approaching the device or the guide tube. The survey must determine that a sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines must be surveyed after each exposure to determine that the machine is off;

5-020.03 Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure devices is placed in a storage area as defined in 180 NAC 5-002, to ensure that the sealed source is in its shielded position; and

5-020.04 Maintain records in accordance with 180 NAC 5-034.

5-021 SURVEILLANCE: During each radiographic operation, the radiographer must ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in 180 NAC 1 except at permanent radiographic installations where all entryways are locked and the requirements of 180 NAC 5-012 are met.

5-022 POSTING: All areas in which industrial radiography is being performed must be conspicuously posted as required by 180 NAC 4-034. The exceptions listed in 180 NAC 4-035 do not apply to industrial radiographic operations.

RECORDKEEPING REQUIREMENTS

5-023 RECORDS FOR INDUSTRIAL RADIOGRAPHY: Each licensee or registrant must maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Department, or until the Department terminates the license or registration.

5-024 RECORDS OF RECEIPT AND TRANSFER OF SOURCES OF RADIATION

5-024.01 Each licensee or registrant must maintain records showing the receipts and transfers of sealed sources, devices for using DU for shielding, and radiation machines, and retain each record for three years after it is made.

5-024.02 These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

5-025 RECORDS OF RADIATION SURVEY INSTRUMENTS: Each licensee or registrant must maintain records of the calibrations of its radiation survey instruments that are required under 180 NAC 5-008 and retain each record for three years after it is made.

5-026 RECORDS OF LEAK TESTING OF SEALED SOURCES AND DEVICES CONTAINING DU: Each licensee must maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (μCi). The licensee must retain each record for three years after it is made or until the source in storage is removed.

5-027 RECORDS OF QUARTERLY INVENTORY

5-027.01 Each licensee or registrant must maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by 180 NAC 5-010, and retain each record for three years from the date of inventory.

5-027.02 The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

5-028 UTILIZATION LOGS

5-028.01 Each licensee or registrant must maintain utilization logs showing for each source of radiation the following information:

1. A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;
2. The identity and signature of the radiographer to whom assigned;
3. The location and dates of use, including the dates removed and returned to storage; and
4. For permanent radiographic installations, the dates each radiation machine is energized.

5-028.02 The licensee or registrant must retain the logs required by 180 NAC 5-028.01 for three years after the log is made.

5-029 RECORDS OF INSPECTION AND MAINTENANCE OF RADIATION MACHINES, RADIOGRAPHIC EXPOSURE DEVICES, TRANSPORT, AND STORAGE CONTAINERS, ASSOCIATED EQUIPMENT, SOURCE CHANGERS, AND SURVEY INSTRUMENTS

5-029.01 Each licensee or registrant must maintain records specified in 180 NAC 5-011 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for three years after it is made.

5-029.02 The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

5-030 RECORDS OF ALARM SYSTEM AND ENTRANCE CONTROL CHECKS AT PERMANENT RADIOGRAPHIC INSTALLATIONS: Each licensee or registrant must maintain records of alarm systems and entrance control device tests required by 180 NAC 5-012 and retain each record for three years after the record is made.

5-031 RECORDS OF TRAINING AND CERTIFICATION

5-031.01 Each licensee or registrant must maintain the following records for three years:

1. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and
2. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the Radiation Safety Officer or designee.

5-032 COPIES OF OPERATING AND EMERGENCY PROCEDURES: Each licensee or registrant must maintain a copy of current operating and emergency procedures until the Department terminates the license or registration. Superseded material must be retained for three years after the change~~s~~ is made.

5-033 RECORDS OF PERSONNEL MONITORING

5-033.01 Each licensee or registrant must maintain the following exposure records specified in 180 NAC 5-019:

1. Direct reading dosimeter readings and yearly operability checks required by 180 NAC 5-019.02 and 5-019.03 for three years after the record is made;
2. Records of alarming ratemeter calibrations three years after the record is made;
3. Personnel dosimeter results received from the accredited NVLAP processor until the Department terminates the license or registration; and
4. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost of damaged personnel dosimeters until the Department terminates the license or registration.

5-034 RECORDS OF RADIATION SURVEYS: Each licensee must maintain a record of each exposure device survey conducted before the device is placed in storage as specified in 180 NAC 5-020.03. Each record must be maintained for three years after the record is made.

5-035 FORM OF RECORDS: Each record required by 180 NAC 5 must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials and signatures. The licensee or registrant must maintain adequate safeguards against tampering with and the loss of records.

5-036 LOCATION OF DOCUMENTS AND RECORDS

5-036.01 Each licensee or registrant must maintain copies of records required by 180 NAC 5 and other applicable Chapters of Title 180 at the location specified in 180 NAC 5-004.01, item 11.

5-036.02 Each licensee or registrant must also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

1. The license or registration authorizing the use of sources of radiation;
2. A copy of 180 NAC 1, 4, 5, and 10 ;
3. Utilization logs for each source of radiation dispatched from the location as required by 180 NAC 5-028;
4. Records of equipment problems identified in daily checks of equipment as required by 180 NAC 5-029.01;
5. Records of alarm system and entrance control checks required by 180 NAC 5-030, if applicable;
6. Records of dosimeter readings as required by 180 NAC 5-033;
7. Operating and emergency procedures required by 180 NAC 5-032;
8. Evidence of the latest calibrations and of radiation survey instruments in use at the site, as required by 180 NAC 5-025;
9. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 180 NAC 5-033

10. Survey records as required by 180 NAC 5-034 and 180 NAC 4-049 as applicable, for the period of operation at that site;
11. The shipping papers for the transportation of radioactive materials required by 180 NAC 013 and;
12. When operating under reciprocity pursuant to 180 NAC 3 or registration pursuant to 180 NAC 2, a copy of the applicable State license or registration, or U.S. Nuclear Regulatory Commission license authorizing the use of sources of radiation.

NOTIFICATIONS

5-037 NOTIFICATIONS

5-037.01 In addition to the reporting requirements specified in 180 NAC 3-026 and 180 NAC 4, each licensee or registrant must provide a written report to the Department within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

1. Unintentional disconnection of the source assembly from the control cable;
2. Inability to retract the source assembly to its fully shielded position and secure it in this position;
3. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or
4. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

5-037.02 The licensee or registrant must include the following information in each report submitted under 180 NAC 5-037.01, and in each report of overexposure submitted under 180 NAC 4-060 which involves failure of safety components of radiography equipment:

1. Description of the equipment problem;
2. Cause of each incident, if known;
3. Name of the manufacturer and model number of equipment involved in the incident;
4. Place, date, and time of the incident;
5. Actions taken to establish normal operations;
6. Corrective actions taken or planned to prevent recurrence; and
7. Names and qualifications of personnel involved in the incident.

5-037.03 Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, must notify the Department prior to exceeding the 180 days.

5-038 RECIPROCITY

5-038.01 All reciprocal recognition of licenses by the Department will be granted in accordance with 180 NAC 3-028.

5-038.02 Reciprocal recognition by the Department of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in 180 NAC 5-002;
2. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by 180 NAC 5-016.01;
3. The applicant presents the certification to the Department prior to the entry into the state; and
4. No escalated enforcement action is pending with the U.S. Nuclear Regulatory Commission or in any other State.

5-038.03 Certified individuals who are granted reciprocity by the Department must maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, must met the requirements of 180 NAC 5-016.01.

5-039 SPECIFIC REQUIREMENTS FOR RADIOGRAPHIC PERSONNEL PERFORMING INDUSTRIAL RADIOGRAPHY

5-039.01 At a job site, the following must be supplied by the licensee or registrant:

1. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;
2. A current whole body personnel monitor (film badge, TLD or OSLD) for each person performing radiographic operations;
3. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations;
4. An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and
5. The appropriate barrier ropes and signs.

5-039.02 Each radiographer at a job site must have on his/her person a valid certification ID card issued by a certifying entity.

5-039.03 Industrial radiographic operations must not be performed if any of the items in 180 NAC 5-039.01 and 5-039.02 are not available at the job site or are inoperable.

5-039.04 During an inspection, the Department may terminate an operation if any of the items in 180 NAC 5-039.01 and 180 NAC 5-039.02 are not available or operable, or if the required number of radiographic personnel are not present. Operations must not be resumed until all required conditions are met.

APPENDIX A

I. Requirements for an Independent Certifying Organization

An independent certifying organization must:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

2. Make its membership available to the general public nationwide. Membership must not be restricted because of race, color, religion, sex, age, national origin or disability;

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its field of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the U.S. Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the U.S. Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. Requirements for Certification Programs

All certification programs must:

1. Require applicants for certification to:
   a. Receive training in the topics set forth in 180 NAC 5-016.07 or equivalent Agreement State or U.S. Nuclear Regulatory Commission regulations, and
   b. Satisfactorily complete a written examination covering these topics;

2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

   a. Received training in the topics set forth in 180 NAC 5-016.07 or equivalent Agreement State or U.S. Nuclear Regulatory Commission regulations;

   b. Satisfactorily completed a minimum period of on-the-job training as specified in180 NAC 5-016.01 and

   c. Received verification by an Agreement State licensee or registrant or an U.S. Nuclear Regulatory Regulation licensee that the applicant has demonstrated the capability of independently working as a radiographer.

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;

5. Provide a certification period of not less than three years nor more than five years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in 180 NAC 5-016.07 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements;

2. Written in multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in180 NAC 5-016.07.

TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS OTHER THAN DENTAL RADIATION GENERATING EQUIPMENT IN THE HEALING ARTS

APPENDIXES

Attachment Number 6-1 Public Law 90-602, the Radiation Control for Health and safety Act of 1968

~~Attachment Number 6-2 21 CFR 1020.30 and 1020.31~~

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at: http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS OTHER THAN DENTAL RADIATION GENERATING EQUIPMENT IN THE HEALING ARTS

6-001 SCOPE AND AUTHORITY

6-001.01 180 NAC 6 establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

6-001.02 The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment must be by or under the supervision of one licensed to practice the healing arts in Nebraska.

6-001.03 The use of x-ray equipment in the practice of veterinary medicine must be by or under the supervision of an individual licensed to practice veterinary medicine in the State of Nebraska.

6-001.04 The provisions of 180 NAC 6 are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 16, 17 , 18, and 20.

6-002 DEFINITIONS: As used in Title 180, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

~~Accessory component means:~~

~~(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of 180 NAC 6 but which requires an initial determination of compatibility with the system; or~~

~~(2) A component necessary for compliance of the system with applicable provisions of 180 NAC 6 but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or~~

~~(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.~~

~~Added filtration means any filtration which is in addition to the inherent filtration.~~

~~Air kerma means kerma in air [see definition of "Kerma"]~~

~~Air kerma rate (AKR) means the air kerma per unit time.~~

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[2] or other materials having equivalent attenuation.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

Automatic exposure rate control (AERC) means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

Barrier [See "Protective barrier"]

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Bone densitometry systems means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

C-arm ~~x-ray~~ fluoroscopic system means an x-ray system in which the image receptor and x-ray tube housing assembly are connected or coordinated ~~by a common mechanical support system in order~~ to maintain a desired spatial relationship. ~~This~~Such a system ~~is designed to~~ allows a change in the directions of the beam axis with respect to the patient. ~~Without a chane in the position of the patient~~

Certified diagnostic x-ray components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968 because they come within the definitions in Section 355 (1) and (2) of that law, attached hereto as Attachment Number 6-1 and incorporated herein by this reference.

[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, maximum 0.12 percent copper.
[2]Ibid.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film [imaging] cassette during an x-ray exposure.

~~Certified system means any x-ray system which has one or more certified component(s).~~

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

Computed tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.
Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device:

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

"CT" ~~([~~See "Computed tomography"~~])~~

CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

Cumulative air kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Deadman switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
Detector ~~([~~See “Radiation detector” ~~])~~

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human [or animal] body for the purpose of diagnosis or visualization.

Direct scatteredd radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam ({[See "Scattered radiation"]}).

~~Entrance exposure rate means the exposure free in air per unit time.~~

Equipment {[See "X-ray equipment"]}

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to preferentially absorb selected radiations.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a visible fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), ~~such as the image intensifier and spot-film device,~~ electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term “radioscopy” in the standards of the International Electrotechnical Commission.

Focal spot (actual) means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield means a protective barrier for the testes or ovaries.

Half-value layer means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Hand-held x-ray equipment means x-ray equipment that is designed to be hand-held during operation.

Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

HVL ~~([~~See "Half-value layer"]~~)~~

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term “image receptor” must mean the preselected portion of the device.

~~Image receptor support means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.~~

~~Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.~~

Interpretative Fluoroscopic Procedures, for the purpose of these regulations, means the use of radiation in continuous mode to provide information, data and film or hardcopy images for diagnostic review and interpretation by a licensed practitioner as the images are being produced.

Irradiation means the exposure of matter to ionizing radiation.

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged participles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as “air kerma.”

Kilovolts peak [See "Peak tube potential"]

kV means kilovolts.

kVp [See Peak tube potential]

kWs means kilowatt second. It is equivalent to E + 3 kV mA s, i.e.

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{kV \times mA \times s} = \frac{XYZ\ kWs}{E+3}$$

Last image hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

1. The useful beam; and
2. Radiation produced when the exposure switch or timer is not activated.

~~Leakage technique~~ Leakage technique factors means the technique factors associated with the diagnostic assembly which are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.
2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
3. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Linear attenuation coefficient or u means the quotient of dN/N divided by d1 when dN/N is the fraction of unchanged ionizing radiation that experience interactions in traversing a distance d1 in a specified material.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential , as follows:

$$\text{Percent line-voltage regulation} = 100\ (V_n - V_l)/V_l$$

where:

V_n = No-load line potential; and
V_l = Load line potential.

mA means milliampere.

mAs means milliampere second.

~~mC/kg means millicoulomb/kilogram.~~

Mobile x-ray equipment ~~([~~See "X-ray equipment"~~])~~

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation does not comprise a mode of operation different from the one that has been selected.

Non-image-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

PBL ("~~See~~ Positive beam limitation")

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

Portable x-ray equipment [See "X-ray equipment"]

Positive beam limitation means the automatic or semi-automatic adjustment of an x-ray bean to the size of the selected image receptor, whereby exposure cannot be made without such adjustment.

Primary protective barrier ~~(See Protective barrier)~~ means the material, excluding filters, placed in the useful beam, to reduce the radiation exposure [beyond the patient and cassette holder] for protection purposes.

Protective apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

~~Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:~~

~~Primary protective barrier means the material, excluding filters, placed in the useful beam;~~

~~Secondary protective barrier means a barrier sufficient to attenuate the stray radiation to the required degree.~~

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Pulsed mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Qualified expert means an individual who meets the requirements of 180 NAC 15-013.03.

Radiation detector means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation therapy simulation system means a fluoroscopic or radiographic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiography means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Radiological medical physicist means an individual who meets the requirements of 180 NAC 15-013.01.

Radiological health physicist mean an individual who meets the requirements of 180 NAC 15-013.02.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a ~~permanent~~ retrievable form of an image resulting from x-ray photons.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction ~~{[~~See "Direct scattered radiation"]~~}~~

~~Secondary protective barrier (See "Protective barrier").~~

Shutter means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID ~~{[~~See “Source-image receptor distance”]~~}~~

Source means the focal spot of the x-ray tube.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Source-skin distance (SSD) means the distance between the source to the center of the entrant x-ray field in the plane tangent to the patient ~~and the~~ skin surface ~~of the patient~~.

Spot check means a procedure which is performed to assure that a previous calibration continues to be valid.

Spot film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of a~~n~~ fluoroscopic image intensifier for the purpose of making a radiograph.

Stationary x-ray equipment ~~{[~~See “X-ray equipment”]~~}~~

Stray radiation means the sum of leakage and scattered radiation.

Technique factors means the conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
3. For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
4. For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5 For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Traceable to a national standard means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation emanating from the tube housing port and ~~or the radiation head and passing through~~ the aperture of the beam-limiting device when the exposure switch or timer is activated ~~controls are in a mode to cause the system to produce radiation~~.

Visible area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray exposure control means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timer and back-up timers.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and 180 NAC 6-004, 6-005, and 6-006.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

6-003 GENERAL REQUIREMENTS

6-003.01 Administrative Controls

1. Registrant: The registrant must be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent must assure that the requirements of 180 NAC 6-003.01, item 1. are met in the operation of the x-ray system(s).

   a. An x-ray system which does not meet the provisions of Title 180 must not be operated for diagnostic purposes.
   b. Registrants must assure that individuals who will operate x-ray systems under the direction of healing arts practitioners must meet the requirements as specified in ~~180 NAC 16~~ Neb. Stat. Rev. §§ 38-1901 thru 1920 (Medical Radiography Practice Act).
   c. A chart must be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information.

      (1) Patient's body part and anatomical size, or body part thickness, or age (for pediatrics) versus technique factors to be utilized;
      (2) Type and focal distance of the grid to be used, if any;
      (3) Source to image receptor distance to be used:
      (4) Type and location of placement of gonad shielding to be used; and
      (5) Type and size of the film or film-screen combination to be used.

   d. The registrant of a facility must create and make available to x-ray operators written safety procedures, including patient holding and any restriction of the operating technique required for the safe operation of the particular x-ray system. The operator must be able to demonstrate familiarity with these procedures.

~~(1) Doors that are an integral part of room shielding must be closed during x-ray procedures; and~~
~~(2) The door in 180 NAC 6-003.01, item 1.d.(1) must be posted "Close door during x-ray procedures".~~

e. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training may be in the room during the radiographic exposure. Other than the patient being examined:

(1) All individuals must be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent.
(2) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure must be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
(3) Human patients who cannot be removed from the room must be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or must be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

f. Gonad shielding of not less than ~~0.25~~0.5 millimeter lead equivalent must be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

g. Individuals must not be exposed to the useful beam except for healing arts purposes and unless such exposure has been specially and individually ordered by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and
(2) Exposure of an individual for the purpose of healing arts screening except as authorized by 180 NAC 6-003.01, item 1. k.

h. When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices must be used when the technique permits. The written safety procedures, required by 180 NAC 6-003.01, item 1., d., must list projections where holding devices cannot be utilized;
(2) The human holder must be instructed in personal radiation safety and protected as required by 180 NAC 6-003, item 1. e.;
(3) No individual must be used routinely to hold film or patients;

(4) Written safety procedures, as required by 180 NAC 6-003.01, item 1. d.; must indicate the requirements for selecting a holder and the procedure the holder must follow; and

(5) In those cases where the patient must hold the film, any portion of the body other than the area of clinical interest struck by the useful beam must be protected by not less than 0.5 millimeter lead equivalent material.

(6) ~~a.~~ Each facility must have leaded protective aprons and protective gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

i. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information must be utilized.

(1) The speed of film or screen and film combinations must be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens must not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography.

(2) The radiation exposure to the patient must be the minimum exposure required to produce images of good diagnostic quality.

(3) Portable or mobile x-ray equipment must be used only for examinations where it is not feasible to transfer the patient(s) to a stationary x-ray installation.

(4) X-ray systems subject to 180 NAC 6-006 must not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.

(5) ~~14.~~ If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid must:

(a) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;

(b) If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

j. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 180 NAC 4-005, 4-021, 4-022, and 4-050. ~~In addition, exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~

k. Healing Arts Screening: Any person proposing to conduct a healing arts screening program must not initiate such a program without prior approval of the Department. When requesting such approval, that person must submit the information outlined in Appendix A of 180 NAC 6. If any information submitted to the Department becomes invalid or outdated, the Department must be immediately notified.

l. Doors that are an integral part of room shielding must be closed during x-ray procedures and must be posted "Close door during x-ray procedures" or words having a similar intent.

2. Information and Maintenance Record and Associated Information The registrant must maintain the following information for each x-ray system for inspection by the Department:

a. Model and serial numbers of all certifiable components, and user's manuals for those components;
b. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and
c. Tube rating carts and cooling curves
~~c.~~d. A scale drawing must be available of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing must include:

(1) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
(2) The type and thickness of materials, or lead equivalency, of each protective barrier; and

~~d.~~e. A copy of all correspondence with this Department regarding that x-ray system.

6-003.02 X-Ray Utilization Log: Each facility must maintain an x-ray log or chart containing the patient's ~~name~~ identification, the type of examinations, the dates the examinations were performed, and the x-ray equipment operator's name. When the patient or film must be provided with human auxiliary support, the name of the human holder must be recorded.

6-003.03 Plan Review, Other Than Facilities Using Only Bone Densitometers

1. The floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays must be submitted to an individual meeting the requirements of 180 NAC 2-005.04, item 4 ~~qualified expert~~ for review and comment. ~~The required information is denoted in Appendix B of 180 NAC 6. Shielding reviews for facilities utilizing equipment capable of operating at greater than 50 kVp must utilize the services of an individual meeting the requirement of 180 NAC 15-013.01 or 15-013.02.~~
2. The review of such plans does not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 and 4-013.

6-003.04 X-ray Film Processing Facilities and Practices

1. Each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) must have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film:

(1) Processing tanks must be constructed of mechanically rigid, corrosion resistant material; and

(2) The temperature of solutions in the tanks must be maintained within the range of 60° F to 80° F (16° C to 27° C). Film must be developed in accordance Film must be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8

16.1	61	8½
15.6	60	9½

(3) Devices must be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(4) The specified developer temperature and development time must be posted in the darkroom.

b. Automatic processors and other closed processing systems: Films must be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film must be developed using the following chart:

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
[a/] *Immersion time only, no crossover time included.*		

c. Processing deviations from the requirements of 180 NAC 6-003.04 item 1 must be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

2. Other Requirements.

a. The darkroom must be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed must not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes must preclude fogging of the film.

b. Film must be stored in a cool, dry place and must be protected from exposure to stray radiation. Film in open packages must be stored in a light tight container.

c. Film cassettes and intensifying screens must be inspected periodically and must be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

d. Outdated x-ray film must not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed ~~the base plus fog level is less than 0.35 optical density.~~

e. Film developing solutions must be prepared in accordance with the directions given by the manufacturer, and must be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

f. Pass boxes, if provided, must be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

~~g. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed~~

6-004 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS: In addition to other requirements of 180 NAC 6-004 all diagnostic x-ray systems must meet the following requirements:

6-004.01 Warning Label: The control panel containing the main power switch must bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

6-004.02 Battery Charge Indicator: On battery-powered x-ray generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6-004.03 Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source must not exceed 0.88 milligray (mGy) air kerma (100 milliroetgen (mR)exposure) ~~25.8 uC/kg(100 milliroentgens)~~ in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means must be provided to limit the maximum x-ray tube potential to that of the

diagnostic source assembly. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.04 Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly must not exceed an air kerma of 18 microgray (2 milliroentgens exposure) ~~0.5 C/kg (2 milliroentgens)~~ in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.05 Beam Quality

1. Half-value Layer: The half-value layer of the useful beam for a given x-ray tube potential must not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table #I, linear interpolation or extrapolation may be made. Positive means must be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE I

Design Operating Range	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		All Other Diagnostic X-Ray Systems\1\	All Other Diagnostic X-Ray Systems\2\
Below 51	30	0.3	0.3
	40	0.4	0.4
	50	0.5	0.5
51 to 70	51	1.2	1.3
	60	1.3	1.5
	70	1.5	1.8
Above 70	71	2.1	2.5
	80	2.3	2.9
	90	2.5	3.2
	100	2.7	3.6
	110	3.0	3.9
	120	3.2	4.3

	130	3.5	4.7
	140	3.8	5.0
	150	4.1	5.4

\1\ All x-ray systems manufactured before June 10, 2006.
\2\ All x-ray systems manufactured on or after June 10, 2006.

~~b. For capacitor energy storage equipment, compliance with the requirements of 180 NAC 6-004.05 must be determined with the maximum quantity of charge per exposure.~~

~~c. The required minimal aluminum equivalent filtration must include the filtration contributed by all materials which are always present between the source and the patient.~~

2. Filtration Control:

a. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more must provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of this subsection. The selection of this additional x-ray filtration must be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam must be provided.

b. ~~Filtration Controls:~~ For x-ray systems which have variable kVp and variable filtration for the useful beam, a device must link the kVp selector with the filter(s) and must prevent an exposure unless the minimum amount of filtration required by 180 NAC 6-004.05, item 1.a. is in the useful beam for the given kVp which has been selected.

3. Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

6-004.06 Modification of certified diagnostic x-ray components and systems.

1. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 must not be modified such that the component or system fails to comply with any applicable provision of this 180 NAC 6-004.

2. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this 180 NAC 6. The owner who causes such modification need not submit the reports required by 180 NAC 6, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with 180 NAC 6-004.

6-004.0~~6~~7 Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated prior to initiation of the exposure. This indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6-004.0~~7~~8 Mechanical Support of Tube Head: The tube housing assembly supports must be adjusted such that the tube housing assembly will remain stable during the exposure unless the tube housing movement is a designed function of the x-ray system.

6-004.0~~8~~9 Technique Indicators

1. The technique factors to be used during an exposure must be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure must be indicated.
2. ~~The requirement of 180 NAC 6-004.08, item 1.~~ On equipment having fixed technique factors, this requirement may be met by permanent markings ~~on equipment having fixed technique factors~~. Indication of technique factors must be visible from the operator's position except in the case of spot films made by the fluoroscopist.

6-004.~~09~~10 Maintaining Compliance: Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) must be maintained in compliance with applicable requirements of that standard.

6-004.11~~10~~ Locks: All position locking, holding, and centering devices on x-ray systems components and systems must function as intended.

6-004.12~~11~~ Equipment Performance Evaluation: For all radiation generating equipment, except Bone Densitometry , Veterinary and Computed Tomography (CT), the registrant must perform or cause to be performed, tests necessary to insure the proper function of equipment and a measurement of the in air exposure(s) at the technique factor(s) for an average adult thickness for ~~routine~~ most common procedure(s) preformed at the facility. At a minimum these tests must be at least performed every three years and must include:

1. Timer:

   a. The accuracy of the timer must meet the manufacturer’s specifications. If the manufacturer’s specifications are not obtainable, the timer accuracy must be ±10% of the indicated time with testing performed at 0.5 second.
   b. Means must be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it must not be possible to make an exposure when the timer is set to a “zero” or “off” position if either position is provided.

2. Exposure Reproducibility: When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the

coefficient of variation of exposure for both manual and automatic exposure control systems will not exceed 0.05.

3. Kilovolt Peak: If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine must meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak must be accurate to within ± 10% of the indicated setting(s).

4. Tube Stability: The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant will assure proper and free movement of the radiation generating equipment.

5. Collimation: Field limitation must meet the requirements of 180 NAC 6-005.01, item 2 and 6-006.01, item 1.

6. Any items not meeting the specifications of the tests must be corrected or repaired. Correction or repair must begin within 30 days following the check and must be performed according to a plan designated by the registrant. Correction or repair must be completed no longer than 90 days from discovery unless authorized by the Department. Records of corrections or repairs will be maintained by the registrant in accordance with 180 NAC 6-003.01, item 2.

6-005 FLUOROSCOPIC X-RAY SYSTEMS: Use of nonimage intensified fluoroscopic equipment is prohibited. All fluoroscopic x-ray systems must meet the following requirements: The provisions of this 180 NAC 6-005 apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

6-005.01 ~~Limitation of Useful Beam~~ Primary Protective Barrier

1. Limitation of useful beam. The fluoroscopic imaging assembly must be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy must not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor must not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems will be exempt from this requirement provided the systems are intended only for remote control operation.

~~a. The fluoroscopic imaging assembly must be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID.~~

~~b The x-ray tube used for fluoroscopy must not produce x-rays unless the barrier is in position to intercept the entire useful beam.~~

2. Measuring compliance. The AKR must be measured in accordance with 180 NAC 6-005.01, item 1. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor must be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement must be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices must be removed from the useful beam during the measurement. For all measurements, the attenuation block must be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

6-005.02 Field Limitation

1. Angulation. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with 180 NAC 6-005.02, item 3 and 4 will be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. Further means for limitation: Means must be provided to permit further limitation of the x-ray field to sizes smaller than the limits of 180 NAC 6-005.02, item 3 and 4. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than 300 square cm, must be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square cm must be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm. 180 NAC 6-005.02, item 2 does not apply to non-image-intensified fluoroscopy.

3. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors:

a. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor must exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width must be no greater than 4 percent of the SID.
(2) For rectangular x-ray fields used with circular image receptors, the error in alignment must be determined along the length and width

dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

b. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor must conform with one of the following requirements:

(1) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor, or

(2) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm.

4. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies:

a. Neither the length nor width of the x-ray field in the plane of the image receptor must exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width must be no greater than 4 percent of the SID.

b. The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch must be clearly labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

6-005.02 Field Limitation and alignment for spot-film devices: The following requirements must apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment must be accomplished automatically when the x-ray field size in the plane of the

image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size must not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the x-ray field in the plane of the image receptor must differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences must not exceed 4 percent of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the x-ray field in the plane of the image receptor must be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

4. Means must be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

   a. For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or
   b. For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, must be containable in a square of 5 cm by 5 cm.

5. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position must indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch must be clearly labeled as follows:

For X-ray Field Limitation System Failure

~~2. Fluoroscopic Beam Limitation~~

~~a. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor must exceed that of the visible area of the image receptor by more than 3% of the SID. The sum of the excess length and the excess width must be no greater than 4% of the SID.~~

~~b. For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) must be no larger than the largest spot film size for which the device is designed. Measurements must be made at the maximum SID available but at no less than 20 centimeters table top to the film plane distance.~~

c. For uncertified fluoroscopic systems without a spot film device, the requirements of 180 NAC 6-005.01, item 1.a. apply.

d. Other requirements for fluoroscopic beam limitation:

(1) Means must be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters must be provided with means for stepless adjustment of the x-ray field;

(2) All equipment with a fixed SID and a visible area of 300 square centimeters or less must be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less.

(3) Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 by 5 centimeters or less;

(4) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

(5) For non-circular x-ray fields used with circular image receptor, the error in alignment must be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

3. Spot-film Beam Limitation. Spot-film devices must meet the following requirements:

(a) Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment must be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size must be only at the operator's option;

(b) Neither the length nor the width of the x-ray field in the plane of the image receptor must differ from the corresponding dimensions of the selected portion of the image receptor by more than 3% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences must not exceed 4% of the SID;

(c) It must be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID must be equal to, or less than, 5 centimeters by 5 centimeters;

(d) The center of the x-ray field in the plane of the film must be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

(e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means

~~must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.~~

~~4. Override: If a means exists to override any of the automatic x-ray field size adjustments required in 180 NAC 6-005.01, item 2 or 3, that means:~~

~~(a) Must be designed for use only in the event of system failure;~~
~~(b) Must incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and~~
~~(c) Must be clearly and durably labeled as follows:~~

~~FOR X-RAY FIELD~~
~~LIMITATION SYSTEM FAILURE~~

6-005.0~~2~~3 Activation of the Fluoroscopic Tube: X-ray production in the fluoroscopic mode must be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist must be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6-005.0~~3~~4 Air Kerma Rates. For fluoroscopic equipment, the following requirements apply: ~~Eposure Rate Limites~~

1. Fluoroscopic equipment manufactured before May 19, 1995.

   a. Equipment provided with automatic exposure rate control (AERC) must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3, except as specified in 180 NAC 6-004.04, item 1.e.
   b. Equipment provided without AERC must not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3, except as specified in 180 NAC 6-004.04, item 1.e..
   c. Equipment provided with both an AERC mode and a manual mode must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in 180 NAC 6-005.04, item 3., except as specified in 180 NAC 6-004.04, item 1.e..
   d. Equipment may be modified in accordance with this 180 NAC 6-004.04 to comply with 180 NAC 6-005.04, item 2. When the equipment is modified, it must bear a label indicating the date of the modification and the statement:

      MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

   e. Exceptions:

(1) During recording of fluoroscopic images, or
(2) When a mode of operation has an optional high-level control, in which case that mode must not be operable at any combination of tube potential and current that will result in an AKR in excess of the rates specified in 180 NAC 6-005.04, item 1. a. b. and c. at the measurement point specified in 180 NAC 6-005.04, item 3, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control must be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high-level control is being employed.

2. Fluoroscopic equipment manufactured on or after May 19, 1995.

a. Must be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3. Provision for manual selection of technique factors may be provided.
b. Must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3, except as specified in 180 NAC 6-005.04, item 2(c).
c. Exceptions

(1) For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.
(2) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.
(3) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3. Special means of activation of high-level controls must be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high-level control is employed.

3. Measuring compliance: Compliance with this 180 NAC 6-005 must be determined as follows:

a. If the source is below the x-ray table, the AKR must be measured at 1 cm above the tabletop or cradle.

b. If the source is above the x-ray table, the AKR must be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

c. In a C-arm type of fluoroscope, the AKR must be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

d. In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR must be measured at the minimum SSD.

e. In a lateral type of fluoroscope, the air kerma rate must be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it must be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

4. Exemptions: Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

6-005.05 Indication of potential and current: During fluoroscopy and cinefluorography, x-ray tube potential and current must be continuously indicated. Deviation of x-ray tube potential and current from the indicated value must not exceed the maximum deviation as stated by the manufacturer.

6-005.06 Source skin distance:

1. Means must be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in 180 NAC 6-005.06, provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means must be provided to limit the source-skin distance to not less than 19 cm. Such systems must be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in 180 NAC 6-005.06, item 2, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

6-005.07 Fluoroscopic irradiation time, display, and signal

1. Fluoroscopic equipment manufactured before June 10, 2006:

a. Must be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device must not exceed 5 minutes without resetting. A signal audible to the fluoroscopist must indicate the completion of any preset cumulative irradiation time. Such signal must continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(g) to comply with the requirements of 180 NAC 6-005.07, item 1. When the equipment is modified, it must bear a label indicating the statement:

b. As an alternative to 180 NAC 7-005.07, item 2.b. radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

2. For x-ray controls manufactured on or after June 10, 2006, there must be provided for each fluoroscopic tube:

a. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display must function independently of the audible signal described in this 180 NAC 6-005. The following requirements apply:

(1) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every 6 seconds.

(2) The fluoroscopic irradiation time must also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.

(3) Means must be provided to reset the display to zero prior to the beginning of a new examination or procedure.

b. A signal audible to the fluoroscopist must sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least 2 seconds.

6-005.08 Mobile and portable fluroscopes: In addition to the other requirements of 180 NAC 6-005, mobile and portable fluoroscopes must provide an image receptor incorporating more than a simple fluorescent screen.

6-005.09 Display of last image-hold (LIH): Fluoroscopic equipment manufactured on or after June 10, 2006, must be equipped with means to display LIH image following termination of the fluoroscopic exposure.

1. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection must be indicated prior to initiation of the fluoroscopic exposure.

2. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image must be selectable prior to the fluoroscopic exposure, and the combination selected must be indicated prior to initiation of the fluoroscopic exposure.

3. Means must be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph must be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

6-005.10 Displays of values of AKR and cumulative air kerma: Fluoroscopic equipment manufactured on or after June 10, 2006, must display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

1. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min must be continuously displayed and updated at least once every second.

2. The cumulative air kerma in units of mGy must be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

3. The display of the AKR must be clearly distinguishable from the display of the cumulative air kerma.

4. The AKR and cumulative air kerma must represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

   a. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location must be the respective locations specified in 180 NAC 6-005.04, item 3.a., b., or f.
   b. For C-arm fluoroscopes, the reference location must be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location must be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

5, Means must be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

7. The displayed AKR and cumulative air kerma must not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance must be determined with an irradiation time greater than 3 seconds.

~~1. Entrance Exposure Rate Allowable Limits~~

~~a. Fluoroscopic equipment which is provided with automatic exposure rate control must not be operable at any combination of tube potential and current which will result, in an exposure rate in excess of 2.6 mC/kg (10 roentgens)~~

per minute at the point where the center of the useful beam enters the patient, except:

(1) During recording of fluroscopic images; or

(2) When an optional high level control is provided. When so provided. The equipment must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls is required. The high level control must only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high level control is being employed.

b. Fluoroscopic equipment which is not provided with automatic exposure rate control must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the useful beam enters the patient except:

(1) During recording of fluoroscopic images; or

(2) When an optional high level control is activated. Special means of activation of high level controls is required. The high level control must only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high level control is being employed.

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c. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:

(1) During recording of fluoroscopic images; or

(2) When the mode or modes have an optional high level control, in which case that mode or modes must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls is required. The high level control must only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high level control is being employed.

d. Any fluoroscopic equipment manufactured after May 19, 1995 which can exceed 1.3 mC/kg (5 roentgens) per minute are equipped with an automatic exposure rate control. Entrance exposure rate limits must be 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when high level control is activated.

~~e. Compliance with the requirements of 180 NAC 6-005.03 must be determined as follows:~~

~~(1) If the source is below the x-ray table, the exposure rate must be measured 1 centimeter above the tabletop or cradle;~~

~~(2) If the source is above the x-ray table, the exposure rate must be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;~~

~~(3) For a C-arm type of fluoroscope, the exposure rate must be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;~~

~~(4) For a lateral type fluoroscope, the exposure rate must be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it must be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.~~

6-005.11~~2~~ Periodic Measurement of AKR:

1. A ~~P~~periodic measurement of air kerma rate ~~entrance exposure rate~~ (AKR) must be performed ~~by a qualified expert~~ for both typical and maximum values as follows:[3/]

   a. Such measurements must be made annually or after any maintenance of the system which might affect the ~~exposure rate~~ AKR;

   b. Results of these measurements must be posted, for units manufactured before June 10, 2006, where any fluoroscopist may have ready access to such results while using the fluoroscope. ~~and in the record required in 180 NAC 6-003.01 item 2.c.~~

2. The measurement results ~~must~~may be stated in ~~coulombs per kilogram(~~roentgens~~)~~ per minute (R/min) or milliGray per min (mGy/min) and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed must be included in the results;

3.~~c.~~ Conditions of periodic measurement of typical ~~entrance exposure rate~~ AKR are as follows:

   a.~~1.~~ The measurement must be made under the conditions that satisfy the requirements of 180 NAC ~~6-005.03, item 1~~6-005.04, item 3;

[3/] *Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.*

b.~~2.~~ Fluoroscopic systems that do not incorporate an AERC must utilize a milliamperage and kVp ~~The kVp, mA, and/or other selectable parameters must be adjusted to those settings~~ typical of clinical use of the fluoroscopic system ~~a 23 cm thick abdominal patient~~; and

c.~~3.~~ Fluoroscopic system that do incorporate an AERC ~~The x-ray system that incorporates automatic exposure rate control~~ must have sufficient ~~attenuative~~ material placed in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system. ~~kilovoltage to satisfy the conditions of 180 NAC 6-005.03, item 2.c.(2);~~

~~(~~4.~~)~~ Conditions of periodic measurement of maximum AKR ~~entrance exposure~~ rate are as follows:

a. The measurement must be made under the conditions that satisfy the requirements of 180 NAC 6-005.0~~3~~4, item 3~~1.d.~~.

b. Fluoroscopic systems that do not incorporate the AERC must be adjusted to those settings which give the maximum AKR;

c. Fluoroscopic~~The x-ray system(s)~~ that do incorporate~~s~~ AERC ~~automatic exposure control~~ must have sufficient ~~attenuative~~ material placed in the useful beam to produce the maximum ~~entrance exposure rate~~ AKR of the system.

~~6-005.04 Barrier Transmitted Radiation Rate Limits~~

~~1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, must not exceed 0.5 μC/kg (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate.~~

~~2. Measuring Compliance of Barrier Transmission~~

~~a. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~b. If the source is below the tabletop, the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.~~

~~c. If the source is above the tabletop and the SID is variable, the measurement must be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it must not be closer than 30 centimeters.~~

~~d. Movable grids and compression devices must be removed from the useful beam during the measurement.~~

~~6-005.05 Indication of Potential and Current: During fluoroscopy and cinefluorography, the kV and the mA must be continuously indicated and must not exceed the maximum deviation as stated by the manufacturer.~~

~~6-005.06 Source-to-Skin Distance: The SSD must not be less than:~~

~~1. 38 centimeters on stationary fluoroscopes installed after November 23, 1990;~~
~~2. 35.5 centimeters on stationary fluoroscopes which were in operation prior to November 23, 1990;~~
~~3. 30 centimeters on all mobile fluoroscopes; or~~
~~4. 20 centimeters for image intensified fluoroscopes used for specific surgical application.~~

~~6-005.07 Fluoroscopic Timer~~

~~1. Means must be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device must not exceed 5 minutes without resetting.~~
~~2. A signal audible to the fluoroscopist must indicate the completion of any preset cumulative on-time. Such signal must continue to sound while x-rays are produced until the timing device is reset.~~
~~3. The total time of exposure must be recorded.~~

6-005.~~08~~12 Control of Scattered Radiation

1. Fluoroscopic table designs when combined with procedures utilized must be such that no unprotected part of any staff or ancillary individual's body can be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required must be not less than 0.25 millimeter lead equivalent.

2. Equipment configuration when combined with procedures must be such that no portion of any staff or ancillary individual's body, except the extremities, can be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

   a. Is at least 120 centimeters from the center of the useful beam, or
   b. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains in addition to any lead equivalency provided by the protective apron referred to in 180 NAC 6-003.01, item 1.e.

4. The Department may grant exceptions to 180 NAC 6-005.~~08~~12, item 2., where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Department will not permit such exception. See Appendix 6-C for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

~~6-005.09 Spot Film Exposure Reproducibility: Fluoroscopic systems equipped with spot film (radiographic) mode must meet the exposure reproducibility requirements of 180 NAC 6-006.04 when operating in the spot film mode.~~

6-005.1~~3~~0 Fluoroscopic Radiation Therapy Simulation Systems: Fluoroscopic radiation therapy simulation systems are exempt from all the requirements of 6-005.04. In addition, these systems are exempt from the requirements of 180 NAC 6-005.01 provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays.

6-005.~~11~~14 Equipment Operation

1. All imaging formed by the use of fluoroscopic x-ray systems must be under the direction of and interpreted by a licensed practitioner of the healing arts.
2. Only a licensed practitioner can perform interpretative fluoroscopic procedures.
3. Fluoroscopy must not be used as a positioning tool for general purpose radiographic examinations.
4. Facilities must maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record must include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

6-006 RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, BONE DENSITOMETRY, VETERINARIAN, OR COMPUTED TOMOGRAPHY X-RAY SYSTEMS:

6-006.01 Control and indication of technique factors

1. Visual indication: The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

2. Timer: Means must be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

   a. Except during serial radiography, the operator must be able to terminate the exposure at any time during an exposure of greater than one-half second. Termination of exposure must cause automatic resetting of the timer to its initial setting or to zero. It must not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.
   b. During serial radiography, the operator must be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. Automatic exposure controls: When an automatic exposure control is provided:

   a. Indication must be made on the control panel when this mode of operations is selected;

b. When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliampere-seconds (mAs), whichever is greater;

c. Either the product of peak x-ray tube potential, current, and exposure time must be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time must be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time must be limited to not more than 2,000 mAs per exposure; and

d. A visible signal must indicate when an exposure has been terminated at the limits described in 180 NAC 6-006.01, item 3.c., and manual resetting must be required before further automatically timed exposures can be made.

4. Accuracy: Deviation of measured technique factors from indicated values of kVp and exposure time must not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation must not exceed 10% of the indicated value for kVp and 10% for time.

6-006.02 Reproducibility: The following requirements must apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

1. Coefficient of variation: For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma must be no greater than 0.05.

2. Measuring compliance: Determination of compliance must be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, will be subject to the additional requirement that all variable controls for technique factors must be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation must be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance must be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

~~6-006.01 Beam Limitation, Except Mammographic Systems: The useful beam must be limited to the area of clinical interest.~~

~~1. General Purpose Stationary and Mobile X-Ray Systems~~

~~a. Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field must be used.~~

~~b. A method must be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the~~

visually defined field must not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

2. Additional Requirements for Stationary General Purpose X-Ray Systems: In addition to the requirements of 180 NAC 6-006.01, item 1., stationary general purpose x-ray systems, both certified and noncertified, must meet the following requirements:

a. A method must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2% of the SID, and to indicate the SID to within 2%;
b. The beam-limiting device must indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
c. Indication of field size dimensions and SID's must be specified in inches and/or centimeters, and must be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

3. X-Ray Systems Designed for One Image Receptor Size: Radiographic equipment designed for only one image receptor size at a fixed SID must be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or must be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4. X-Ray Systems Other Than Those Described in 180 NAC 6-006.01, item 1, 2 and 3

a. Means must be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
b. Means must be provided to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or means must be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
c. 180 NAC 6-006.01, item 4.a. and b. may be met with a system that meets the requirements for a general purpose x-ray system as specified in 180 NAC 6-006.01, item 1. or, when alignment means are also provided, may be met with either:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such

~~device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or~~

~~(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use.~~

6-006.03 Linearity: The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

~~6-006.07 mA/mAs Linearity: The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated:~~

~~Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product ($C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings must not differ by more than 0.10 times their sum:~~

1. Equipment having independent selection of x-ray tube current (mA): The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

2. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings must not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

~~2. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector: The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of $C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings must not differ by more than 0.10 times their sum:~~

~~$$X_1 - X_2 \leq 0.10\ (X_1 + X_2)$$~~

~~where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.~~

~~3. Measuring Compliance: Determination of compliance must be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer~~

3. Measuring compliance: Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

6-006.04 Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems must meet the following requirements:

1. Variable x-ray field limitation: A means for stepless adjustment of the size of the x-ray field must be provided. Each dimension of the minimum field size at an SID of 100 cm must be equal to or less than 5 cm

2. Visual definition

a. Means for visually defining the perimeter of the x-ray field must be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field must not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

b. When a light localizer is used to define the x-ray field, it must provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance must be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

c. The edge of the light field at 100 cm or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance must be determined with a measuring aperture of 1 mm.

6-006.05 Field indication and alignment on stationary general purpose x-ray equipment: Except when spot-film devices are in service, stationary general purpose x-ray systems must meet the following requirements in addition to those prescribed in 180 NAC 6-006, item 4:

1. Means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device must numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs must be specified in centimeters and/or inches and must be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

6-006.06 Field limitation on radiographic x-ray equipment other than general purpose radiographic systems:

1. X-ray systems designed for one image receptor size: Radiographic equipment designed for only one image receptor size at a fixed SID must be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

2. Other x-ray systems: Radiographic systems not specifically covered in 180 NAC 6-006.04, item 4, 5, 6.b., 6.c. and .6d, and ., and systems covered in 180 NAC 6-006.05, item 1., which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, must be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means must be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means must be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

a. A system which performs in accordance with 180 NAC 6-004.04 and 6-004.05; or when alignment means are also provided, may be met with either;
b. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device must have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
c. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use.

6.006.07 Positive beam limitation (PBL) This requirements of this subsection must apply to radiographic systems which contain PBL

1. Field size: When a PBL system is provided, it must prevent x-ray production when:

a. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or
b. The sum of the length and width differences stated in 180 NAC 6-006.07 item 1, (a) without regard to sign exceeds 4 percent of the SID.
c. The beam-limiting device is at an SID for which PBL is not designed for sizing.

2. Conditions for PBL: When provided, the PBL system shall function as described in 180 NAC 6-006.07 item 1. whenever all the following conditions are met:

a. The image receptor is inserted into a permanently mounted cassette holder
b. The image receptor length and width are less than 50 cm;
c. The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;
d. The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and
e. Neither tomographic nor stereoscopic radiography is being performed.

3. Measuring compliance: Compliance with the requirements of 180 NAC 6-006.07. item 1.must be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 180 NAC 6-006.07 item 2. are met. Compliance must be determined no sooner than 5 seconds after insertion of the image receptor.

4. Operator initiated undersizing: The PBL system must be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm must be equal to or less

than 5 cm. Return to PBL function as described in 180 NAC 6-006.07, item 1 must occur automatically upon any change of image receptor size or SID.

5. Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key must be required for any override capability that is accessible to the operator. It must not be possible to remove the key while PBL is overridden. Each such key switch or key must be clearly and durably labeled as follows:

For X-Ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

6-006.08 Field limitation and alignment for spot-film devices: The following requirements must apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment must be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size must not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the x-ray field in the plane of the image receptor must differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences must not exceed 4 percent of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the x-ray field in the plane of the image receptor must be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

4. Means must be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

a. For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

b. For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, must be containable in a square of 5 cm by 5 cm.

5. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position must indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

6-006.0~~3~~9 Source-to-Skin Distance: All mobile or portable radiographic systems must be provided with means to limit the source-to-skin distance to greater than or equal to 30 centimeter.

6-006.~~05~~10 Radiation from Capacitor Energy Storage Equipment~~ in Standby Status~~: Radiation emitted from the x-ray tube ~~when the system is fully charged and the exposure switch or timer is not activated must~~ must not exceed ~~a rate of 0.5 μC/kg (2 milliroentgens) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.:~~

1. An air kerma of 0.26 microGy (0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance must be determined by measurements averaged over an area of 100 square cm, with no linear dimensions greater than 20 cm: and

2. An air kerma of 0.88 mGy (100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements must be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

6-006.11 Beam Limitation, Except Mammographic Systems: The useful beam must be limited to the area of clinical interest. This must be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 180 NAC 6-006.08 have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

6-006.~~02~~12 Radiation Exposure Control

1. Exposure Initiation: Means must be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure must not be initiated without such an action. In addition, it must

not be possible to initiate an exposure when the timer is set to a “zero” or ”off” position if either position is provided.

2. Exposure Indication: Means must be provided for visual indication observable at or from the operator’s protected position whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated.

3. Operator Protection: Stationary x-ray systems must be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

4. Exposure Control Location: The x-ray exposure control must be so placed that the operator can view the patient while making any exposure.

~~6-006.02 Radiation Exposure Control~~

~~1. Exposure Initiation: Means must be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure must not be initiated without such an action. In addition, it must not be possible to initiate an exposure when the timer is set to a “zero” or ”off” position if either position is provided.~~

~~2. Exposure Indication: Means must be provided for visual indication observable at or from the operator’s protected position whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated.~~

~~3. Exposure Termination: Means must be provided to terminate the exposure at a preset time interval, preset product of current time, a preset number of pulses, or a preset radiation exposure to the image receptor~~

~~a. Manual Exposure Control: An x-ray control must be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:~~

~~(1) Exposure of ½ second or less; or~~
~~(2) During serial radiography when means must be provided to permit completion of any single exposure of the series in process.~~

~~b. Automatic Exposure Controls: When an automatic exposure control is provided:~~

~~(1) Indication must be made on the control panel when this mode of operation is selected;~~
~~(2) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation must be equal to or less than a time interval equivalent to 2 pulses;~~
~~(3) The minimum exposure time for all equipment other than that specified in 180 NAC 6-006.02, item 3.b. must be equal to or less than one-~~

sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

(4) Either the product of peak x-ray tube potential, current, and exposure time must be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time must be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time must be limited to not more than 2000 mAs per exposure; and

(5) A visible signal must indicate when an exposure has been terminated at the limits required by 180 NAC 6-006.02, item 3.d. and manual resetting must be required before further automatically timed exposures can be made.

4. Exposure Duration (Timer) Linearity: For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings must not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

5. Exposure Control Location: The x-ray exposure control must be so placed that the operator can view the patient while making any exposure.

6-006.13 6.006.09 Tube Stands for Portable X-Ray Systems: A tube stand or other mechanical support must be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

6-006.04 Exposure Reproducibility: When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems must not exceed 0.05. This requirement applies to clinically used technique.

6-006.06 Accuracy: Deviation of measured technique factors from indicated values of kVp and exposure time must not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation must not exceed 10% of the indicated value for kVp and 10% for time.

6-006.08 Additional Requirements Applicable to Certified Systems Only: Diagnostic x-ray systems incorporating one or more certified component(s) must be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

a. There must be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters must be equal to or less than 5 centimeters by 5 centimeters.

b. When a light localizer is used to define the x-ray field, it must provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination must be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

c. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance must be determined with a measuring instrument aperture of 1 millimeter in diameter.

2. Beam Limitation and Alignment on Stationary General Purpose X-Ray Systems Equipped with PBL. If PBL is being used, the following requirements must be met:

a. PBL must prevent the production of x-rays when:

(1) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 180 NAC 6-006.08, item 2.c., from the corresponding image receptor dimensions by more than 3% of the SID; or

(2) The sum of the length and width differences as stated in 180 NAC 6-006.08, item 2.a(1) without regard to sign exceeds 4% of the SID;

b. Compliance with 180 NAC 6-006.08, item 2.a. must be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance must be determined no sooner than 5 seconds after insertion of the image receptor;

c. The PBL system must be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters must be equal to or less than 5 centimeters by 5 centimeters;

d. The PBL system must be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 180 NAC 6-006.08, item 2.a., then any change of image receptor size or SID must cause the automatic return.

~~3. Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems must meet the beam limitation requirements of 180 NAC 6-006.01, item 1 and 180 NAC 6-006.08, item 1.~~

6-007 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

6-007.01 Equipment

1. The protective tube housing must be equivalent to the requirements of 180 NAC 6-004.03.
2. Diaphragms or cones must be provided for collimating the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the housing.
3. The total filtration permanently in the useful beam must not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.
4. A device must be provided to terminate the exposure after a preset time or exposure.
5. A dead-man type of exposure switch must be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83m) from the animal during all x-ray exposures.

6-007.02 Structural Shielding: All wall, ceiling, and floor areas must be equivalent to or provided with applicable protective barriers to assure compliance with 180 NAC 4-005, 4-011, and 4-013.

6-007.03 Operating Procedures:

1. The operator must be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or must be so positioned that the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor.
2. No individual other than the operator may be in the x-ray room while exposures are being made unless such individual's assistance is required.
3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual must be protected with appropriate shielding devices, such as protective gloves and apron, and be so positioned that no part of the body will be struck by the useful beam.

6-007.04 Veterinary Assistant's Training Requirements:

1. Eight hours of classroom instruction in the fundamentals of radiation safety, radiographic equipment, state regulations, and operating and emergency procedures or
2. Have graduated from an accredited veterinarian technicians program.

6-008 COMPUTED TOMOGRAPHY SYSTEMS

6-008.01 Definitions: In addition to the definitions provided in 180 NAC 1-002 and 180 NAC 6-002, the following definitions must be applicable to 180 NAC 6-008:

1. Computed tomography dose index means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\mathrm{CTDI} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.
D(z) = Dose at position z.
T = Nominal tomographic section thickness.
n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

2. TDI (See "Computed tomography dose index").

3. Contrast scale means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{\mathrm{CS}} = \frac{\mu_x - \mu_w}{\overline{\mathrm{CTN}}_x - \overline{\mathrm{CTN}}_w}$$

where:

u_x = Linear attenuation coefficient of the material interest.
u_w = Linear attenuation coefficient of water.
$\overline{\mathrm{CTN}}_x$ = CTN of the material of interest.
$\overline{\mathrm{CTN}}_w$ = CTN of water.

4 . CS (See "Contrast scale").

5. CT conditions of operation means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 180 NAC 6-002.

6. CTDI (See "Computed tomography dose index").

7. CT Gantry means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

8. CTN (See "CT number").

9. CT number means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(u_x - u_w)}{u_w}$$

where:

k = A constant, a normal value of 1,000 when the Houndsfield scale of CTN is used;
u_x= Linear attenuation coefficient of the material of interest;
u_w= Linear attenuation coefficient of water.

11. Dose profile means the dose as a function of position along a line.

121. Elemental area means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

13. Modulation transfer function means the modulus of the Fourier transform of the impulse response of the system.

124. Multiple tomogram system means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

135. Noise means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (s_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{u_w}$$

where:

CS = Linear attenuation coefficient of the material of interest.
u_w = Linear attenuation coefficient of water.
s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

146. Nominal tomographic section thickness means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

157. Picture element means an elemental area of a tomogram.

1~~6~~8. Reference plane means a plane which is displaced from and parallel to the tomographic plane.

19. Remanufacturing means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in this subsection to "manufacture," "manufacturer," or "manufacturing" includes remanufacture, remanufacturing, respectively.

~~17~~20. Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

~~18~~21. Scan increment means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement.

~~19~~22. Scan sequence means a pre-selected set of two or more scans performed consecutively under preselected CT conditions of operation.

22. Sensitivity profile means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

2~~1~~3. Single tomogram system means a CT system which obtains x-ray transmission data during a scan to produce a single tomogram.

2~~2~~4. Tomographic plane means that geometric plane which is identified as corresponding to the output tomogram.

2~~3~~5. Tomographic section means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

6-008.02 Requirements for Equipment

1. Termination of Exposure

a. Means must be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination must occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices which monitor equipment function.

b. A visible signal must indicate when the x-ray exposure has been terminated through the means required by 180 NAC 6-008.02, item 1.a.

c. The operator must be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half second duration.

2. Tomographic Plane Indication and Alignment

a. For any single tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

b. For any multiple tomogram system, means must be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

c. If a device using a light source is used to satisfy the requirements of 180 NAC 6-008.02, item 2.a. or b., the light source must provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and Shutter Status Indicators and Control Switches

a. The CT x-ray control and gantry must provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

b. Each emergency button or switch must be clearly labeled as to its function.

4. Indication of CT Conditions of Operation: The CT System must be designed such that the CT conditions of operation to be used during a scan or a scan sequence must be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation must be visible from any position from which scan initiation is possible.

5. Entraneous Radiation: When data are being collected for image production, the radiation adjacent to the tube port must not exceed that permitted by 180 NAC 6-004.03.

6. Maximum Surface CTDI Identification: The angular position where the maximum surface CTDI occurs must be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985:

a. The total error in the indicated location of the tomographic plane or reference plane must not exceed 5 millimeters.

b. If the x-ray production period is less than one-half second, the indication of x-ray production must be actuated for at least one-half second. Indicators at or near the gantry must be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

c. The deviation of indicated scan increment versus actual increment must not exceed plus or minus 1 millimeter with any mass of 0 to 100 kilograms resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented

distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

d. Premature termination of the x-ray exposure by the operator must necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

6-008.03 Facility Design Requirements

1. Aural Communication Provision must be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing Systems

a. Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous observation of the patient during irradiation and must be so located that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) must be available for use in the event of failure of the primary viewing system.

6-008.04 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

a. All CT x-ray systems must have a survey made by, or under the direction of, a radiological medical physicist or radiological health physicist. In addition, such surveys must be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

b. The registrant must obtain a written report of the survey from the radiological medical physicist or radiological health physicist, and a copy of the report must be made available to the Department upon request.

2. Radiation Calibrations

a. The calibration of the radiation output of the CT x-ray system must be performed by, or under the direction of, a radiological medical physicist or radiological health physicist who is physically present at the facility during such calibration.

b. The calibration of a CT x-ray system must be performed at intervals specified by a radiological medical physicist or radiological health physicist and after any change or replacement of components which, in the opinion of the radiological medical physicist or radiological health physicist could cause a change in the radiation output and at least every two years.

c. The calibration of the radiation output of a CT x-ray system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years.

d. CT dosimetry phantom(s) must be used in determining the radiation output of a CT x-ray system. Such phantom(s) must meet the following specifications and conditions of use:

(1) The phantom must be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom must be at least 14 centimeters in length and must have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode.

(2) The phantom must provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience.

(3) Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters must be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

~~(1) CT dosimetry phantom(s) must be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) must be at least 14 centimeters in length and must have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.~~

~~(2) CT dosimetry phantom(s) must provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.~~

~~(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters must be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.~~

(4) All dose measurements must be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration must be required for each type of head, body, or whole-body scan performed at the facility.

f. Calibration must meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal

tomographic section thickness used by the registrant must be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination must be performed for each available nominal tomographic section thickness.

(2) The CTDI[4] along the two axes specified in 180 NAC 6-008.04, item 2.d.(2) must be measured. The CT dosimetry phantom must be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation must correspond to typical values used by the registrant.

(3) The spot checks specified in 180 NAC 6-008.04, item 3. must be made.

g. Calibration procedures must be in writing. Records of calibrations performed must be maintained for inspection by the Department.

3. Spot Checks

a. The spot-check procedures must be in writing and must have been developed by a radiological medical physicist or radiological health physicist.

b. The spot-check procedures must incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

c. All spot checks must be included in the calibration required by 180 NAC 6-008.04, item 2. and at time intervals and under system conditions specified by a radiological medical physicist or radiological health physicist.

d. Spot checks must include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 180 NAC 6-008.04, item 2. The images must be retained, until a new calibration is performed, in two forms as follows:

(1) Photographic copies of the images obtained from the image display device; or

(2) Images sorted in digital form on a storage medium compatible with the CT x-ray system.

e. Written records of the spot checks performed must be maintained for inspection by the Department.

4. Operating Procedures

a. The CT x-ray system must not be operated except by an individual who has been specifically trained in its operation.

[4]For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

b. Information must be available in the control area regarding the operation and calibration of the system. Such information must include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.
(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system.
(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

c. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the radiological medical physicist or radiological health physicist, use of the CT x-ray system on patients must be limited to those uses permitted by established written instructions of the radiological medical physicist or radiological health physicist.

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APPENDIX 6-A
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Department approve a healing arts screening program must submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

3. A detailed description of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert must show that such system(s) do satisfy all requirements of Title 180. The evaluation must include a measurement of patient exposure from the x-ray examination to be performed.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of each individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation must be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

14. ~~15.~~ An indication of the frequency of screening and the duration of the entire screening program.

15. ~~16.~~ Documentation that supports this procedure as being of benefit to public health.

APPENDIX 6-B

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

~~In order for the Department to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.~~

1. The plans should show, as a minimum, the following:

   (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

   (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

   (c) The dimensions of the room(s) concerned.

   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

   (e) The make and model of the x-ray equipment and the maximum technique factors.

   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

3. ~~If the services of a qualified expert have been utilized to determine the shielding requirements, a~~A report, including all basic assumptions used, must be included with the plans.

APPENDIX 6-C
EXEMPTIONS FROM SHIELDING
FOR CERTAIN FLUOROSCOPIC PROCEDURES

a. Angiograms

b. Arthrograms

c. Biliary drainage procedures

d. Fluoroscopic biopsy procedures

e. Myelograms

f. Percutaneous cholangiograms

g. Percutaneous nephrostomies

h. Sinograms or fistulograms

i. T-tube cholangiograms

Public Law 90-602
90th Congress, H. R. 10790
October 18, 1968

An Act

amend the Public Health Service Act to provide for the protection of the public health from radiation emissions from electronic products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Radiation Control for Health and Safety Act of 1968.

SHORT TITLE

SECTION 1. This Act may be cited as the "Radiation Control for Health and Safety Act of 1968".

AMENDMENTS TO PUBLIC HEALTH SERVICE ACT

58 Stat. 703; 81 Stat. 536. 42 USC 262-263a.

SEC. 2. Part F of title III of the Public Health Service Act is amended—

(1) by striking out the heading for such part and inserting in lieu thereof the following:

"PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES AND CONTROL OF RADIATION

"SUBPART 1—BIOLOGICAL PRODUCTS";

(2) by inserting immediately above the section heading of section 353 the following:

"SUBPART 2—CLINICAL LABORATORIES"; and

(3) by adding at the end of such part F the following new subpart:

"SUBPART 3—ELECTRONIC PRODUCT RADIATION CONTROL

"DECLARATION OF PURPOSE

82 STAT. 1173
82 STAT. 1174

"SEC. 354. The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions.

"DEFINITIONS

"SEC. 355. As used in this subpart—

"(1) the term 'electronic product radiation' means—

"(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

"(B) any sonic, infrasonic, or ultrasonic wave,

which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

"(2) the term 'electronic product' means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) elec-

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~~**ATTACHMENT 6-2**~~

~~**21 CFR 1020.30 and 1020.31**~~

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(3) *Test conditions.* (i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) *Instructions, labels, and warnings.* (i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and:

(*a*) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and (*b*) in the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability*—(1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32 which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and § 1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) "Technique factors";

(iii) Section 1020.30(b) "CT," "Dose," "Scan," "Scan time," and "Tomogram";

(iv) Section 1020.30 (h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33 (a) and (b);

(vii) Section 1020.33(c)(1) as it affects § 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and § 1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) *Definitions.* As used in this section and §§ 1020.31, 1020.32, and 1020.33, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable

provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Aluminum equivalent means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions as the material in question.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters by 20 centimeters by 3.8 centimeters.

Automatic exposure control means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device which provides a means to restrict the dimensions of the x-ray field.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 centimeters beyond the support.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Coefficient of variation means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}}\left[\sum_{i=1}^{n}\frac{(X_i - \bar{X})^2}{n-1}\right]^{1/2}$$

where:

s = Estimated standard deviation of the population.
$\bar{X}$ = Mean value of observations in sample.
X_i = ith observation sampled.
n = Number of observations sampled.

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in "Aluminum Standards and Data" (1969). Copies may be obtained from: The Aluminum Association, New York, NY.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperes-seconds (mAs);

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through a body.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device means a beam-limiting device which has the capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) *Mobile x-ray equipment* means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) *Portable x-ray equipment* means x-ray equipment designed to be hand-carried; and

(3) *Stationary x-ray equipment* means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Compliance and Surveillance of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

(d) *Assemblers' responsibility.* An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by §§ 1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements.* Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to the Center for Devices and Radiological Health in the report required under § 1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in §1010.3 of this chapter, manufacturers of components subject to this section and §§1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized pursuant to paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified pursuant to paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels, that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, he shall provide necessary information to allow the assembler to determine the

maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) *Information to be provided to users.* Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) *Tube rating charts.* If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided;

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(i) [Reserved]

(j) *Warning label.* The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(k) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 2.58×10^{-5} coulombs per kilogram (C/kg) (100 milliroentgens (mR)) in 1 hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed 5.16×10^{-7} C/kg (2 mR) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Beam quality*—(1) *Half-value layer.* The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in table I under "Specified dental systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; and under "Other x-ray systems," for all other x-ray systems subject to this section. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table I, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

TABLE I

X-ray tube voltage (kilovolt peak)		Minimum HVL (millimeters of aluminum)	
Designed operating range	Measured operating potential	Specified dental systems	Other X-ray systems
Below 51	30	1.5	0.3
	40	1.5	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(2) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* Except

[2] In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlock with the kilovoltage selector which will prevent x-ray emission if the minimum required filtration is not in place.

when used in a CT x-ray system, the aluminum equivalent of each of the items listed in table II, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has a HVL of 2.7 millimeters of aluminum. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE II

Item	Aluminum equivalent (millimeters)
Front panel(s) of cassette holder (total of all)	1.0
Front panel(s) of film changer (total of all)	1.0
Cradle	2.0
Tabletop, stationary, without articulated joint(s)	1.0
Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.5
Tabletop, with radiolucent panel having one articulated joint	1.5
Tabletop, with radiolucent panel having two or more articulated joints	2.0
Tabletop, cantilevered	2.0
Tabletop, radiation therapy simulator	5.0

(o) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(p) [Reserved]

(q) *Modification of certified diagnostic x-ray components and systems*—(1) Diagnostic x-ray components and systems certified in accordance with §1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with §1010.4 of this chapter or an exemption under sections 358(a)(5) or 360B(b) of the Public Health Service Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of §1020.31, §1020.32, or §1020.33. The owner who causes such modification need not submit the reports required by subpart B of part 1002 of this chapter, provided the owner records the date and the details of the modification, and provided the modification of the x-ray system does not result in a failure to comply with §1020.31, §1020.32, or §1020.33.

[58 FR 26396, May 3, 1993, as amended at 59 FR 26403, May 19, 1994; 64 FR 35927, July 2, 1999; 65 FR 17138, Mar. 31, 2000]

§1020.31 Radiographic equipment.

The provisions of this section apply to equipment for the recording of images, except equipment involving use of an image intensifier or computed tomography x-ray systems manufactured on or after November 28, 1984.

(a) *Control and indication of technique factors*—(1) *Visual indication.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure

when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls.* When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliamperes-seconds (mAs), whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kW's) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph (a)(3)(iii) of this section, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with §1020.30(h)(3);

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of §1020.30(h)(3);

(1) *Coefficient of variation.* For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05.

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity.* The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with the requirements of §1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Equipment having independent selection of x-ray tube current (mA).* The average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1-X_2| \leq 0.10(X_1+X_2)$; where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at each of two consecutive tube current settings or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) *Equipment having selection of x-ray tube current-exposure time product (mAs).* For equipment manufactured after May 3, 1994 the average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) *Measuring compliance.* Determination of compliance will be based on 10 exposures, made within ±1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within #1 of the mean value for all measurements at these technique factors.

(d) *Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.* Except when spot-film devices or special attachments for mammography are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters.

(2) *Visual definition.* (i) Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illuminance shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1 I_2, where I_1 is the illuminance 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 millimeter.

(e) *Field indication and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices or special attachments for mammography are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(3) Indication of field size dimensions and SID's shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(4) Compliance measurements will be made at discrete SID's and image receptor dimensions in common clinical

use (such as SID's of 100, 150, and 200 centimeters and/or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 centimeters and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(ii) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for mammography.* (i) Mammographic beam-limiting devices manufactured after September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. For systems that allow changes in the SID, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Each image receptor support device intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2), (f)(3), and (h) of this section and systems covered in paragraph (f)(1) of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) of this section; or when alignment means are also provided, may be met with either;

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Positive beam limitation (PBL).* The requirements of this paragraph shall apply to radiographic systems which contain PBL.

(1) *Field size.* When a PBL system is provided, it shall prevent x-ray production when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (g)(1)(i) of this section without regard to sign exceeds 4 percent of the SID.

(iii) The beam limiting device is at an SID for which PBL is not designed for sizing.

(2) *Conditions for PBL.* When provided, the PBL system shall function as described in paragraph (g)(1) of this section whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are less than 50 centimeters;

(iii) The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(3) *Measuring compliance.* Compliance with the requirements of paragraph (g)(1) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (g)(2) of this section are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(4) *Operator initiated undersizing.* The PBL system shall be capable of operation such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters. Return to PBL function as described in paragraph (g)(1) of this section shall occur automatically upon any change of image receptor size or SID.

(5) *Override of PBL.* A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SID's and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(h) *Field limitation and alignment for spot-film devices.* The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(2) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not

exceed 4 percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

(4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(i) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square centimeters; or

(ii) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(i) *Source-skin distance*—(1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(i) Eighteen centimeters if operable above 50 kVp; or

(ii) Ten centimeters if not operable above 50 kVp.

(2) Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 centimeters.

(j) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(k) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(l) *Radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube shall not exceed:

(1) 8.6×10^{-9} C/kg (0.03 mR) in 1 minute at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square centimeters, with no linear dimension greater than 20 centimeters; and

(2) 2.58×10^{-5} C/kg (100 mR) in 1 hour at 100 centimeters from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum exposure per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Primary protective barrier for mammography x-ray systems.* For mammography x-ray systems manufactured after September 30, 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross

section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed $2.58X10^{-8}$ C/kg (0.1 mR) for each activation of the tube.

(4) Compliance for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

[58 FR 26401, May 3, 1993; 58 FR 31067, May 28, 1993, as amended at 64 FR 35927, July 2, 1999]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier if provided, shall not exceed 3.34×10^{-3} percent of the entrance exposure rate, at a distance of 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 1020.30(g). Additionally, the manufacturer shall provide to users, pursuant to § 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(2) *Measuring compliance.* The entrance exposure rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Nonimage-intensified fluoroscopy.* (i) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of the field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(ii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the

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CHAPTER 7 MEDICAL USE OF RADIOACTIVE MATERIAL

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FORM(S)

Form NRH-7 Application for Radioactive Material License – Medical
Form NRH-7A Medical Use Training and Experience and Preceptor Attestation

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 7 MEDICAL USE OF RADIOACTIVE MATERIAL

GENERAL INFORMATION

7-001 SCOPE AND AUTHORITY: 180 NAC 7 establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of 180 NAC 7 are in addition to, and not in substitution for, others in Title 180. The requirements and provisions of 180 NAC 1, 3, 4, 10, 13, 15, 17, and 18 apply to applicants and licensees subject to 180 NAC 7 unless specifically exempted. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

7-002 DEFINITIONS: As used in 180 NAC 7, the following definitions apply:

Accredited institution means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.

Address of use means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

Authorized medical physicist means an individual who:

1. Meets the requirements in 180 NAC 7-023.01 and 7-027; or
2. Is identified as an authorized medical physicist or teletherapy physicist on a specific license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized medical physicist on a permit issued by an Department, Nuclear Regulatory Commission or Agreement State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized nuclear pharmacist means a pharmacist who:

1. Meets the requirements of 180 NAC 7-024.01 and 7-027; or
2. Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial

nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Department, Nuclear Regulatory Commission or Agreement State; or

3. Is identified as an authorized nuclear pharmacist on a permit issued by the Department, Nuclear Regulatory Commission or Agreement State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized user means a physician, dentist, or podiatrist who:

1. Meets the requirements in 180 NAC 7-027 and 7-043.01, 7-047.01, 7-052.01, 7-053.01, 7-054.01, 7-063.01, 7-066.01 or 7-084.01; or
2. Is identified as an authorized user on a specific license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized user on a permit issued by an Department, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material.

Brachytherapy means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address means the address of use or a temporary job site for the purpose of providing mobile medical service in accordance with 180 NAC 7-038.

Dedicated check source means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

High dose-rate remote afterloader (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Low dose-rate remote afterloader (LDR), means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

Management means the individual having the authority to manage, direct, or administer the licensee's activities, or that persons' designee(s).

Manual brachytherapy means a type of therapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually applied or inserted.

Medical institution means an organization in which several medical disciplines are practiced.

Medical use means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader (MDR) means a brachytherapy device that remotely delivers a dose rate of greater that 2 gray (200 rads) per hour, but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Misadministration means an event that meets the criteria in 180 NAC 7-115.

Mobile medicine service means the transportation of radioactive material and\or its medical use at the client's address.

Nuclear medicine technologist means an individual who meets the requirements of 180 NAC 7-025.01 and is under the supervision of an authorized user, to prepare or administer radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.

Nuclear medicine technology means the science and art of *in vivo* or *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a nuclear medicine technologist, a radiation therapy technologist or a Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of radioactive drug as documented:

1. In a written directive as specified in 180 NAC 7-019; or
2. In accordance with the directions of the authorized user for procedures performed per 180 NAC 7-041, 7-044 and 7-048.

Prescribed dose means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive;
3. For manual brachytherapy, either the total source strength and exposure time or the total dose as documented in the written directive; or
4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the “high dose-rate” range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and;
2. Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer (RSO) means an individual who:

1. Meets the requirements in 180 NAC 7-022.01 and 7-026;
2. Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Department for similar types and uses of radioactive material.

Radiation therapist means an individual who meets the requirements of 180 NAC 7-025.02 and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

Radiation therapy technology means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

Radioactive drug means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

Sealed Source and Device Registry means the national registry that contains all the registration certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

Structured education program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary job site means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic dosage means a radiation dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use means use of radioactive material as specified in 180 NAC 7-041, 7-044, 7-048, 7-055, 7-065, 7-067 or 7-085.

Unit dosage means a dosage that:

1. Is obtained or prepared in accordance with the regulations for uses described in 180 NAC 7-041, 7-044, or 7-048; and
2. Is to be administered as a single dosage to patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of a radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 180 NAC 7-019.

7-003 MAINTENANCE OF RECORDS: Each record required by this 180 NAC 7 must be legible throughout the retention period specified by Title180. The record may be the original, a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

7-004 PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS: A licensee may conduct research involving human subjects using radioactive material provided:

7-004.01 That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee may apply for and receive approval of a specific amendment to its Department license before conducting such research. Both types of licensees must, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

7-004.02 The research involving human subjects authorized in 180 NAC 7-004.01 maybe conducted using radioactive material authorized for medical use in the license; and

7-004.03 Nothing in 180 NAC 7-004 relieves the licensee from complying with the requirements in 180 NAC 7.

7-005 U.S. FOOD AND DRUG ADMINISTRATION (FDA), FEDERAL AND STATE REQUIREMENTS: Nothing in this 180 NAC 7 relieves the licensee from complying with applicable FDA, Federal, and State requirements governing radioactive drugs or devices.

7-006 IMPLEMENTATION:

7-006.01 A licensee must implement the provisions in 180 NAC 7 on the effective date of these regulations, with the exception of requirements listed in 180 NAC 7-006.02.

7-006.02 When a requirement of 180 NAC 7 differs from the requirement in an existing license condition, the requirement in 180 NAC 7 will govern.

7-006.03 Any existing license condition that is not affected by a requirement in 180 NAC 7 remains in effect until there is a license amendment or license renewal.

7-006.04 If a license condition exempted a licensee from a provision of 180 NAC 7, it will continue to exempt a licensee from the corresponding provision in 180 NAC 7.

7-006.05 If a license condition cites provisions in 180 NAC 7 that has been deleted , then the license condition remains in effect until there is a license amendment or renewal that modifies or removes the license condition.

7-006.06 Licensees must continue to comply with any license condition that requires it to implement procedures required by 180 NAC 7-070, 7-076, 7-077 and 7-078 until there is a license amendment or renewal that modifies the license condition.

GENERAL REGULATORY REQUIREMENTS

7-007 LICENSE REQUIRED

7-007.01 A person may only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State, or as allowed by 180 NAC 7-007.02 or 7-007.03.

7-007.02 An individual may receive, possess, use or transfer radioactive material in accordance with 180 NAC 7 under the supervision of an authorized user as provided in 180 NAC 7-018, unless prohibited by license condition.

7-007.03 An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in 180 NAC 7 under the supervision of an authorized nuclear pharmacist or authorized user as provided in 180 NAC 7-018, unless prohibited by license condition.

7-008 APPLICATION FOR LICENSE, AMENDMENT, OR RENEWAL

7-008.01 An application must be signed by the applicant's or licensee's management.

7-008.02 An application for a license for medical use of radioactive material as described in 180 NAC 7-041, 7-044, 7-048, 7-055, 7-065, 7-067 and 7-085 must be made by filing an original of Form NRH-7 and 7A (Medical), "Application for Radioactive Material License - Medical". For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides.

7-008.03 A request for a license amendment or renewal may be submitted as an original in letter format. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide.

7-008.04 In addition to the requirements of 180 NAC 7-008.02 and 7-008.03, an application for a license or amendment for medical use of radioactive material as described in 180 NAC 7-085 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 180 NAC 7-001 through 7-040, as well as any specific information on:

1. Radiation safety precautions and instructions;
2. Training and experience of proposed users;
3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

7-008.05 An applicant or licensee must also provide any other information requested by the Department that has been determined to be reasonable and necessary for the review of the application.

7-008.06 An applicant that satisfies the requirements specified in 180 NAC 3-013.02 may apply for a Type A specific license of broad scope.

7-009 MOBILE MEDICAL SERVICE ADMINISTRATIVE REQUIREMENTS

7-009.01 The mobile medical service must be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service must be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

7-009.02 Mobile medical service licensees must obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter must clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letters must document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

7-009.03 A mobile medical service must not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

7-009.04 A mobile medical service must inform the authorized user identified in 180 NAC 7-018.03 at each client's address of use at a time prior to the radioactive material being administered.

7-009.05 A licensee providing mobile medical services must retain the letter required in 180 NAC 7-009.02 in accordance with 180 NAC 7-097.

7-009.06 A mobile medical service licensee must, at a minimum, maintain the following documents on each mobile unit:

1. The current operating and emergency procedures;
2. A copy of the license;
3. Copies of the letter required by 180 NAC 7-009.02;
4. Current calibration records for each survey instrument, diagnostic equipment, and dose calibration systems in use;
5. Quality control tests and records of quality control required by 180 NAC 7-028; and
6. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

7-009.07 A mobile medical service licensee must maintain all records required by 180 NAC 4 and 7 at a location within the Department's jurisdiction that is:

1. A single address of use:

    a. Identified as the records retention location; and
    b. Staffed at all reasonable hours by individual(s) authorized to provide the Department with access for purposes of inspection; or

2. On the mobile unit:

    a. Identified in the license; and
    b. Whose current client's address schedule and location is reported to the Department.

7-010 LICENSE AMENDMENTS: A licensee must apply for and receive a license amendment before:

7-010.01 Receiving, preparing or using radioactive material for a type of use that is permitted under 180 NAC 7-007, but that is not authorized on the licensee's current license issued under 180 NAC 7;

7-010.02 Permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is:

1. An authorized user, who meets the requirements in 180 NAC 7-027 and 7-043.01, 7-047.01, 7-051.01, 7-052.01, 7-053.01, 7-063.01, 7-066.01,and 7-084.01;
2. An authorized nuclear pharmacist, who meets the requirements in 180 NAC 7-024 and 7-027;
3. An authorized medical physicist, an individual who meets the requirements in 180 NAC 7-027 and 7-023.01 and 7-023.04; ;
4. Identified as an authorized user, authorized nuclear pharmacist or authorized medical physicist on a U.S. Nuclear Regulatory Commission or Agreement State or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively;
5. Identified as an authorized user on a permit that authorized nuclear pharmacist, or authorized medical physicist on a permit by a Nuclear Regulatory Commission or Agreement State specific license of broad scope that authorize the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

7-010.03 Changing a Radiation Safety Officer, except as provided in 180 NAC 7-015.05;

7-010.04 Receiving~~es~~ radioactive material in excess of the amount or in a different physical or chemical form, than is authorized on the license;

7-010.05 Adding to or changing the areas of use identified in the application or on the license;

7-010.06 Changing the address(s) of use identified in the application or on the license;

7-010.07 Changing statements, representations, and procedures which are incorporated into the license; and

7-010.08 Releasing licensed facilities for unrestricted use.

7-011 NOTIFICATIONS

7-011.01 A licensee must provide to the Department a copy of the board certification and the written attestation(s), signed by a preceptor, the U.S. Nuclear Regulatory Commission or Agreement State license, the permit issued by a U.S. Nuclear Regulatory Commission master material licensee, the permit issued by a U.S. Nuclear Regulatory Commission or Agreement State licensee of a broad scope, or the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee, or documentation that only accelerator produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission and for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, pursuant to 180 NAC 7-010.02. For individuals permitted to work under 180 NAC 7-010.02, items within the same 30 day time frame, the licensee must also provide as appropriate, verification of completion of:

1. Any additional case experience required in 180 NAC 7-051.02, item 1.b.(6) for an authorized user under 180 NAC 7-048;
2. Any additional training required in 180 NAC 7-084.04 for an authorized user under 180 NAC 7-067; and
3. Any additional training required in 180 NAC 7-023.04 for an authorized medical physicist.

7-011.02 A licensee must notify the Department by letter no later than 30 days after:

1. An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change; or
2. The licensee's mailing address changes; or
3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 180 NAC 3-017.02.

7-011.03 The licensee must mail documents required in 180 NAC 7-010 to the appropriate address identified in 180 NAC 1-002.

7-012 EXEMPTIONS REGARDING TYPE A SPECIFIC LICENSE OF BROAD SCOPE: A licensee possessing a Type A specific license of broad scope for medical use, issued under 180 NAC 03-013 is exempt from:

7-012.01 The provisions of 180 NAC 7-008.04 regarding the need to file an amendment to the license for medical use of radioactive material as described in 180 NAC 7-085.

7-012.02 The provisions of 180 NAC 7-010.02 regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;

7-012.03 The provisions of 180 NAC 7-010.05 regarding additions to or changes in the areas of use at the addresses specified in the license;

7-012.04 The provisions of 180 NAC 7-011.01 regarding notification to the Department for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists;

7-012.05 The provisions of 180 NAC 7-021.01 regarding supplier for sealed sources.

7-013 LICENSE ISSUANCE

7-013.01 The Department will issue a license for the medical use of radioactive material if:

1. The applicant has filed NRH-5A (Medical), “Application for Radioactive Material License – Medical” in accordance with instructions in 180 NAC 7-008.
2. The applicant has paid any applicable fee as provided in 180 NAC 18;
3. The applicant meets the requirements of 180 NAC 3; and
4. The Department finds the applicant equipped and committed to observe the safety standards established by the Department in 180 NAC for the protection of public health and safety.

7-013.02 The Department will issue a license for mobile medical service if the applicant:

1. Meets the requirements in 180 NAC 7-013.01; and
2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with 180 NAC 7-037.

7-014 SPECIFIC EXEMPTIONS: The Department may, upon application or upon its own initiative, grant such exemptions from the requirements of 180 NAC 7 as it determines are authorized by law and will not results in undue hazard to public health and safety or property.

GENERAL ADMINISTRATIVE REQUIREMENTS

7-015 RADIATION PROTECTION PROGRAM

7-015.01 The program must include notice to workers of the program's existence and workers responsibility to help keep dose equivalents ALARA, a review of the summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety measures, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make every reasonable effort to maintain individual and collective occupational doses ALARA.

7-015.02 The licensee must retain a current written description of the ALARA program for the duration of the license. The written description must include:

1. A commitment by management to keep occupational doses as low as reasonably achievable;
2. A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program; and
3. Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

7-015.03 In addition to the radiation protection program requirements of 180 NAC 4-004, a licensee's management will approve in writing: Requests for a license application, renewal, or amendment before submittal to the Department;

1. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and
2. Radiation protection program changes that do not require a license amendment and are permitted under 180 NAC 7-016;

7-015.04 A licensee's management must appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

7-015.05 For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer (RSO) to function as a temporary Radiation Safety Officer and perform the functions of a Radiation Safety Officer, as provided in 180 NAC 7-015.07, provided the licensee takes the actions required in 180 NAC 7-015.02, 7-015.06, 7-015.07 and 7-015.010. A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

7-015.06 A licensee must establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

7-015.07 A licensee must provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources and management prerogative to:

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations; and,
4. Verify implementation of corrective actions.

7-015.08 Licensees that are authorized for ~~one~~two or more different types of use under 180 NAC 7-048, 7-055, 7-067 and 7-085, or one or more types of units under 180 NAC 7-067, will establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members the licensee deems appropriate.

7-015.09 A licensee's Radiation Safety committee will meet as necessary, but at a minimum will meet at intervals not the exceed six months. The licensee will maintain minutes of each meeting in accordance with 180 NAC 7-086.

7-015.10 A licensee must retain a record of actions taken under 180 NAC 7-015.01, 7-015.02 and 7-015.05 in accordance with 180 NAC 7-086.

7-016 RADIATION PROTECTION PROGRAM CHANGES

7-016.01 A licensee may revise its radiation protection program without Department approval if:

1. The revision does not require a license amendment under 180 NAC 7-010;
2. The revision is in compliance with the regulations and the license;
3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
4. The affected individuals are instructed on the revised program before the changes are implemented.

7-016.02 A licensee must retain a record of each change in accordance with 180 NAC 7-087.

7-017 DUTIES OF AUTHORIZED USER AND AUTHORIZED MEDICAL PHYSICIST

7-017.01 Only authorized users for the type of radioactive material used can:

1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and
2. Direct, as specified in 180 NAC 7-018 and 7-019, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;
3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with 180 NAC 7-007.02, 7-007.03 and 7-018;
4. Perform the final interpretation of the results of tests, studies, or treatments.

7-017.02 Only authorized medical physicists can perform, as applicable:

1. Full calibration measurement as described in 180 NAC 7-073, 7-074, and 7-075; and
2. Radiation surveys as described in 180 NAC 7-080.

7-018 SUPERVISION

7-018.01 A licensee permitting the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 180 NAC 7-007.02, must:

1. In addition to the requirements of 180 NAC 10-003, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of 180 NAC 7, and the license conditions with respect to the use of radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 180 NAC 7, and license conditions with respect to the medical use of radioactive material.
3. Require that only those individuals specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.
4. Require the authorized user to audit the performance of each supervised individual initially and at least annually. The audit must include verification that the supervised individual is meeting the requirements of 180 NAC 7-018.01, item 2 and physical observation of the individual performing the duties the authorized user has delegated to them.

7-018.02 A licensee permitting the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 180 NAC 7-007.03, must:

1. Train and instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of 180 NAC 7, and license conditions.

7-018.03 Unless physical presence as described in other sections of 180 NAC 7 is required, a licensee who permits supervised activities under 180 NAC 7-018.01 and 7-018.02 must require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and

7-018.04 A licensee that permits supervised activities under 180 NAC 7-018.01 and 7-018.02 is responsible for the acts and omissions of the supervised individual.

7-019 WRITTEN DIRECTIVES

7-019.01 A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

7-019.02 The written directive must contain the patient or human research subject's name and the following information:

1. For any administration of dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and the route of administration;
2. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
3. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
4. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
5. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

    a. Prior to implantation: treatment site, the radionuclide, and dose; and

b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or the total dose).

7-019.03 A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

1. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

7-019.04 The licensee must retain a copy of the written directive in accordance with 180 NAC 7-088.

7-020 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

7-020.01 For any administration requiring a written directive, the licensee will develop, implement, and maintain written procedures to provide high confidence that:

1. The patient’s or human research subject’s identity is verified before each administration; and
2. Each administration is in accordance with the written directive.

7-020.02 The procedures required by 180 NAC 7-020.01 must, at a minimum, address the following items that are applicable to the licensee’s use of radioactive material:

1. Verifying the identity of the patient or human research subject:
2. Verifying that the specific details of the administration is in accordance with the treatment plan, if applicable, and the written directive.
3. Checking both manual and computer-generated dose calculations; and
4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 180 NAC 7-067 or 7-085.

7-021 SUPPLIERS FOR SEALED SOURCES OR DEVICES FOR MEDICAL USE: For medical use, a licensee may only use:

7-021.01 Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 180 NAC 3 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, or another Agreement State;

7-021.02 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 180 NAC 3, or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

7-022 TRAINING FOR RADIATION SAFETY OFFICER: Except as provided in 180 NAC 7-026, the licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in 180 NAC 7-015 to be:

7-022.01 An individual who is certified by a specialty board whose certification process has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission and who meets the requirements in 180 NAC 7-022.04 and 7-022.05. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's web page.)

1. To have its certification process recognized, a specialty board will require all candidates for certification to:

   a. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
   b. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
   c. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. Require all candidates for certification to:

   a. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
   b. Have two years of full-time practical training and/or supervised experience in medical physics:

      (1) Under the supervision of a medical physicist who is certified in medical physicist by a specialty board recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission; or
      (2) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements or for authorized users in 180 NAC 7-026, 7-047 or 7-

051.

c. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

7-022.02 An individual who:

1. Has completed a structured educational program consisting of both:

a. 200 hours of classroom and laboratory training in the following areas:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Radiation biology; and
(5) Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Department, U.S. Nuclear Regulatory Commission or Agreement State license or permit issued by the a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

(1) Shipping, receiving, and performing related radiation surveys;
(2) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;
(3) Securing and controlling radioactive material;
(4) Using administrative controls to avoid mistakes in the administration of radioactive material;
(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
(6) Using emergency procedures to control radioactive material; and
(7) Disposing of radioactive material, or

7-022.03 An individual who is a:

1. Medical physicist who has been certified by a specialty board whose certification process has been recognized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State in 180 NAC 7-023.01 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirement in 180 NAC 7-022.04 and 7-022.05; or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and ~~who meets the requirements in 180 NAC 7-022.04 and 7-022.05.~~

7-022.04 An individual who has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 180 NAC 7-022.05 and in 180 NAC 7-022.01, item 1.a. and b. or 180 NAC 7-022.01, item 2.a. and b, or 180 NAC 7-022.02 item 1 or 180 NAC 7-022.03 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

7-022.05 An individual who has training in the radiation safety, regulatory issues and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

7-023 TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST: Except as provided in 180 NAC 7-026 the licensee must require the authorized medical physicist to be:

7-023.01 An individual who is certified by a specialty board whose certification process has been recognized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements of 180 NAC 7-023.03 and 7-023.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
2. Have two years of full-time practical training and/or supervision experience in medical physics:

   a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission, or
   b. In a clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 180 NAC

7-026, 7-063 or 7-084; and

3. Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

7-023.02 An individual who:

1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

   a. Performing sealed source leak tests and inventories;
   b. Performing decay corrections;
   c. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
   d. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Meets the requirements of 180 NAC 7-023.03. and 7-023.04.

7-023.03 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-023.04 and 180 NAC 7-023.01, item 1 and 2, or 180 NAC 7-023.02, item 1 and 180 NAC 7-023.04, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 180 NAC 7-023, 7-026 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

7-023.04 Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by

an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

7-024 TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST: The licensee will require the authorized nuclear pharmacist to be a pharmacist who:

7-024.01 Is certified by a specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-024.03. (The names of the board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
2. Hold a current, active license to practice pharmacy;
3. Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience;
4. Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

7-024.02 Completed all of the following requirements:

1. 700 hours in a structured educational program consisting of both:

   a. 200 hours of classroom and laboratory training in the following areas:

      (1) Radiation physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity;
      (4) Chemistry of radioactive material for medical use; and
      (5) Radiation biology; and

   b. Supervised practical experience in nuclear pharmacy involving:

      (1) Shipping, receiving, and performing related radiation surveys;
      (2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(3) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
(4) Using administrative controls to avoid medical events in the administration of radioactive material; and
(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

2. Meets the requirement of 180 NAC 7-024.03.

7-024.03 Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements of 180 NAC 7-024.01, item 1, 2, and 3 or 7-024.02 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

7-025 TRAINING AND TECHNICAL REQUIREMENT FOR NUCLEAR MEDICINE TECHNOLOGISTS AND RADIATION THERAPISTS

7-025.01 The licensee will require a individual performing nuclear medicine technology under the supervision of an authorized user to be an individual who:

1. Is certified in;

   a. Nuclear Medicine by the Nuclear Medicine Technology Certification Board (NMTCB);
   b. Nuclear Medicine by the American Registry of Radiologic Technologists (ARRT) with competency in Nuclear Medicine; or,

2. Be board eligible to take the NMTCB or ARRT(N) examinations; or,
3. Has successfully completed a training program in nuclear medicine which has resulted in certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,
4. Has training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:

   a. 200 hours of classroom and laboratory training in the following areas:

      (1) Radiation Physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity;
      (4) Chemistry of radioactive material for medical use; and
      (5) Radiation biology;
      (6) Imaging Technology; and

   b. Work experience, under the supervision of an authorized user involving:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(3) Calculating, measuring, and safely preparing patient or human research subject dosages;
(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

c. Supervised clinical experience under the supervision of an authorized user that includes:

(1) Reviewing the case histories of individuals to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
(2) Identifying radiopharmaceuticals for clinical procedures and calculating and measuring the dosages;
(3) Administering dosages to individuals and using syringe radiation shields; and
(4) Acquiring and manipulating diagnostic data.

d. Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of 180 NAC 7-025.01, item 4.a. and b. and has achieved a level of radiation safety competency sufficient to independently function as a nuclear medicine technologist.

7-025.02 The licensee must require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or
2. Be board eligible to take the ARRT(T) examination; or,
3. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology,[1] or,
4. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:

[1] "Essentials and guidelines of an Accredited Education Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, January 1, 2002.

a. 200 hours of classroom and laboratory training in the following areas:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity; and
(4) Radiation biology; and

b. Work experience, under the supervision of an authorized user involving:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Assisting the authorized user in simulating the patient for treatment;
(3) Preparing the patient for treatment;
(4) Implementing treatment plans as prescribed by the authorized user;
(5) Providing written documentation of treatment setup and patient treatments;
(6) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;
(7) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;
(8) Delivering doses to patients or human research subjects under the supervision of the authorized user;
(9) Maintaining running inventories of radioactive material on hand;
(10) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,
(11) Properly implementing emergency procedures; and

c. Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of 180 NAC 7-025.02 item 4.a. and 4.b. and has achieved a level of radiation safety competency sufficient to independently function as a radiation therapist.

7-025.03 The licensee must maintain records of the above training as specified in 180 NAC 7-100.

7-026 PROVISIONS FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST AND AUTHORIZED NUCLEAR PHARMACIST

7-026.01 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist or a authorized medial physicist, or a authorized nuclear pharmacist on a U.S. Nuclear Regulatory Commission, an Agreement State, or a Department license or on a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State or a Department broad scope licensee or master material license permit

or by a master material licensee permittee of broad scope that authorizes medical use or practice of nuclear pharmacy, before July 11, 2009 ~~the effective date of these regulations~~ need not comply with the training requirements of 180 NAC 7-022 through 7-024.

7-026.02 Physicians, dentists, or podiatrists identified as authorized users for the medical, use of radioactive material on a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or the Department, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission, an Agreement State or the Department broad scope licensee, or on a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee before July 11, 2009 ~~the effective date of these regulations~~, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements 180 NAC 7-041 through 7-084 .

7-26.03 Individuals who need not comply with training requirements as described in 180 NAC 7-026 may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

7-027 RECENTNESS OF TRAINING: The training and experience specified in 180 NAC 7 must have been obtained within seven years preceding the date of license application or the individual must have had related continuing education and experience since the required training and experience was completed.

GENERAL TECHNICAL REQUIREMENTS

7-028 QUALITY CONTROL OF DIAGNOSTIC EQUIPMENT: Each licensee must establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies must be those recommended by equipment manufacturers or procedures, which have been approved by the Department. The licensee must conduct quality control procedures in accordance with written procedures.

7-029 POSSESSION, USE, AND CALIBRATION OF INSTRUMENTS USED TO MEASURE THE ACTIVITY OF UNSEALED RADIOACTIVE MATERIAL

7-029.01 For direct measurements performed in accordance with 180 NAC 7-031, a licensee must possess and use instrumentation to measure the activity of unsealed radioactive material prior to administration to each patient or human research subject.

7-029.02 A licensee must test the instrumentation required in 180 NAC 7-029.01 in accordance with nationally recognized standards or the manufacturer's instructions.

7-029.03 The tests required in 180 NAC 7-029.02 must at minimum include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

7-029.04 A licensee will must a record of each instrument test required by 180 NAC 7-029 in accordance with 180 NAC 7-091.

7-030 CALIBRATION OF SURVEY INSTRUMENTS

7-030.01 A licensee must ensure that the survey instruments used to show compliance with 180 NAC 7 and 180 NAC 4 have been calibrated before first use, annually and following any repair that affects the calibration.

7-030.02 To satisfy the requirements of 180 NAC 7-030.01, the licensee must:

1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with a radiation source;
2. Have each radiation survey instrument calibrated:

    a. At energies appropriate for use and at annual intervals or after servicing instrument, except for battery changes;
    b. For linear scale instruments at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range and each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 mSv (2 and 1,000 mrem) per hour; and
    c. For dose rate instruments, so that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.

3. Conspicuously note on the instrument the date of calibration.

7-030.03 The licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%.

7-030.04 A licensee must check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

7-030.05 A licensee must maintain a record of each survey instrument calibration in accordance with 180 NAC 7-092.

7-031 DETERMINATION OF DOSAGES OF RADIOACTIVE MATERIAL FOR MEDICAL USE

7-031.01 A licensee must determine and record the activity of each dosage prior to medical use.

7-031.02 For unit dosages not requiring a written directive, this determination must be made by:

1. Direct measurement of radioactivity; or

2. A decay calculation, based on the measurements made by:
   a. A manufacturer or preparer licensed pursuant to 180 NAC 3 or equivalent provision of the U.S. Nuclear Regulatory Commission or Agreement State or
   b. A Department, U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigation New Drug (IND) protocol accepted by FDA; or
   c. A PET radioactive drug producer licensed in 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

7-031.03 For unit dosages requiring a written directive this determination must be made by direct measurement of radioactivity in accordance with 180 NAC 7-029.

7-031.04 For other than unit dosages not requiring a written directive, this determination must be made bydirect measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 180 NAC 3 or equivalent provision of the U.S. Nuclear Regulatory Commission or Agreement State or a PET radioactive drug producer licensed in 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

7-031.05 For other than unit dosages requiring a written directive this must be made by direct measurement of radioactivity in accordance with 180 NAC 7-029.

7-031.06 A licensee may not use a dosage if the dosage differs from the prescribed dosage by more than 20%.

7-031.07 A licensee must retain a record of the dosage determination required by 180 NAC 7 in accordance with 180 NAC 7-093.

7-032 AUTHORIZATION FOR CALIBRATION, TRANSMISSION AND REFERENCE SOURCES: Any person authorized by 180 NAC 7-007 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

7-032.01 Sealed sources manufactured and distributed by persons specifically licensed pursuant to 180 NAC 3 or equivalent provisions of the U.S. Nuclear Regulatory Commission, or Agreement State and that do not exceed 1.11 GBq (30 mCi) each;

7-032.02 Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 MBq (15 mCi);

7-032.03 Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

1. 7.4 MBq (200 μCi); or
2. 1000 times the quantities in Appendix B of 180 NAC 3 and

7-032.04 Technetium-99m in amounts as needed.

7-033 REQUIREMENTS FOR POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES

7-033.01 A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer, or equivalent instructions approved by the Department.

7-033.02 A licensee in possession of a sealed source must:

1. Test the source for leakage in accordance with 180 NAC 1-011; and.
2. Test the source for leakage at intervals not to exceed six months or at intervals approved by the Department, another Agreement State, or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

7-033.03 If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee must:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of 180 NAC 1-011.06 and 180 NAC 4; and
2. File a report within five days of the leak test in accordance with 180 NAC 7-118.

7-033.04 A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotatic radiosurgery sources, must conduct a semi-annual physical inventory of all such sources. The licensee must retain each inventory record in accordance with 180 NAC 7-094

7-034 LABELS: Each syringe and vial that contains a unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

7-035 VIAL SHIELDS AND SYRINGE SHIELD

7-035.01 A licensee must require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

7-035.02 A licensee must keep syringes that contain radioactive material to be administered in a radiation shield.

7-035.03 A licensee must require each individual who prepares or administers radioactive drugs to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

7-036 SURVEYS FOR AMBIENT RADIATION DOSE RATE AND CONTAMINATION

7-036.01 ~~Except as provided in 180 NAC 7-036.02 a~~ A licensee must survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs ~~containing radioactive material requiring a written directive were~~ are routinely prepared for use or administered.

7-036.02 A licensee must survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

7-036.03 A licensee must conduct the surveys required by 180 NAC 7-036.01 and 7-036.02 so as to be able to measure dose rates as low as 1 µSv (0.1 mrem) per hour.

7-036.04 A licensee must establish dose rate action levels for the surveys required by 180 NAC 7-036.01 and 7-036.02 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

7-036.05 A licensee must survey for:

1. Removable contamination once each day all areas where generators and bulk radioactive drugs are prepared for use or administered.
2. Removable contamination once each week where unsealed radioactive materials are prepared for use or administered and where unsealed radioactive materials are stored.

7-036.06 A licensee must conduct the surveys required by 180 NAC 7-036.05 so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm).

7-036.07 A licensee must establish removable contamination action levels for the surveys required by 180 NAC 7-036.05 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

7-036.08 A licensee must retain a record of each survey in accordance with 180 NAC 7-095.

7-037 RELEASE OF INDIVIDUALS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS

7-037.01 A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive drugs or implants containing radioactive material if

the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[2]

7-037.02 For patients administered radioactive material for which a written directive is required, a licensee must provide the released individual, or individual's parent or guardian with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

1. Guidance on the interruption or discontinuation of breast-feeding and
2. Information on the potential consequences, if any, of failure to follow the guidance.

7-037.03 Release of the patient must be approved by an individual listed as an authorized user on the Department license or an approved individual who is operating directly under the supervision of the authorized user and that authorized user is approved for the type of radioactive material use for which the patient being released has received.

7-037.04 The licensee must maintain a record of the basis for authorizing the release of an individual in accordance with 180 NAC 7-096.

7-037.05 The licensee must maintain a record of instructions provided to a breast-feeding female in accordance with 180 NAC 7-096.

7-037.06 The licensee must notify the Department in accordance with 180 NAC 7-119:

1. When they are aware that a patient containing radioactive material and who has been released in accordance with 180 NAC 7-037 dies; and,
2. If it is possible that any individual could receive exposures in excess of 5 mSV (500 mrem) as a results of the deceased's body.

7-038 MOBILE MEDICINE SERVICE TECHNICAL REQUIREMENTS: A licensee providing mobile nuclear medicine service must:

7-038.01 Transport to each address of use only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

7-038.02 Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

[2]U.S. Nuclear Regulatory Commission's - NUREG-1556, Vol.9 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

7-038.03 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

7-038.04 Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each address of use or on each day of use, whichever is more frequent. At a minimum, the check for proper function must include a constancy check;

7-038.05 Check survey instruments for consistent response with a dedicated check source before use at each client's address;

7-038.06 Prior to leaving a client's address of use, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with the requirements in 180 NAC 4.

7-038.07 Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and,

7-038.08 Retain a record of each survey required by 180 NAC 7-038.05 in accordance with 180 NAC 7-097.

7-039 STORAGE AND CONTROL OF VOLATILES AND GASES

7-039.01 A licensee must store volatile radioactive material and radioactive gases in a radiation shield and container.

7-039.02 A licensee must store and use a multi-dose container in a properly functioning fume hood.

7-039.03 A licensee who administers radioactive aerosols or gases must do so with a system that will keep airborne concentrations within the limits prescribed in 180 NAC 4.

7-039.04 The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

7-039.05 A licensee must check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements must be maintained for three years.

7-039.06 A licensee must only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

7-039.07 Before receiving, using, or storing a radioactive gas, the licensee must calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix 4-B of 180 NAC 4. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

7-039.08 A licensee must post the time calculated in 180 NAC 7-039.07 at the area of use and requires that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

7-039.09 A copy of the calculations required in 180 NAC 7-039.07 must be recorded and retained for the duration of the license.

7-040 DECAY-IN-STORAGE: See 180 NAC 4-039.03 for decay-in-storage requirements.

UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE NOT REQUIRED

7-041 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for diagnostic use involving measurements of uptake, dilution, or excretion that is:

7-041.01 Obtained from:

1. A manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent regulations of the U.S. Nuclear Regulatory Commission or Agreement State; or
2. A PET radioactive drug producer licensed pursuant to 180 NAC 3-010.11 or equivalent regulations of the U.S. Nuclear Regulatory Commission or Agreement State; or

7-041.02 Excluding production of PET radionuclides, prepared by:

1. An authorized nuclear pharmacist;
2. A physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051 and 7-047.03, item 1.b.(7); or
3. An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 180 NAC 7-041.02, item 1 or the physician who is authorized user in 180 NAC 7-041.02, item 2; or

7-041.03 Obtained from and prepared by an U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7-041.04 Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7-042 POSSESSION OF SURVEY INSTRUMENT: A licensee authorized to use radioactive material for uptake, dilution, and excretion studies must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 µSv (0.1 mrems) per hour to 1000 µSv (100 mrems) per hour. The instrument must be operable and calibrated in accordance with 180 NAC 7-030.

7-043 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in 180 NAC 7-041 to be a physician who:

7-043.01 Is certified by a medical specialty board whose certification process has been recognized by the Department, U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 180 NAC 7-043.04. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 180 NAC 7-043.03, items 1.and 2; and
2. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

7-043.02 Is an authorized user under 180 NAC 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or

7-043.03 Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. Classroom and laboratory training in the following areas:

    a. Radiation physics and instrumentation;
    b. Radiation protection;
    c. Mathematics pertaining to the use and measurement of radioactivity;
    d. Chemistry of radioactive material for medical use; and
    e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the

requirements in 180 NAC 7-026, 7-043, 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
c. Calculating, measuring, and safely preparing patient or human research subject dosages;
d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
f. Administering dosages of radioactive drugs to patients or human research subjects; and

3. Meet the requirements of 180 NAC 7-043.04.

7-043.04 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-043, 7-047, or 7-051, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirement in 180 NAC 7-043.01, item 1 or 7-043.03, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 180 NAC 7-041.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE NOT REQUIRED

7-044 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 180 NAC 7-019 that is:

7-044.01 Obtained from:
1. A manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State ; or
2. A PET radioactive drug producer licensed pursuant to 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State; or

7-044.02 Excluding production of PET radionuclides prepared by:

1. An authorized nuclear pharmacist;
2. A physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047, or 7-051 and 7-047.03, item 1.b.(7), or
3. An individual under the supervision, as specified in 180 NAC 7-018; of, the

authorized nuclear pharmacist in paragraph 180 NAC 7-044.02, item 1 or the physician who is an authorized user in paragraph 180 NAC 7-044.02, item 2;

7-044.03 Obtained from and prepared by an U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7-044.04 Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

7-045 RADIONUCLIDE CONTAMINANTS

7-045.01 A licensee must not administer to humans a radioactive drug containing:

1. More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m).
2. More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-82 per mCi of rubidium-82 chloride injection).
3. More than 0.02 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-85 per mCi of rubidium-82 chloride injection).

7-045.02 To demonstrate compliance with 180 NAC 7-045, the licensee preparing radioactive drugs from radionuclide generators must:

1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;
2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

7-045.03 A licensee that uses strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical must, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 180 NAC 7-045.01.

7-045.04 A licensee who must measure radionuclide concentration must retain a record of each measurement in accordance with 180 NAC 7-099.

7-045.05 A licensee must report immediately to the Department each occurrence of a concentration exceeding the limits specified in 180 NAC 7-045.01.

7-046 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for imaging and localization studies must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour. If generators (Mo99/Tc99m or Sr82/Rb82) are utilized, a portable

radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-047 TRAINING FOR IMAGING AND LOCALIZATION STUDIES: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in 180 NAC 7-044 to be a physician who:

7-047.01 Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets to requirement in 180 NAC 7-047.04. (The names of board certification which have been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 180 NAC 7-047.03, item 1.a. through item 1.b.(7) ; and
2. Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

7-047.02 Is an authorized user in 180 NAC 7-051 and meets the requirements in 180 NAC 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

7-047.03 The physician:

1. Completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include at a minimum:

    a. Classroom and laboratory training in the following areas:

        (1) Radiation physics and instrumentation;
        (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
        (3) Mathematics pertaining to the use and measurement of radioactivity;
        (4) Chemistry of radioactive material for medical use;
        (5) Radiation biology; and

b. Work experience, under the supervision of an authorized user, who meets the requirements in 180 NAC 7-026, 7-047, or 7-051 and 7-047.03, item 1.b.(7)~~, and 180 NAC 7-051~~ or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving;

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(3) Calculating, measuring, and safely preparing patient or human research subject dosages;
(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
(6) Administering dosages of radioactive drugs to patients or human research subjects; and
(7) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Meets the requirement of 180 NAC 7-047.04.

7-047.04 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-047, or 7-051 and 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-047.01, item 1 or 180 NAC 7-047.03, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-041 and 7-044 .

UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE REQUIRED

7-048 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

7-048.01 Obtained from:
1. A manufacturer or preparer licensed in 180 NAC 3-014.10; or equivalent U.S. Nuclear Regulatory Commission or Agreement State; or
2. A PET radioactive drug producer licensed pursuant to 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State; or

7-048.02 Excluding production of PET radionuclides, prepared by:

1. An authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051;
2. An individual under the supervision of either as specified in 180 NAC 7-018; or
3. An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 7-048,02, item 1 or the physician who is authorized in 7-048.02, item 2; or

7-048.03 Obtained from and prepared by the Department, U.S. Nuclear Regulatory Commission or Agreement State licensee in accordance with a Radioactive Drug Research Committee's approval protocol or an Investigational New Drug (IND) protocol accepted by FDA for use in research; or

7-048.04 Prepared by the licensee for use in research in accordance with an approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7-049 SAFETY INSTRUCTION AND SAFETY PRECAUTIONS

7-049.01 In addition to the requirements of 180 NAC 10-003,

1. A licensee must provide radiation safety instruction to all personnel caring for patients or human research subjects that have received therapy with radioactive drug, and cannot be released in accordance with 180 NAC 7-037. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

    a. Patient or human research subject control;
    b. Visitor control to include the following:

        (1) Routine visitation to hospitalized individuals in accordance with 180 NAC 4-013.01, item 1; and
        (2) Visitation authorized in accordance with 180 NAC 4-013.03.

    c, Contamination control;
    d. Waste control; and
    e. Notification of the Radiation Safety Officer or his/her designee and the authorized user if the patient or the human research subject has a medical emergency or dies.

2. A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-101.

7-049.02 Safety Precautions

1. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 180 NAC 7-037, a licensee must:

a. Quarter the patient or the human research subject either in:

(1) A private room with a private sanitary facility; or
(2) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who also cannot be released under 180 NAC 7-037;

b. Visibly post the patient's or the human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

c. Either:

(1) Monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding; or
(2) Handle such material and items as radioactive waste.

2. The Radiation Safety Officer, or his/her designee, and the authorized user must be notified immediately if the hospitalization patient dies or has a medical emergency. The licensee must also notify the Department in accordance with 180 NAC 7-119 if it is possible that any individual could receive exposures in excess of 180 NAC 4-013 as a result of the deceased's body.

3. Measure the thyroid burden of each individual who helped prepare or administer a liquid dosage of iodine-131 or in all cases where the patient's vomits or the capsule is compromised. The measurement must be done within three days after administering the dosage, and retain for the period required by 180 NAC 4-052 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

7-050 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for which a written directive is required must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 µSv (0.1 mrem) per hour to 1,000 µSv (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 µSv (1 mrem) per hour to 10 mSV (1000 mrems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-051 TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A

WRITTEN DIRECTIVE IS REQUIRED: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized under 180 NAC 7-048 to be a physician who:

7-051.01 Is certified by a medical specialty board whose certification process has been recognized by the Department an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) who meets the requirements in 180 NAC 7-051.02, item 1.b.(6) and 7-051.03. (Specialty Boards whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To be recognized, a specialty board must require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 180 NAC 7-051.02, item 1.a. through 7-051.02, item 1.b.(5). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

7-051.02 The physician:

1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

   a. Classroom and laboratory training in the following areas:

      (1) Radiation physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity;
      (4) Chemistry of radioactive material for medical use; and
      (5) Radiation biology; and

   b. Work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051, or equivalent U.S. Nuclear Regulatory or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051.02, must also have

experience in administering dosages in the same dosage category or categories (that is , 180 NAC 7-051.02, item 1., b.(6)) as the individual requesting authorized user status. The work experience must involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
(3) Calculating, measuring, and safely preparing patient or human research subject dosages;
(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
(6) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(a) Oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131, for which a written directive is required;
(b) Oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131[3];
(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or
(d) Parenteral administration of any other radionuclide, for which a written directive is required; and

2. Meets the requirements of 180 NAC 7-051.03.

7-051.03 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-051.01, item 1 and 7-051.02, item 1.b.(6) or 7-051.02, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirement in 180 NAC 7-051.02 must have experience in administering dosages in the same dosage category or categories (that is, 180 NAC 7-051.02, item 1.b.(6)) as the individual requesting authorized user status.

7-052 TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 IN

[3]Experience with at least 3 cases in 180 NAC 7-051.02, item 1.b. (6) (b) also satisfies the requirement in 180 NAC 7-051.02, item 1.b.(6)(a).

QUANTITIES LESS THAN OR EQUAL TO 1.22 GIGABECQUERELS (33 MILLICURIES) FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 GBq (33 mCi), for which a directive is required, to be a physician who:

7-052.01 Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-052.03, item 1. and 2. and whose certification has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-052.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) or

7-052.02 Is an authorized user under 180 NAC 7-051.01, 7-051.02 for uses listed in 180 NAC 7-051.02, item 1.b.(6)(a) or (b), 180 NAC 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

7-052.03 The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

    a. Radiation physics and instrumentation;
    b. Radiation protection;
    c. Mathematics pertaining to the use and measurement of radioactivity;
    d. Chemistry of radioactive material for medical use; and
    e. Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b). The work experience must involve:

    a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    b. Performing quality control procedures on instruments used to determine the activity of dosages and performing check for proper operation of survey meters;
    c. Calculating, measuring, and safely preparing patient or human research subject dosages;
    d. Using administrative controls to prevent a misadministration involving the use of radioactive material;
    e. Using procedures to contain spilled radioactive material safely and using

proper decontamination procedures; and

f. Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131; and

3. Meets the requirements of 180 NAC 7-052.04.

7-052.04 Has obtained written attestation that the individual has satisfactorily completed the requirements in180 NAC 7-052.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b).

7-053 TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE 1-131 IN QUANTITIES GREATER THAN 1.22 GIGABECQUERELS (33 MILLICURIES) FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the oral administration of sodium iodide 1-131 in quantities greater than 1.22 GBq (33 mCi), to be a physician who:

7-053.01 Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-053.03, item 1. and 2. and whose certification has been recognized the Department, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC)and who meets the requirements in 180 NAC 7-053.04. (The name of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's Web page.) or

7-053.02 Is an authorized user under 180 NAC 7-051, for uses listed in 180 NAC 7-051.02, item 1.b.(6)(b), or equivalent Agreement State, or U.S. Nuclear Regulatory Commission requirements; or

7-053.03 The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

a. Radiation physics and instrumentation;
b. Radiation protection;
c. Mathematics pertaining to the use and measurement of radioactivity;
d. Chemistry of radioactive material for medical use; and
e. Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(b). The work experience must involve:

   a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
   b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
   c. Calculating, measuring, and safely preparing patient or human research subject dosages;
   d. Using administrative controls to prevent a misadministration event involving the use of radioactive material;
   e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
   f. Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131; and

3. Meets the requirement of 180 NAC 7-053.04.

7-053.04 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-053.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051 or, 7-053, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.(6)(b).

7-054 TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE: Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

7-054.01 Is an authorized user under 180 NAC 7-051 for uses listed in 7-051.02, item 1.b. (6)(c) or (d),or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

7-054.02 Is an authorized user under 180 NAC 7-063 or 7-084, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who meets the requirements in 180 NAC 7-054.04; or

7-054.03 Is certified by a medical specialty board whose certification process has been recognized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State under 180 NAC 7-063 or 7-084; and who meets the requirements in 180 NAC 7-054.04.

7-054.04 The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

    (1) Radiation physics and instrumentation;
    (2) Radiation protection;
    (3) Mathematics pertaining to the use and measurement of radioactivity;
    (4) Chemistry of radioactive material for medical use; and
    (5) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051 or 7-054, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d). The work experience must involve:

    a. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
    b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
    c. Calculating, measuring, and safely preparing patient or human research subject dosages;
    d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
    e Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
    f. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at

least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-054.02 or 7-054.03, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, or 7-054, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d).

MANUAL BRACHYTHERAPY

7-055 USE OF SOURCES FOR MANUAL BRACHYTHERAPY: A licensee must use only brachytherapy sources for therapeutic medical uses:

7-055.01 As approved in the Sealed Source and Device Registry; or

7-055.02 For research in accordance with an active Investigational Device Exemption (IDE) application that has been accepted by the FDA, provided the requirements of 180 NAC 7-021.01 are met.

7-056 SURVEYS AFTER SOURCE IMPLANT AND REMOVAL

7-056.01 Immediately after implanting sources in a patient or a human research subject, the licensee must make a survey to locate and account for all sources that have not been implanted.

7-056.02 Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee must make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

7-056.03 A licensee must retain a record of the surveys in accordance with 180 NAC 7-102.

7-057 BRACHYTHERAPY SOURCES INVENTORY

7-057.01 A licensee must maintain accountability at all times for all brachytherapy sources in storage or use.

7-057.02 Promptly after removing sources from a patient or a human research subject, a licensee must return brachytherapy sources to a secure storage area.

7-057.03 A licensee must maintain a record of the brachytherapy source accountability in accordance with 180 NAC 7-103.

7-058 SAFETY INSTRUCTION: In addition to the requirements of 180 NAC 10-003,

7-058.01 The licensee must provide radiation safety instruction, initially and at least annually, to personnel caring for a patient or human research subjects that are undergoing implant therapy and can not be released under 180 NAC 7-037. The instruction must be commensurated with the duties of the personnel and will include the following:

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions;
3. Patient or human research subject control;
4. Visitor control, including both:

    a. Routine visitation of hospitalized individual in accordance with 180 NAC 4-013.01 and
    b. Visitation authorized in accordance with 180 NAC 4-013.01; and

5. Notification of the Radiation Safety Officer or his/her designee, and authorized user if the patient or the human research subject dies or has a medical emergency. The licensee will also notify the Department in accordance with 180 NAC 7-119 if it is possible that any individual could receive exposures in excess of 5 mSv (500 mrem) as a result of the deceased's body.

7-058.02 A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-101.

7-059 SAFETY PRECAUTIONS FOR PATIENTS OR HUMAN RESEARCH SUBJECTS RECEIVING BRACHYTHERAPY

7-059.01 For each patient or human research subject that is receiving brachytherapy that cannot be released pursuant to 180 NAC 7-037 a licensee must:

1. Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy; and
2. Visibly post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign; and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

7-059.02 A licensee must have radiological emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

1. Dislodged from the patient; and
2. Lodged within the patient following removal of the source applicators.

7-059.03 The Radiation Safety Officer, or his/her designee, and authorized user must be notified immediately if the hospitalized patient or human research subject has a medical emergency or dies.

7-060 CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES

7-060.01 Prior to the first medical use of a brachytherapy source a licensee must have performed the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of 180 NAC 7-072.01;
2. Determine source positioning accuracy within applicators; and
3. Use published protocols currently accepted by nationally recognized bodies to meet the requirements of 180 NAC 7-060.01, item 1. and 2.

7-060.02 A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 180 NAC 7-060.01.

7-060.03 A licensee must mathematically correct the outputs or activities determined in 180 NAC 7-060.01 for physical decay at intervals consistent with one percent physical decay.

7-060.04 An authorized medical physicist must perform or review the calculation measurements made pursuant to 180 NAC 7-060.01, 7-060.02, or 7-060.03.

7-060.05 Only an authorized medical physicist must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with 180 NAC 7-060.01, 7-060.02, or 7-060.03.

7-060.06 A licensee must retain a record of each calibration in accordance with 180 NAC 7-104.

7-060.07 A licensee must retain a record of decay calculations required by 180 NAC 7-060.5 in accordance with 180 NAC 7-105.

7-061 THERAPY-RELATED COMPUTER SYSTEMS: The licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

7-061.01 The source-specific input parameters required by the dose calculation algorithm;

7-061.02 The accuracy of dose, dwell time, and treatment time calculations at

representative points;

7-061.03 The accuracy of isodose plots and graphic displays; and

7-061.04 The accuracy of the software used to determine sealed source positions from radiographic images.

7-062 POSSESSION OF SURVEY INSTRUMENT: A licensee authorized to use manual brachytherapy sources must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 µSv (0.1 mrem) per hour to 1,000 µSv (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 µSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-063 TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of a manual brachytherapy source for the uses authorized under 180 NAC 7-055 to be a physician who:

7-063.01 Is certified by a medical specialty board whose certification has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC), and who meets to requirements of 180 NAC 7-063.03. (The names of board certifications which have been recognized an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
2. Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use manual brachytherapy; or

7-063.02 The physician:

1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

    a. 200 hours of classroom and laboratory training in the following areas:

        1. Radiation physics and instrumentation;
        2. Radiation protection;
        3. Mathematics pertaining to the use and measurement of

radioactivity; and

4. Radiation biology; and

b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing brachytherapy sources;
4. Maintaining running inventories of material on hand;
5. Using administrative controls to prevent a misadministration involving the use of radioactive material;
6. Using emergency procedures to control radioactive material; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 180 NAC 7-026, 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements, as a part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdocutoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 180 NAC 7-063.02, item 1.b.; and

3. Meet the requirements of 180 NAC 7-063.03.

7-063.03 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-063, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-063.01, item 1 or 7-063.02, item 1 and 2 and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 180 NAC 7-055.

7-064 TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90: Except as provided in 180 NAC 7-026, the licensee must require the authorized user of strontium-90 for ophthalmic uses authorized under 180 NAC 7-055 to be a physician who:

7-064.01 Is an authorized user under 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or

7-064.02 The physician:

1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

   a. Radiation physics and instrumentation;
   b. Radiation protection;
   c. Mathematics pertaining to the use and measurement of radioactivity; and
   d. Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

   a. Examination of each individual to be treated;
   b. Calculation of the dose to be administered;
   c. Administration of the dose; and
   d. Follow up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-063 or 7-064 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-064.01 and 7-064.02 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

SEALED SOURCES FOR DIAGNOSIS

7-065 USE OF SEALED SOURCES FOR DIAGNOSIS: A licensee must use only sealed sources for diagnostic medical uses:

7-065.01 Approved in the U.S. Nuclear Regulatory Commission's Sealed Source and Device Registry; and

7-065.02 Handled in accordance with the manufacturer's radiation safety instructions.

7-066 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS: Except as provided in 180 NAC 7-026, the licensee must require the authorized user of a diagnostic sealed source for use in a device authorized under 180 NAC 7-065 to be a physician, dentist or podiatrist who:

7-066.01 Is certified by a specialty board whose certification includes all of the requirements in 180 NAC 7-066.02 and 7-066.03 whose certification has been recognized by, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC). (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.); or

7-066.02 The physician, dentist, or podiatrist:

1. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

    a. Radiation physics and instrumentation;
    b. Radiation protection;
    c. Mathematics pertaining to the use and measurement of radioactivity; and
    d. Radiation biology; and

7-066.03 Has completed training in the use of the device for the uses requested.

PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPHY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-067 USE OF A SEALED SOURCE IN A REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNIT: A licensee must use sealed sources in photon emitting remote afterloader units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

7-067.01 As approved in the U.S. Nuclear Regulatory Commission Sealed Source and Device Registry; or

7-067.02 For research in accordance with an active Investigational Device Exemption (IDE) application that has been accepted by the FDA provided the requirements of 180 NAC 7-021.01 are met.

7-068 SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS TREATED WITH A REMOTE AFTERLOADER UNIT

7-068.01 Before releasing a patient or a human research subject from licensee control, a licensee must make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the shielded position.

7-068.02 A licensee must retain a record of surveys in accordance with 180 NAC 7-102.

7-069 INSTALLATION, MAINTENANCE, ADJUSTMENT, AND REPAIR

7-069.01 Only a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State may install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical

component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

7-069.02 Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State may install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

7-069.03 For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or an authorized medical physicist may install, replace, relocate, or remove a sealed source(s) contained in the unit.

7-069.04 A licensee must retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 180 NAC 7-106.

7-070 SAFETY PROCEDURES AND INSTRUCTIONS FOR REMOTE AFTERLOADER UNITS, TELETHERAPHY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-070.01 A licensee must:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
3. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

    a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
    b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
    c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

7-070.02 A copy of the procedures required by 180 NAC 7-070.01, item 4 must be physically located at the unit console.

7-070.03 A licensee must post instructions at the unit console to inform the operator of:

1. The location of the procedures required by 180 NAC 7-70.01, item 4; and
2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

7-070.04 A licensee must provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

1. The procedures identified in 180 NAC 7-070.01, item 4; and
2. The operating procedures for the unit.

7-070.05 A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

7-070.06 A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-070.04, in accordance with 180 NAC 7-101.

7-071 SAFETY PRECAUTIONS FOR REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-071.01 A licensee must control access to the treatment room by a door at each entrance.

7-071.02 A licensee must equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
2. Cause the source(s) to be shielded promptly when an entrance door is opened; and
3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

7-071.03 A licensee must require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

7-071.04 Except for low-dose remote afterloader units, a licensee will construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

7-071.05 For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

7-071.06 In addition to the requirements specified in 180 NAC 7-071.01 through 7-071.05, a licensee must:

1. For low dose-rate, medium dose-rate and pulsed dose-rate remote afterloader units, require:

   a. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
   b. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

2. For high dose-rate remote afterloader units, require:

   a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
   b. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

4. Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency and immediately if the patient dies.

7-071.07 A licensee must have applicable radiological emergency response equipment available near each treatment room to respond to a source that inadvertently:

1. Remains in the unshielded position; or
2. Lodges within the patient following completion of the treatment.

7-072 DOSIMETRY EQUIPMENT

7-072.01 Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following conditions must be met.

1. The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or
2. The system must have been calibrated within the previous four years. Within 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee must use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

7-072.02 The licensee must have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 180 NAC 7-072.01. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 180 NAC 7-072.01.

7-072.03 The licensee must retain a record of each calibration, intercomparison, and comparison in accordance with 180 NAC 7-107.

7-073 FULL CALIBRATION MEASUREMENTS ON TELETHERAPY UNITS

7-073.01 A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:

a. Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;
b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and
c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

7-073.02 To satisfy the requirement of 180 NAC 7-073.01, full calibration measurements must include determination of:

1. The output within +/-3% for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
4. Timer accuracy, and linearity over the range of use;
5. “On-off" error; and
6. The accuracy of all distance measuring and localization devices in medical use.

7-073.03 A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required by 7-073.02, item 1. may then be made using a dosimetry system that indicates relative dose rates.

7-073.04 A licensee must make full calibration measurements required by 180 NAC 7-073.01 in accordance with published protocols accepted by nationally recognized bodies.

7-073.05 A licensee must mathematically correct the outputs determined in 180 NAC 7-073.02, item 1, for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1% decay for all other nuclides.

7-073.06 Full calibration measurements required by 180 NAC 7-073.01 and physical decay corrections required by 180 NAC 7-073.05 must be performed by a authorized medical physicist.

7-073.07 A licensee must maintain a record of each calibration in accordance with 180 NAC 7-108.

7-074 FULL CALIBRATION MEASUREMENTS ON REMOTE AFTERLOADER UNITS

7-074.01 A licensee authorized to use a remote afterloader unit for medical use must perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

    a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
    b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one calendar quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
4. At intervals not exceeding one year for low dose-rate remote afterloader units.

7-074.02 To satisfy the requirement of 7-074.01, full calibration measurements must include, as applicable, determination of:

1. The output within ± 5%;
2. Source positioning accuracy to within ±1 millimeter;
3. Source retraction with backup battery upon power failure;
4. Length of the source transfer tubes;
5. Timer accuracy and linearity over the typical range of use;
6. Length of the applicators; and
7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

7-074.03 In addition to the requirements for full calibration for low dose-rate remote afterloader units in 180 NAC 7-074.02, a licensee must perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one calendar quarter.

7-074.04 A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output.

7-074.05 A licensee must make full calibration measurements required by 180 NAC 7-074.01 in accordance with published protocols accepted by nationally recognized bodies.

7-074.06 For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with180 NAC 7-074.01 through 7-074.05.

7-074.07 A licensee must mathematically correct the outputs determined in 180 NAC 7-074.02, item 1 for physical decay at intervals consistent with one percent physical decay.

7-074.08 Full calibration measurements required by 180 NAC 7-074.01 and physical decay corrections required by 180 NAC 7-074.07 must be performed by the authorized medical physicist.

7-074.09 A licensee must retain a record of each calibration in accordance with 180 NAC 7-108.

7-075 FULL CALIBRATION MEASUREMENTS ON GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-075.01 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

    a. Whenever spot-check measurements indicate that the output differs by +/- 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;
    b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
    c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

7-075.02 To satisfy the requirement of 180 NAC 7-075.01, full calibration measurements must include determination of:

1. The output within ±3%;
2. Relative helmet factors; (to verify that the helmet material provides the required shielding to the patient);
3. Isocenter coincidence; (to confirm the centering accuracy of the radiation beam relative to the alignment helmet openings);
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity; (to determine the rotational center of the source relative to the alignment helmet openings);
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches; (to determine if the switches terminate the radiation beam when);

9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

7-075.03 A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 180 NAC 7-075.02, item 1 may be made using a dosimetry system that indicates relative dose rates.

7-075.04 A licensee must make full calibration measurements required by 180 NAC 7-075.01 in accordance with published protocols accepted by nationally recognized bodies.

7-075.05 A licensee must mathematically correct the outputs determined in 180 NAC 7-075.02, item 1 at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1% physical decay for all other radionuclides.

7-075.06 Full calibration measurements required by 180 NAC 7-075.01 and physical decay corrections required by 180 NAC 7-075.05 must be performed by the authorized medical physicist.

7-075.07 A licensee must retain a record of each calibration in accordance with 180 NAC 7-108.

7-076 PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS

7-076.01 A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy, and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in 180 NAC 7-072.02; and
6. The difference between the measurement made in 180 NAC 7-076.01, item 5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

7-076.02 A licensee must perform measurements required by 180 NAC 7-076.01 in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist need not actually perform the spot-check measurements.

7-076.03 A licensee must have the authorized medical physicist review and sign the results

of each spot-check within 15 days. The authorized medical physicist must notify the licensee within 10 days in writing of the results of each spot-check.

7-076.04 A licensee authorized to use a teletherapy unit for medical use must perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

7-076.05 If the results of the checks required in 180 NAC 7-076.02 and 7-076.04 indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7-076.06 A licensee must retain a record of each spot-check required by 180 NAC 7-076.01 and 7-076.04 and in accordance with 180 NAC 7-109.

7-077 PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER UNITS

7-077.01 A licensee authorized to use a remote afterloader unit for medical use must perform spot-checks of each remote afterloader facility and on each unit:

1. At the beginning of each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;
2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and
3. After each source installation.

7-077.02 The licensee must have the authorized medical physicist establish written procedures for performing the spot-checks required in 180 NAC 7-077.01. The authorized medical physicist need not actually perform the spot-check measurements.

7-077.03 A licensee must have the authorized medical physicist review and sign the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee within 10 days in writing of the results of each spot-check.

7-077.04 To satisfy the requirements of 180 NAC 7-077.01, spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
4. Radiological emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

7-077.05 If the results of the checks required in 180 NAC 7-077.04 indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7-077.06 A licensee must retain a record of each check required by 180 NAC 7-077.04 in accordance with 180 NAC 7-110.

7-078 PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-078.01 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

7-078.02 The licensee must have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in 180 NAC 7-078.01; and
2. Review and sign the results of each spot-check required by 180 NAC 7-078.01 within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist must notify the licensee within 10 days in writing of the results of the spot check.

7-078.03 To satisfy the requirements of 180 NAC 7-078.01, item 1, spot-checks must, at a minimum:

1. Assure proper operation of:

    a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
    b. Helmet microswitches;

c. Emergency timing circuits; and
d. Stereotactic frames and localizing devices (trunnions).

2. Determine:

a. The output for one typical set of operating conditions measured with the dosimetry system described in 180 NAC 7-072.02;
b, The difference between the measurement made in 180 NAC 7-078.03, item b. and the anticipated output, expressed as a percentage of the anticipated output, (that is, the value obtained at last full calibration corrected mathematically for physical decay);
c. Source output against computer calculation;
d. Timer accuracy and linearity over the range of use;
e. On-off error; and
f. Trunnion centricity.

7-078.04 To satisfy the requirements of 180 NAC 7-078.01, item 2 and 3, spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

7-078.05 A licensee must arrange for the repair of any system identified in 180 NAC 7-078.03 that is not operating properly.

7-078.06 If the results of the checks required in 180 NAC 7-078.04 indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7-078.07 A licensee must retain a record of each check required by 180 NAC 7-078.03 and 7-078.04 and in accordance with 180 NAC 7-111.

7-079 ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS

7-079.01 A licensee providing mobile remote afterloader service must:

1. Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
2. Account for all sources before departure from a client's address of use.

7-079.02 In addition to the periodic spot-checks required by 180 NAC 7-077 a licensee authorized to use mobile afterloaders for medical use will perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
5. Radiation monitors used to indicate room exposures;
6. Source positioning (accuracy); and
7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

7-079.03 In addition to the requirements for checks 180 NAC 7-079.02, a licensee must ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

7-079.04 If the results of the checks required in 180 NAC 7-079.02 indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7-079.05 A licensee must retain a record of each check required by 180 NAC 7-079.02 in accordance with 180 NAC 7-112.

7-080 RADIATION SURVEYS

7-080.01 In addition to the survey requirement in 180 NAC 4-021, a person licensed to possess or a use remote afterloader, teletherapy or gamma stereotactic radiosurgery unit must perform surveys of the device and ensure the results of the surveys from the surface of the main source safe, with the sources in the shielded position, do not exceed the maximum and average radiation levels listed in the sealed source and device registry.

7-080.02 The licensee must make the survey required by 180 NAC 7-080.01 upon installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

7-080.03 A licensee must retain a record of the radiation surveys required by 180 NAC 7-080.01 in accordance with 180 NAC 7-113.

7-081 FIVE-YEAR INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-081.01 A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

7-081.02 This inspection and servicing must only be performed by persons specifically licensed to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

7-081.03 A licensee must maintain a record of the inspection and servicing in accordance with 180 NAC 7-114.

7-082 THERAPY-RELATED COMPUTER SYSTEMS: The licensee must perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

7-082.01 The source-specific input parameters required by the dose calculation algorithm;

7-082.02 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7-082.03 The accuracy of isodose plots and graphic displays;

7-082.04 The accuracy of the software used to determine radioactive source positions from radiographic images; and

7-082.05 The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

7-083 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 µSv (0.1 mrem) per hour to 1,000 µSv (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 µSv(1 mrem) per hour to 10 mSv (1000 mrems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-084 TRAINING FOR USE OF REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of a sealed source for a use authorized under 180 NAC 7-067 to be a physician who:

7-084.01 Is certified by a medical specialty board whose certification process has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets the requirements of 180 NAC 7-084.03 and 7-084.04.

(The names of board certifications which have been recognized the Department, an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's Web page.) To be recognized, a specialty board must require all candidates for certification to:

1. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

7-084.02 The physician:

1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

   a. 200 hours of classroom and laboratory training in the following areas:

      (1) Radiation physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity; and
      (4) Radiation biology; and

   b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-084 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving:

      (1) Reviewing full calibration measurements and periodic spot-checks;
      (2) Preparing treatment plans and calculating treatment doses and times;
      (3) Using administrative controls to prevent a misadministration involving the use of radioactive material;
      (4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
      (5) Checking and using survey meters; and
      (6) Selecting the proper dose and how it is to be administered; and

2. Has completed three years of supervised clinical experience in radiation

therapy, under an authorized user who meets the requirements in 180 NAC 7-026, 7-084, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 180 NAC 7-084.02, item 1.b.; and

3. Meets the requirements of 180 NAC 7-084.03 and 7-084.04.

7-084.03 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-084.01, item 1 or 7-084.02, item 1 and 2, and 7-084.04 has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-084 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

7-084.04 Has received training in device operation, safety procedures, and clinical use of the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

7-085 OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL: A licensee may use radioactive material or radiation sources approved for medical use which is not specifically addressed in 180 NAC 7:

7-085.01 The applicant or licensee has submitted the information required by 180 NAC 7-008.02 through 7-008.04; and

7-085.02 The applicant or licensee has received written approval from the U.S. Nuclear Regulatory Commission or Agreement State in a license and uses the material in accordance with the regulations and specific conditions the U.S. Nuclear Regulatory Commission or Agreement State considers necessary for the medical use of the material.

RECORDS

7-086 RECORDS OF AUTHORITY AND RESPONSIBILITIES FOR RADIATION PROTECTION PROGRAMS

7-086.01 A licensee must retain a record of actions taken by the licensee's management in accordance with 180 NAC 7-015.02 and 7-015.03 for five years. The record must include a summary of the actions taken and a signature of licensee management.

7-086.02 The licensee must retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 180 NAC 7-015.06, and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 180 NAC 7-015.04. The record must include the signature of the Radiation Safety Officer and licensee management.

7-086.03 The minutes of each Radiation Safety Committee meeting held in accordance with 180 NAC 7-015.09 must include:

1. The date of the meeting;
2. Members present;
3. Members absent; and
4. Summary of deliberations and discussions.

7-087 RECORDS OF RADIATION PROTECTION PROGRAM CHANGES: A licensee must retain a record of each radiation protection program made in accordance with 180 NAC 7-016.01 for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

7-088 RECORDS OF WRITTEN DIRECTIVES: A licensee must retain a copy of each written directive as required by 180 NAC 7-019 for three years.

7-089 RECORDS OF MISADMINISTRATION: A licensee must retain a record of misadministration reported in accordance with 180 NAC 7-115 for three years. The record must contain the licensee's name; name of the individual involved; the social security number or other identification number; if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any taken, or planned, to prevent recurrence; and whether the licensee notified the individual (or the individual's responsible relative or guardian): and, if not, whether such failure to notify was based on guidance from the referring physician.

7-090 RECORDS OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD: A licensee must retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 180 NAC 7-117 for three years. The record must contain the licensee's name; name of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken or planned, to prevent recurrence; and whether the licensee notified the

pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

7-091 RECORDS OF CALIBRATION OF INSTRUMENTS USED TO MEASURE THE ACTVITY OF UNSEALED RADIOACTIVE MATERIAL: A licensee must maintain a record of instrument calibrations required by 180 NAC 7-029 for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

7-092 RECORDS OF RADIATION SURVEY INSTRUMENT CALIBRATIONS: A licensee must maintain a record of radiation survey instrument calibration required by 180 NAC 7-030 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

7-093 RECORDS OF DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE: A licensee must maintain a record of dosage determinations required by 180 NAC 7-031 for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

7-094 RECORDS OF INVENTORY OF SEALED SOURCES AND BRACHYTHERAPY SOURCES: A licensee must retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 180 NAC 7-033.04 for three years. The inventory records must include the model number of each source, the serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the test.

7-095 RECORDS OF ~~LEAKS TESTS AND~~ SURVEYS FOR AMBIENT RADIATION EXPOSURE RATE AND CONTAMINATION: A licensee must retain a record of each survey required by 180 NAC 7–036 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

7-096 RECORDS OF THE RELEASE OF INDIVIDUALS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS CONTAINING RADIOACTIVE MATERIAL

7-096.01 A licensee must retain a record signed by the authorized user, or the basis for authorizing the release of an individual, for three years after the date of release.

7-096.02 A licensee must retain a record, for three years after the date of release, that the instructions required by 180 NAC 7-037.02 were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

7-096.03 A licensee must retain a record, for three years after the date of release, that the instructions required by 180 NAC 7-037.02 were provided to a breast-feeding woman.

7-097 RECORDS OF ADMINISTRATIVE AND TECHNICAL REQUIREMENTS THAT APPLY TO THE PROVISION OF MOBILE SERVICES

7-097.01 A licensee must retain a copy of each letter that permits the use of radioactive material at a client's address, as required by 180 NAC 7-09.02, for three years after the last provision of service.

7-097.02 A licensee must retain the record of each survey required by 180 NAC 7-038.06, for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

7-098 RECORDS OF DECAY-IN-STORAGE: See 180 NAC 4-054.02.

7-099 RECORDS OF RADIONUCLIDE PURITY: A licensee must maintain a record of the radionuclide contaminant concentration tests required by 180 NAC 7-045.02 for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

7-100 RECORDS OF TRAINING: A licensee must maintain records of training required by 180 NAC 7-025 for three years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

7-101 RECORDS OF SAFETY INSTRUCTION AND TRAINING: A licensee must maintain a record of safety instructions required by 180 NAC 7-049, 7-058 and 7-070 for three years. The record must include a list of topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

7-102 RECORDS OF SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS: A licensee must maintain a record of the surveys required by 180 NAC 7-056 and 7-068 for three years. Each record must include the date and the results of the survey, the specific survey instrument used, and the name of the individual who made the survey.

7-103 RECORDS OF BRACHYTHERAPY SOURCE INVENTORY

7-103.01 A licensee must maintain a record of brachytherapy source accountability required by 180 NAC 7-057 for three years.

7-103.02 For temporary implants, the record must include:

1 The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and
2. The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

7-103.03 For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
2. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of sources permanently implanted in the patient or human research subject.

7-104 RECORDS OF CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES

7-104.01 A licensee must maintain a record of the calibrations of brachytherapy sources required by 180 NAC 7-060 for three years after the last use of the source. The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;
3. The source output or activity;
4. The source positioning accuracy within the applicators; and
5. The signature of the authorized medical physicist.

7-105 RECORDS OF DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS

7-105.01 A licensee must maintain a record of the activity of a strontium-90 source required by 180 NAC 7-060 for the life of the source.

7-105.02 The record must include:

1. The date and initial activity of the source as determined under 180 NAC 7-060; and
2. For each decay calculation, the date and the source activity as determined under 180 NAC 7-060.

7-106 RECORDS OF INSTALLATION, MAINTENANCE, ADJUSTMENT, AND REPAIR: A licensee must retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 180

NAC 7-069 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

7-107 RECORDS OF DOSIMETRY EQUIPMENT

7-107.01 A licensee must retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 180 NAC 7-072 for the duration of the license.

7-107.02 For each calibration, intercomparison, or comparison, the record must include:

1. The date;
2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 180 NAC 7-072.01 and 7-072.02;
3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and
4. The names of the individuals who performed the calibration, intercomparison, or comparison.

7-108 RECORDS OF TELETHERAPY, REMOTE AFTERLOADER, AND GAMMA STEREOTACTIC RADIOSURGERY FULL CALIBRATIONS

7-108.01 A licensee must maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by 180 NAC 7-073 through 7-075 for three years.

7-108.02 The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);
3. The results and an assessment of the full calibrations;
4. The results of the autoradiograph required for low dose-rate remote afterloader units; and
5. The signature of the authorized medical physicist who performed the full calibration.

7-109 RECORDS OF PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS

7-109.01 A licensee must retain a record of each periodic spot-check for teletherapy units required by 180 NAC 7-076 for three years.

7-109.02 The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

7-110 RECORDS OF PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER UNITS

7-110.01 A licensee must retain a record of each spot-check for remote afterloader units required by 180 NAC 7-077 for three years.

7-110.02 The record must include, as applicable:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

7-111 RECORDS OF PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-111.01 A licensee must retain a record of each spot-check for gamma stereotactic radiosurgery units required by 180 NAC 7-078 for three years.

7-111.02 The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the gamma

stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

7-112 RECORDS OF ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS

7-112.01 A licensee must retain a record of each check for mobile remote afterloader units required by 180 NAC 7-079 for three years.

7-112.02 The record must include:

1. The date of the check;
2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
3. Notations accounting for all sources before the licensee departs from a facility;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and
5. The signature of the individual who performed the check.

7-113 RECORDS OF SURVEYS OF THERAPEUTIC TREATMENT UNITS

7-113.01 A licensee must maintain a record of radiation surveys of treatment units made in accordance with 180 NAC 7-080 for the duration of use of the unit.

7-113.02 The record must include:

1. The date of the measurements;
2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the individual who performed the test.

7-114 RECORDS OF FIVE YEAR INSPECTIONS FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-114.01 A licensee must maintain a record of the five year inspections for teletherapy and gamma stereotactic radiosurgery units required by 180 NAC 7-081 for the duration of use of the unit.

7-114.02 The record must contain:

1. The inspector's radioactive materials license number;
2. The date of inspection;
3. The manufacturer's name and model number and serial number of both the treatment unit and source;
4. A list of components inspected and serviced, and the type of service; and
5. The signature of the inspector.

REPORTS

7-115 REPORT AND NOTIFICATION OF MISADMINISTRATION

7-115.01 Other than events that result from intervention by a patient or human research subject, a licensee must report any event in which the administration of radioactive material or radiation from radioactive material results in:

1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

    a. The total dose delivered differs from the prescribed dose by 20% or more; or
    b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or
    c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

    a. An administration of a wrong radioactive drug;
    b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;
    c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment; or
e. A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

7-115.02 A licensee must report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

7-115.03 The licensee must notify the Department by telephone, no later than the next business day after the discovery of a misadministration.

7-115.04 The licensee must submit a written report to the Department within 15 days after discovery of the misadministration.

1. The written report must include:

a. The licensee's name;
b. The name of the prescribing physician;
c. A brief description of the event;
d. Why the event occurred;
e. The effect, if any, on the individual(s) who received the administration;
f. What actions, if any, have been taken or are planned to prevent recurrence; and
g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report can not contain the individual's name or any other information that could lead to identification of the individual.

7-115.05 The licensee must provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that s/he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of 180 NAC

7-115.05, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.

7-115.06 Aside from the notification requirement, nothing in 180 NAC 7-115 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

7-115.07 A licensee must retain a record of a misadministration in accordance with 180 NAC 7-089. A copy of the record required under 180 NAC 7-089 must be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

7-116 RECORDS OF SUPERVISION AUDITS: A licensee must maintain a record of audits required by 180 NAC 7-018.01, item 4 for three years. The record must include a list of items audited, the date of the audit, the name of the supervised individual, and the name and signature of the authorized user conducting the audit.

7-117 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

7-117.01 A licensee must report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

7-117.02 A licensee must report any dose to a nursing child that was not specifically approved, in advance, by the authorized user; that is a result of an administration of radioactive material to a breast-feeding individual that:

1. Is greater than 5 mSv (500 mrem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

7-117.03 The licensee must notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 180 NAC 7-117.01 or 7-117.02.

7-117.04 The licensee must submit a written report to the Department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 180 NAC 7-117.01 or 7-117.02.

1. The written report must include:

a. The licensee's name;
b. The name of the prescribing physician;
c. A brief description of the event;
d. Why the event occurred;
e. The effect, if any, on the embryo/fetus or the nursing child;
f. What actions, if any, have been taken or are planned to prevent recurrence; and
g. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report can not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

7-117.05 The licensee must provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting in 180 NAC 7-117.01 and 7-117.02, unless the referring physician personally informs the licensee either that s/he will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee must make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of 180 NAC 7-117.05, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee must inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.

7-117.06 A licensee must retain a record of a dose to an embryo/fetus or a nursing child in accordance with 180 NAC 7-090. A copy of the record required under 180 NAC 7-090 must be provided to the referring physician, if other than the licensee, within 15 days after the discovery of the event.

7-118 REPORTS OF LEAKING SOURCES: A licensee must file a report within 5 days if a leak test required by 180 NAC 7-033 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

7-119 NOTIFICATION OF DECEASED PATIENT OR HUMAN RESEARCH SUBJECTS CONTAINING RADIOACTIVE MATERIAL

7-119.01 The licensee must notify the Department by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 180 NAC 4-013 as a result of the deceased's body.

7-119.02 The licensee must submit a written report to the Department within 30 days after discovery that the patient or human research subject reference in 180 NAC 7-119.01 has died. The written report must include:

1. The licensee's name;
2. The date of death;
3. The radionuclide, chemical and physical form and calculated activity at time of death; and
4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 mSv (500 mrem).

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
RADIOLOGICAL HEALTH
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - Medical

INSTRUCTIONS - (Use additional sheets where necessary.)
Retain one copy for your files and submit original application to: Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Hospital, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip +4: _____

Telephone #: _____

FAX #: _____

e-Mail Address: _____

1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)

(1) Permanent Address: _____

`

_____

City, State Zip +4: _____

(2) Temporary Job Sites Throughout Nebraska? □ Yes □ No

2. Person to Contact Regarding this Application

_____

Telephone #:_____

3. This is an application for:

□ New License

□ Amendment to License No._____

□ Renewal of License No._____

□ **Table C-2 "Checklist for Items 4-6 of NRH -7" of Regulatory Guide 7.0 (RG 7.0) Appendix C is attached and completed for Items 4-6 of this application instead of completing the items on this form or equivalent pages.** (check if used and attached.) R**G 7.0 Revision** _____ **Date** _____

4. Individual User(s) (Check two)
□ Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials is listed below. **OR**
□ A Equivalent list is attached on 8½" x 11" paper

AND

□ Complete a NRH-7A for each individual listed below.

First Name + Middle Initial	Last Name	Title	Nebraska Medical License #	Place a checkmark for each use of material in 180 NAC 7-						
				041	044	048	055	065	067	085

5. Radiation Safety

5.A. Radiation Safety Officer (RSO)
(Name and Title of Individual designated as Radiation Safety Officer)
_____
Telephone #:_____
Complete a NRH-7A for the RSO.

5.B Radiation Safety Committee(If required by 180 NAC 7-015.08)
□ A description of the Radiation Committee is attached.

Department Use Only

Date Received Stamp

6. Radioactive Material Data

6.A. Radioactive Material for Medical Use

(Can be completed on additional 8½" x 11" paper or use Appendix C of Regulatory Guide 7.0)

Radioactive Material (Elements and mass number)	**Chemical/Physical Form** (Make & Model if sealed source)	**Maximum Activity Requested** (Expressed as Curies, Millicuries, or Micorcuries)	**Use of Each Form** (If sealed source, also give Make and Model Number of the storage and/or device in which the sealed source will be stored and/or used)
Title 180 NAC 3-008.09			For In Vitro Studies
Title 180 NAC 7-041			
Title 180 NAC 7-044			
Title 180 NAC 7-048			
Title 180 NAC 7-055			
Title 180 NAC 7-065			
Title 180 NAC 7-067			
Title 180 NAC 7-085			

6.B. Radioactive Material for Uses not Listed in Item 6.a.

6.b.(1)Element and Mass Number	6.b.(2) Chemical or Physical Form (Make and Model if sealed source)	6.b.(3) Maximum Activity Requested (Expressed as Curies, Millicuries, or Microcuries)	6.b.(4) Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

6.C All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in 180 NAC 3-018 must provide evidence of financial assurance for decommissioning.

☐ **Table C-3 "Checklist for Items 7-9 of NRH -7" of Regulatory Guide 7.0 (RG 7.0) Appendix C is attached and completed for Items 7-9 of this application instead of completing the items on this form or equivalent pages.** (check if used and attached.) R**G 7.0 Revision** _____ **Date** _____

OR

The type and scope of information to be provided for items 7 through 9 is described in "Regulatory Guide 7.0 - Radioactive Material Guidance for Medical Use Programs" (RG 7.0)

The information required of the applicant can be submitted on separate sheets for each item. Identify the item number and date of the application in the lower right hand corner of each page OR the information can be submitted on the appropriate pages from the most recent revision of Regulatory Guide 7.0 (RG 7.0). Revision _____ Date_____. (Please indicate the most recent revision and date of RG 7.0 used to complete this application.)

7. FACILITIES AND EQUIPMENT

7.A. Facility Diagram (check two)
- ☐ Facility Diagrams are attached
- ☐ Facility Descriptions are attached

7.B. Instrumentation (check one)
- ☐ Part 1 of Appendix G of RG 7.0 is attached and will use Appendix G of RG 7.0; **OR**
- ☐ Part 1 of Appendix G of RG 7.0 is attached and Equivalent Procedures are attached

7.C. Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material (check one)
- ☐ Appendix H of RG 7.0 will be used **OR**
- ☐ Equivalent Procedures are attached **OR**
- ☐ Not applicable. (No unsealed radioactive material will be used.)

7.D. Therapy Unit – Calibration and Use (check one)
- ☐ Procedures are attached (For HDR, Gamma Stereotactic Radiosurgery Unit, Teletherapy or Brachytherapy Use) **OR**
- ☐ Not applicable.

7.E. Other Equipment and Facilities (check one)
- ☐ Appendix X is attached **OR**
- ☐ Not applicable.

8. Radiation Protection Program

8.A. Safety Procedures and Instructions (check one)
- ☐ Attached Safety Procedures and Instructions per 180 NAC 7-070 (For Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units) **OR**
- ☐ Not applicable

8.B. Safety Instructions for Individuals Working in or Frequenting Restricted Areas) (check one)
- ☐ Appendix I of R.G. 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.C. Operating and Emergency Procedures (check three)
- ☐ Attach Operating and Emergency procedures

AND
- ☐ Appendix J of RG 7.0 will be used **OR**
- ☐ Equivalent Procedures are attached and will be used

AND ONE OF THE FOLLOWING (Check one)
- ☐ Attachment 1 of Appendix J will be used **OR**
- ☐ Equivalent Attachment is attached and will be used

8.D. Safe Use of Unsealed Radioactive Materials (check one)
- ☐ Appendix K of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures and are attached and will be used; **OR**
- ☐ Not applicable

8.E. Radioactive Gases and Aerosol (e.g., Xenon-133) (check one)
- ☐ Appendix Y is attached; **OR**
- ☐ Equivalent Supporting Information and Calculations Attached **OR**
- ☐ Not applicable

8.F. Minimization of Contamination (check one)
- ☐ Attach a description of how facility design and procedures of operation will minimize contamination

8.G. Ordering and Receiving (check two)
- ☐ Attach Procedures for receipt and accountability; **AND**
- ☐ Appendix L of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.H. Opening Packages Containing Radioactive Material (check one)
- ☐ Appendix M of RG 7.0 will be used **OR**

- ☐ Equivalent Procedures are attached and will be used

8.I. ALARA (check one)
- ☐ Appendix Z of RG 7.0 is attached **OR**
- ☐ Equivalent Procedures are attached and will be used

8.J. Occupational Dose Dosimetry, Internal and External Exposure) (check one)
- ☐ Part 1 of Appendix N is attached

8.K. Area Surveys (check one)
- ☐ Appendix O of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.L. Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources (check one)
- ☐ Appendix AA of RG 7.0 is attached **OR**
- ☐ Not applicable

8.M. Procedures for Administrations when a Written Directive is Required (check one)
- ☐ Appendix P of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used **OR**
- ☐ Not applicable

8.N. Safety Procedures for Treatment When Patients are Hospitalized (check one)
- ☐ Procedures are attached **OR**
- ☐ Not applicable

8.O. Release of Patients or Human Research Subjects (check one)
- ☐ Appendix Q will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used **OR**
- ☐ Not applicable

8.P. Mobile Medical Service (check one)
- ☐ Procedures are attached (See Appendix E of RG 7.0) **OR**
- ☐ Not applicable

8.Q. Leak Tests (check one)
- ☐ Part 1 of Appendix R of RG 7.0 is attached and will use Appendix R of RG 7.0; **OR**
- ☐ Part 1 of Appendix R of RG 7.0 is attached and Equivalent Procedures are attached and will be used

NOTE: No response is required for the following items but will be examined during an inspection.

Public Dose, Audit Program, Sealed Source Inventory, Records of Dosage and Use of Brachytherapy Sources, Recordkeeping, Reporting and Transportation.

9. <u>Waste Management</u> (check one)
- ☐ Appendix W will be used.; **OR**
- ☐ Equivalent Procedures attached

10. . **CITIZENSHIP ATTESTATION**

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ _____

_____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§ 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (Type or print first, middle, last)	Signature	Date

11.
CERTIFICATION
(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services, Title 180, Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. I am authorized to make binding commitments and to sign official documents on the behalf of the applicant.

_____
Applicant Name From Item 1.a.

By: _____ *Date:* _____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

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APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - MEDICAL
NRH - 7A
Medical Use Training and Experience and Preceptor Attestation
Part 1 - Training and Experience

Follow Regulatory Guide for NRH 7A "Medical Use Training & Experience and Preceptor Statement" when determining what information is needed for each type of medical use license.

Note: Description of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations in 180 NAC 7.

1. Name of Individual: _____

Address: _____

Telephone Number: _____ **FAX Number:** _____

E-Mail Address: _____

2. Is the individual a physician or pharmacist who is licensed to dispense drugs in the practice of medicine in Nebraska?

☐ YES (If Yes, list the Nebraska Medical or Pharmacist License #) License #: _____

☐ NO

3. Authorization

☐ **On a current license or permit** (Provide a copy of the license or broadscope permit listing the current authorization)

The individual is identified on a license or permit as a:

- ☐ Radiation Safety Officer for medical use licensee
- ☐ Authorized Medical Physicist
- ☐ Authorized Nuclear Pharmacist
- ☐ Authorized User for _____ use(s).

☐ The license or permit number _____.

☐ The individual is seeking additional authorization, as a:

- ☐ Radiation Safety Officer for medical use licensee
- ☐ Authorized Medical Physicist
- ☐ Authorized Nuclear Pharmacist
- ☐ Authorized User for _____ use(s).

4. Certification

Specialty Board	Category	Month and Year Certified

5. Classroom and laboratory training

Description of Training	Location of training	Dates of Training	Clock Hours in Lecture or Laboratory

6. Work Experience

6.A. Work Experience with Radiation.

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience

6.B. Supervised Clinical Experience (describe experience elements in 6.A.)

Isotope	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Radioactive Materials License Number	Date and/or Clock Hours of Experience

6.C. Training for Radiation Safety Officer, Medical Physicist, Authorized Use of sealed sources for diagnosis or Authorized User of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Training Element	Type of Training*	Locations and Dates

*Types of training may include supervised didactic, or vendor training.

6.D. Formal Training

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Material License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education and the Applicable Regulation)

7. One Year Full-Time Experience and/or Training

7.A. Radiation Safety Officer

☐ YES
☐ NA

Completed one year of full-time radiation safety experience (in areas identified in 6.A.) under the supervision of_____ the RSO of License No. _____.

7.B. Medical Physicist

☐ YES
☐ NA

Completed one year of full-time training (in areas identified in 6a) in medical physics under the supervision of _____ who meets the requirements of a authorized medical physicist or meets the requirements for Authorized Medical Physicist.

AND

☐ YES
☐ NA

Completed one year of full-time experience (at location providing radiation therapy services described and for topic identified in item 5.A.) for (specify use or device)_____ under the supervision of _____ who is meets the requirements for Authorized Medical Physicists (180 NAC 7-023 (specify use or device) _____.

8. Supervising Individual – Identification and Qualifications

The training and experience indicated above was obtained under the supervision of (*if more than one supervising individual is needed to meet requirements in 180 NAC 7, provide the following information for each):*

8.A. Name of Supervisor

_____

8.B. Supervisor is:

☐ Authorized User ☐ Authorized Medical Physicist

☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

8.C. The supervisor meets the requirements of 180 NAC 7-_____ for medical uses in 180 NAC 7-_____.

8.D. Authorized User on Radioactive Material License Number:

8.E. Licensee Name:
Licensee Address:

SUPPLEMENT A Medical Use Training and Experience and Preceptor Attestation
Part 2—Preceptor Attestation

Note: *The individual's preceptor must complete this part. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.*

9. Preceptor Attestation

9.A. I attest that _____(name of individual named in Item 1):

☐ has satisfactorily completed the requirements in 180 NAC 7-_____, as documented in this application.

9.B. ☐ meets the requirements of 180 NAC 7-_____ for types of use, as documented in section(s)_____ of this form.

9.C. ☐ has achieved a level of competency and radiation safety knowledge sufficient to function independently as a: (check one)

☐ Radiation Safety Officer for a medical use licensee

☐ Authorized Medical Physicist

☐ Authorized Nuclear Pharmacist

☐ Authorized User for _____ uses.

9.D. I am a

☐ Authorized User ☐ Authorized Medical Physicist

☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

I meet the requirement of 180 NAC 7-_____ for medical uses in 180 NAC 7-_____.

9.E. Preceptor on Radioactive Material License #:	**9.F**. Licensee Name: Licensee Address:

9.G. Name of Preceptor (type or print clearly)	Signature --Preceptor	Date

TITLE 180 CONTROL OF RADIATION

CHAPTER 8 RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

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TITLE 180 CONTROL OF RADIATION

CHAPTER 8 RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

8-001 SCOPE AND AUTHORITY

8-001.01 180 NAC 8 provides special requirements for analytical x-ray equipment. The regulations are authorized by and implement the Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520. For purposes of this section, analytical x-ray equipment include, but are not limited to, handheld x-ray fluorescence, x-ray spectrography, and x-ray diffraction.

8-001.02 The requirements of this 180 NAC 8 are in addition to, and not in substitution for applicable requirements in 180 NAC 1, 2, ~~3,~~ 4, 10, 15, 17 and 18.

8-002 DEFINITIONS: As used in 180 NAC 8, the following definitions apply:

Analytical x-ray equipment means equipment used for x-ray diffraction or fluorescence analysis.

Analytical x-ray system means a group of components utilizing x or gamma rays to determine the elemental composition or to examine the microstructure of materials.

Fail-safe characteristics means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of safety or warning device.

Local components means part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housing, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

Normal operating procedures mean step-by-step instructions necessary to accomplish the analysis. These procedures must include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures which are related to radiation safety.

Open-beam configuration means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

Open-beam configuration means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

Primary beam means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

Safety device means a device that prevents the entry of any portion of an individual's body into the primary x-ray beam path or that causes the beam to be shut off upon entry into its path.

8-003 EQUIPMENT REQUIREMENTS:

8-003.01 Safety Device.

8-003.01A A safety device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path must be provided on all open-beam configurations.

8-003.01B A registrant or licensee may apply to the Department for an exemption from the requirement of a safety device. Such exemption must be granted provided that the Department makes a finding that the exemption will not constitute a significant risk to the health and safety of the public. Such application must include:

1. A description of the various safety devices that have been evaluated;
2. The reason each of these devices cannot be used; and
3. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

8-003.02 Warning Devices

8-003.02A Open-beam configurations must be provided with a readily discernible indication of:

1. X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

2. Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

8-003.02B Warning devices must be labeled so that their purpose is easily identified. On equipment installed after June 27, 1983, warning devices must have fail-safe characteristics.

8-003.03 Ports: Unused ports on radiation source housings must be secured in the closed position in a manner which will prevent ~~casual~~ inadvertent opening.

8-003.04 Labeling: All analytical x-ray equipment must be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and
2. "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or
3. "CAUTION - RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with 180 NAC 4-033 if the radiation source is a radionuclide.

8-003.05 Shutters: On open-beam configurations installed after June 27, 1983, each port on the radiation source housing must be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

8-003.06 Warning Lights

8-003.06A An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, must be located:

1. Near any switch that energizes an x-ray tube and must be illuminated only when the tube is energized; or
2. In the case of a radioactive source, near any switch that opens a housing shutter, and must be illuminated only when the shutter is open.

8-003.06B On equipment installed after June 27, 1983, warning lights must have fail-safe characteristics.

8-003.07 Radiation Source Housing: Each radiation source housing must be subject to the following requirements:

1. Each x-ray tube housing must be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

2. Each radioactive source housing or port cover or each x-ray tube housing must be so constructed that, with all shutters closed, the radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 0.025 mSv (2.5 mrem) in one hour. For systems utilizing x-ray tubes, this limit must be met at any specified tube rating.

8-003.08 Generator Cabinet. Each x-ray generator must be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 2.5 uSv (0.25 mrem) in one hour.

8-004 AREA REQUIREMENTS

8-004.01 Radiation Levels: The local components of an analytical x-ray system must be located and arranged and must include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 180 NAC 4-013. For systems utilizing x-ray tubes, these levels must be met at any specified tube rating.

8-004.02 Surveys

~~1.~~8-004.02A Radiation surveys, as required by 180 NAC 4-021, of all analytical x-ray systems sufficient to show compliance with 180 NAC 8-004.01 must be performed:

1.~~a.~~ Upon installation of the equipment and at least once every 12 months thereafter;
2.~~b.~~ Following any change in the initial arrangement, number, or type of local components in the system;
3.~~c.~~ Following any maintenance requiring the disassembly or removal of a local component in the system;
4.~~d.~~ During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
5.~~e.~~ Any time a visual inspection of the local components in the system reveals an abnormal condition; and
6.~~f.~~ Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 180 NAC 4-005.

~~2.~~8-004.02B Radiation survey measurements will not be required if a registrant or licensee can demonstrate compliance to the satisfaction of the Department with 180 NAC 8-004.01 in some other manner.

8-004.03 Posting: Each area or room containing analytical x-ray equipment must be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION X-RAY EQUIPMENT" or words having a similar intent in accordance with 180 NAC 4-033.

8-005 OPERATING REQUIREMENTS

8-005.01 Procedures: Normal operating procedures must be written and available to all analytical x-ray equipment workers. No individual will be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless the individual has obtained written approval of the radiation safety officer.

8-005.02 Bypassing: No individual must bypass a safety device or interlock unless the individual has obtained the approval of the radiation safety officer. Such approval must

be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, must be placed on the radiation source housing.

8-005.03 Repair or Modification of X-Ray Tube Systems: Except as specified in 180 NAC 8-005.02, no operation involving removal of covers, shielding materials or tube housing or modifications to shutters, collimators, or beam stops must be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, must be used for routine shutdown in preparation for repairs.

8-005.04 Radioactive Source Replacement, Testing, or Repair: Radioactive source housing must be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct the procedures under a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

8-006 PERSONNEL REQUIREMENTS

8-006.01 Instruction: No individual is permitted to operate or maintain analytical x-ray equipment unless the individual has received four hours of instruction in and demonstrated competence as to:

1. Identification of radiation hazards associated with the use of the equipment;
2. Significance of the various radiation warning and safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
3. Proper operating procedures for the equipment;
4. Recognition of symptoms of an acute localized exposure;
5. Proper procedures for reporting an actual or suspected exposure; and
6. Radiation protection commensurate with the hazards of the device. ~~Have met the training requirements specified in 180 NAC 15-028.~~

8-006.02 Personnel Monitoring

1. Finger or wrist dosimetric devices must be provided to and must be used by:

   a. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
   b. Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

2. Reported dose values must not be used for the purpose of determining compliance with 180 NAC 4-005 unless evaluated by a qualified expert as specified in 180 NAC 15-013.03.

TITLE 180 CONTROL OF RADIATION

CHAPTER 10 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS

FORM(S)

Form NRH-3 Notice to Employees

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TITLE 180 CONTROL OF RADIATION

CHAPTER 10 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS

10-001 SCOPE AND AUTHORITY

10-001.01 180 NAC 10 establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders and licenses issued there under regarding radiological working conditions. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

10.001.02 The regulations in 180 NAC 10 apply to all persons who receive, possess, use, own or transfer sources of radiation licensed by or registered with the Department pursuant to 180 NAC 2, 3, 5, 6, 7, 8, 9, 11, 12, 14, 16,19, 20 and 21.

10-002 POSTING OF NOTICES TO WORKERS

10-002.01 Each licensee or registrant must post current copies of the following documents:

1. The regulations in 180 NAC 10 and 180 NAC 4;
2. The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
3. The operating procedures applicable to activities under the license or registration; and
4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 180 NAC 17 and any response from the licensee or registrant.

10-002.02 If posting of a document specified in 180 NAC 10-002.01, items 1., 2., or 3. is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

10-002.03 Department Form NRH-3, "Notice to Employees" must be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

10-002.04 Department documents posted pursuant to 180 NAC 10-002.01, item 4., must be posted within two working days after receipt of the documents from the Department; the licensee's or registrant's response, if any, must be posted within two working days after dispatch from the licensee or registrant. The documents must remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

10-002.05 Documents, notices or forms posted pursuant to 180 NAC 10-002 must appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, must be conspicuous, and must be replaced if defaced or altered.

10-003 INSTRUCTIONS TO WORKERS

10-003.01 All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) must be:

1. Kept informed of the storage, transfer, or use of radiation and/or radioactive material;
2. Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
3. Instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of Title 180 and licenses for the protection of personnel from exposures to radiation or radioactive material;
4. Instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to, constitute, or cause a violation of the Act, Title 180, and licenses or unnecessary exposure to radiation or radioactive material;
5. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
6. Advised as to the radiation exposure reports which workers must be furnished pursuant to 180 NAC 10-004.

10-003.02 In determining those individuals subject to the requirements of 180 NAC 10-003.01, licensees or registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensees or registrants facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place and must be performed annually.

10-003.03 Records of the instructions to workers required by 180 NAC 10-003 must be maintained by the licensee and/or registrant until reviewed by the Department.

10-004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS

10-004.01 Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual must be reported to the individual as specified in 180 NAC 10-004. The information reported must include data and results obtained pursuant to Title 180, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 180 NAC 4-052. Each notification and report must:

1. Be in writing;
2. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number; ~~preferably social number;~~
3. Include the individual's exposure information; and
4. Contain the following statement:

"This report is furnished to you under the provisions of 180 NAC 10. You should preserve this report for further reference."

10-004.02 Each licensee or registrant must furnish each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to 180 NAC 4-052.

10-004.03 Each licensee or registrant must make dose information available to workers as shown in records maintained by the licensee or registrant under 180 NAC 4-052. The licensee or registrant must provide an annual report to each individual monitored under 180 NAC 4-022 of the dose received in that monitoring year if:

(1) The individual's occupational dose exceed 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or issue; or

(2) The individual requests his/her annual dose report.

The report must be furnished within 30 days from the date of request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report must cover the period of time that the worker's activities involved exposure to sources of radiation and must include the dates and locations of work under the license or registration in which the worker participated during this period.

10-004.04 Each licensee or registrant must furnish to each worker a report of the worker's results of any measurements, analyses and calculations of radioactive material deposited or retained in the body. The report must be furnished to the worker within 30 days of such determination by the licensee or registrant.

10-004.05 When a licensee or registrant is required pursuant to 180 NAC 4-058, 4-059, or 4-060 to report to the Department any exposure of an individual to sources of radiation, the licensee or the registrant must also provide the individual a written report on the exposure data included in the report to the Department. These reports must be transmitted at a time not later than the transmittal to the Department.

10-004.06 At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant must provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

10-005 PRESENCE OF REPRESENTATIVES OF LICENSEES OR REGISTRANTS AND WORKERS DURING INSPECTION

10-005.01 Each licensee or registrant must afford to the Department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to Title 180.

10-005.02 During an inspection, Department inspectors may consult privately with workers as specified in 180 NAC 10-006. The licensee or registrant may accompany Department inspectors during other phases of an inspection.

10-005.03 If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the licensee or registrant must notify the inspectors of the authorization and must give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

10-005.04 Each workers' representative must be routinely engaged in work under control of the licensee or registrant and must have received instructions as specified in 180 NAC 10-003.

10-005.05 Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

10-005.06 With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, must be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

10-005.07 Notwithstanding the other provisions of 180 NAC 10-005, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area must be an individual previously authorized by the licensee or registrant to enter that area.

10-006 CONSULTATION WITH WORKERS DURING INSPECTIONS

10-006.01 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Title 180 and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

10-006.02 During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which

the worker has reason to believe may have contributed to or caused any violation of the Act, Title 180, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing must comply with the requirements of 180 NAC 10-007.01.

10-006.03 The provisions of 180 NAC 10-006.02 must not be interpreted as authorization to disregard instructions pursuant to 180 NAC 10-003.

10-007 REQUESTS BY WORKERS FOR INSPECTIONS

10-007.01 Any worker or representative of workers who believes that a violation of the Act, Title 180 or license conditions exists or has occurred in work under a license or registration to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. Any such notice must be in writing, must set forth the specific grounds for the notice, and must be signed by the worker or representative of the workers. A copy will be provided to the licensee or registrant by the Department no later than at the time of inspection except that, upon the request of the worker giving the notice, his/her name and the name of individuals referred to therein must not appear in the copy or on any record published, released, or made available by the Department, except for good cause shown.

10-007.02 If, upon receipt of the notice, the Department determines that the complaint meets the requirements set forth in 180 NAC 10-007.01, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, s/he must cause an inspection to be made as soon as practicable, to determine if the alleged violation exists or has occurred. Inspections pursuant to 180 NAC 10-007 need not be limited to matters referred to in the complaint.

10-007.03 A licensee, registrant, or contractor or subcontractor of a licensee or registrant must not discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under Title 180 or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself/herself or others of any option afforded by 180 NAC 10.

10-008 INSPECTIONS NOT WARRANTED; INFORMAL REVIEW

10-008.01 Review of determination that no inspection is warranted.

1. If the Department determines, with respect to a complaint under 180 NAC 10-007, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department will notify the complainant in writing of such determination. The complainant may obtain review of the determination by submitting a written statement of position to the Director of the Division of Public Health, who will provide the licensee or registrant with a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or

registrant may submit an opposing written statement of position to the Director of the Division of Public Health, will provide the complainant with a copy of the statement by certified mail.

2. Upon the request of the complainant, the Director of the Division of Public Health, may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Director of the Division of Public Health, will affirm, modify, or reverse the determination of the Department and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

10-008.02 If the Department determines that an inspection is not warranted because the requirements of 180 NAC 10-007.01 have not been met, the Director of the Division of Public Health will notify the complainant in writing of the determination. Such determination must be without prejudice to the filing of a new complaint meeting the requirements of 180 NAC 10-007.01.

Nebraska Department of Health and Human Services
Division of Public Health - Radiological Health, P.O. Box 95026
301 Centennial Mall South
Lincoln, Nebraska 68509-5026

NOTICE TO EMPLOYEES

Standards for Protection Against Radiation; Notices,
Instructions and Reports to Workers; Inspections

In Title 180,Regulations for Control of Radiation, the Nebraska Department of Health and Human Services has established standards for your protection against radiation hazards and has established certain provisions for the options of workers engaged in work under an Department license or registration.

YOUR EMPLOYER'S RESPONSIBILITY:

Your Employer is Required to:

1. Apply these regulations to work involving sources of radiation.

2. Post or otherwise make available to you a copy of Title 180, Regulations for Control of Radiation, and the operating procedures which apply to work you are engaged in, and explain their provisions to you.

3. Post any Notice of Violation involving radiological working conditions, proposed imposition of civil penalties or orders.

YOUR RESPONSIBILITY AS A WORKER:

You should familiarize yourself with those provisions of Title 180, Regulations for Control of Radiation and operating procedures which apply to the work in which you are engaged. You should observe their provisions for your own protection and protection of your co-worker.

WHAT IS COVERED BY THESE REGULATIONS:

1. Limits on exposure to radiation and radioactive material in restricted and unrestricted areas;

2. Measures to be taken after accidental exposure;

3. Personnel monitoring, surveys and equipment;

4. Caution signs, labels, and safety interlock equipment;

5. Exposure records and reports; and

6. Options for workers regarding Department Inspections; and

7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY:

1. The Title 180, Regulations for Control of Radiation require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in any license. The basic limits for exposure to employees are set forth in 180 NAC 4-005, 4-011 and 4-012. These sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air.

2. If you work where personnel monitoring is required:

   (a) Upon your request, your employer must give you a written report of your radiation exposures upon termination of your employment; and
   (b) Your employer must advise you annually of your exposure to radiation.

INSPECTIONS:

All licensed or registered activities are subject to inspection by representatives of the Department of Health and Human Services, Division of Public Health, Radiological Health. In addition, any worker or representative of workers who believes that there is a violation of the Nebraska Radiation Control Act, the regulations issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of Health and Human Services, Division of Public Health, Radiological Health, P.O. Box 95026, 301 Centennial Mall South, Lincoln, Nebraska 68509-5026 . The request must set forth the specific grounds for the notice, and must be signed by the worker as representative of the workers. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which s/he believes contributed to or caused any violation as described above.

POSTING REQUIREMENTS

Copies of this notice must be posted in a sufficient number of places in every establishment where employees are employed in activities licensed or registered, pursuant to 180 NAC 2 and 180 NAC 3 by the Department of Health and Human Services, to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

TITLE 180 CONTROL OF RADIATION
CHAPTER 13 TRANSPORTATION OF RADIOACTIVE MATERIAL

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 13 TRANSPORTATION OF RADIOACTIVE MATERIAL

13-001 SCOPE AND AUTHORITY:

13-001.01 The regulations in this Chapter establish requirements for packaging, preparation for shipment, and transportation of radioactive material. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

13-001.02 10 CFR as published on January 1, 2006 and 49 CFR as published October 1, 2006 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Department of Health and Human Services, Public Health Division, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509-5026.

13-001.03 The regulations in 180 NAC 13 apply to any licensee authorized by specific or general license issued by this Department to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transport the material outside the site of usage as specified in the Department's license, or transport that material on public highways. No provision of 180 NAC 13 authorizes possession of licensed material.

13-002 DEFINITIONS: As used in 180 NAC 13, the following definitions apply:

~~Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.~~

Certificate holder means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.

Certificate of Compliance (CoC) means the certificate issued by the U.S. Nuclear Regulatory Commission under 10 CFR 71 Subpart D which approves the design of a package for the transportation of radioactive material.

Close reflection by water means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

Consignment means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

Containment system means the assembly of components of packaging intended to retain the radioactive material during transport.

Conveyance means:

(1) For transport by public highway or rail any transport vehicle or large freight container;

(2) For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(3) For transport by aircraft any aircraft.

Criticality Safety Index (CSI) means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in 180 NAC 13-011 and 13-012, and 10 CFR 71.59.

Deuterium means, for the purposes of 180 NAC 13-004.04 and 13-011, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

DOT means the U.S. Department of Transportation.

Exclusive use means the sole use of a conveyance by a single consignor for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls and include them with the shipping paper information provided to the carrier by the consignor.

Fissile material means plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition.[1] Certain exclusions from fissile material control are provided in 180 NAC 13-004.04.

Graphite means, for the purposes of 180 NAC 13-004.04 and 13-011, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

[1]Department jurisdiction extends only to "special nuclear material in quantities not sufficient to form a critical mass" as defined in 180 NAC 1-002.

Low specific activity (LSA) Material means radioactive material with limited specific activity which is nonfissile or is excepted under 180 NAC 13-004.04, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(1) LSA-I:

(a) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radonuclides;

(b) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

(c) Radioactive material for which the A_2 value is unlimited; or

(d) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with Appendix 13-A.

(2) LSA-II:

(a) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(b) Other material in which the activity is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(3) LSA-III solids (e g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77 in which:

(a) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

(b) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package leaching, when placed in water for 7 days, would not exceed 0.1 A_2; and

(c) The estimated average specific activity of the solid does not exceed 2 E-3 A_2/g.

Low toxicity alpha emitters means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

Natural thorium means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

Normal form radioactive material means radioactive material which has not been demonstrated to qualify as "special form radioactive material" as defined 180 NAC 1-002.

Optimum interspersed hydrogenous moderation means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

Package means the packaging together with its radioactive contents as presented for transport.

(1) Fissile material package or Type AF package, Type BF package, Type B(U)F package or Type B(M)F package means a fissile material packaging together with its fissile material contents.

(2) Type A package means a Type A packaging together with its radioactive contents. A type A package is defined and must comply with the DOT regulations in 49 CFR part 173.

(3) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by U. S. Nuclear Regulatory Commission (NRC) as B(U) unless the package has a maximum normal operating pressure or more than 700 kPa (100 lb/in^2) gauge or pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR Part 71.73 (hypothetical accident conditions), in which it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see U. S. Department of Transportation (DOT) regulations, 49 CFR Part 173. A Type B package approved before September 6,1983, was designated only as Type B. Limitations on its use are specified 10 CFR 71.19.

Packaging means the assembly of components necessary to ensure compliance with the packaging requirements of 180 NAC 13. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie down system, and auxiliary equipment may be designated as part of the packaging.

Specific activity of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

Surface contaminated object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(1) SCO-1: A solid object on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 Bq/cm^2 (10^{-4} $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} $\mu Ci/cm^2$) for all other alpha emitters.

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4E+4 Bq/cm^2 (1.0 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 4E+3 Bq/cm^2 (0.1 $\mu Ci/cm^2$) for all other alpha emitters; and

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4E+4 Bq/cm^2 (1.0 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 4E+3 Bq/cm^2 (0.1 $\mu Ci/cm^2$) for all other alpha emitters.

(2) SCO-II: A solid object on which the limits for SCO-1 are exceeded and on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} $\mu Ci/cm^2$) or beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} $\mu Ci/cm^2$) for all other alpha emitters;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8E+5 Bq/cm^2 (20 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 8E+4 Bq/cm^2 (2 $\mu Ci/cm^2$) for all other alpha emitters;

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8E+5 Bq/cm^2 (20 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 8E+4 Bq/cm^2 (2 $\mu Ci/cm^2$) for all other alpha emitters.

Transport index means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1 meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter (3.3 ft)).

Type A quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or $A_{2,}$ for normal form radioactive material, where A_1 and A_2 are given in Appendix 13-A, Table A-1 , or may be determined by procedures described in Appendix 13-A.

Type B quantity means a quantity of radioactive material greater than a Type A quantity.

Unirradiated uranium means uranium containing not more than 2×10^3 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium- 235.

Uranium - natural, depleted, enriched

(1) Natural uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) Enriched Uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

GENERAL: REGULATORY PROVISIONS

13-003 REQUIREMENT FOR LICENSE: Except as authorized in a general or specific license issued by the Department, or as exempted in 180 NAC 13-004, no licensee may:

1. Deliver radioactive material to a carrier for transport; or
2. Transport radioactive material.

13-004 EXEMPTIONS

13-004.01 Common and contract carriers, freight forwarders, and warehouse workers which are subject to the requirements of the DOT in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), incorporated by reference, at 39 CFR 111.1 (1997) and attached hereto as Attachment 13-1, are exempt from the requirements of this section to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the DOT or U.S. Postal Service are subject to 180 NAC 13-003 and other applicable requirements of these regulations.

13-004.02 Exemption of physicians: Any physician licensed by the State of Nebraska to dispense drugs in the practice of medicine is exempt from 180 NAC 13-003 with respect to transport by the physician of radioactive material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under 180 NAC 7 or equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations.

13-004.03 Exemption for low-level materials: Any licensee is exempt from the requirements of 180 NAC 13 with respect to shipment or carriage of the following low-level materials:

1. Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the

activity concentration of the material does not exceed 10 times the values specified in Appendix 13-A, Table A-2.

2. Materials for which the activity concentration is not greater than the activity concentration values specified in Appendix 13-A, Table A-2, or for which the consignment activity is not greater than the limit for an exempt consignment found in Appendix 13-A, Table A-2.

13-004.04 Exemption from classification as fissile material: Fissile material meeting the requirements of at least one of the items of 180 NAC 13-004.04, item 1 through 6 are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of 180 NAC 13, except as noted.

1. Individual package containing 2 grams or less fissile material.

2. Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

3. Packages containing:

   a. Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

      (1) There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and
      (2) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

   b. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

4. Uranium enriched in uranium-235 to a maximum of 1% by weight, and with total plutonium and uranium-233 content of up to 1% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5% of the uranium mass.

5. Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2% by mass, with a total plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

6. Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20% by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

13-005 TRANSPORTATION OF LICENSED MATERIAL

13-005.01 Each licensee who transports licensed material outside of the site of usage, as specified in the Department license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, must comply with the applicable requirements of the DOT regulation in 49 CFR part 107, 171 through 180 and 390 through 397 appropriate to mode of transport.

1. The licensee must comply with the applicable DOT regulations in the following areas:

   a. Packaging - 49 CFR Part 173: Subparts A and B and I.
   b. Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.441, of Subpart E.
   c. Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.
   d. Accident Reporting - 49 CFR Part 171: §§ 171.15 and 171.16.
   e. Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.
   f. Hazardous material employee training - 49 CFR Part 172: Subpart H.
   g. Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.
   h. Security plans—49 CFR Part 172; Subpart I.

2. The licensee must also comply with applicable DOT regulations pertaining to the following modes of transportation:

   a. Rail - 49 CFR Part 174: Subparts A through D and K.
   b. Air - 49 CFR Part 175.
   c. Vessel - 49 CFR Part 176: Subparts A through F and M.
   d. Public Highway - 49 CFR Part 177 and Parts 390 through 397.

3. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 180 NAC 4-038.

13-005.02 If, for any reason, the regulations of the DOT are not applicable to a shipment of licensed material, the licensee must conform to the standards and requirements of 49 CFR Parts 107, 171 through 180 and 390 through 397 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements must be filed with, or made to, the Department.

GENERAL LICENSES

13-006 GENERAL LICENSES FOR CARRIERS

13-006.01 A general license is hereby issued to any common or contract carrier not exempt under 180 NAC 13-004 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting[2].

13-006.02 A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

13-006.03 Persons who transport radioactive material pursuant to the general licenses in 180 NAC 13-006.01 or 13-006.02 are exempt from the requirements of 180 NAC 4 and 10 to the extent that they transport radioactive material.

13-007 GENERAL LICENSE: U.S. NUCLEAR REGULATORY COMMISSION NRC APPROVED PACKAGES

13-007.01 A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the NRC.

13-007.02 This general license applies only to a licensee who:

1. Has a copy of the specific license, certificate of compliance, or other approval by the NRC of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;
2. Complies with the terms and conditions of the license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of 180 NAC 13;
3. Prior to the licensee's first use of the package, has registered with the NRC; and
4. Has a quality assurance program required by 180 NAC 13-021.

13-007.03 The general license in 180 NAC 13-007.01 applies only when the package approval authorizes use of the package under this general license.

13-007.04 For a Type B or fissile material package, the design of which was approved before April 1, 1996 the general license is subject to the additional restrictions of 10 CFR 71.19.

[2]Notification of incidents must be filed with, or made to, the Department as prescribed in 49 CFR, regardless of and in addition to notification made to DOT or other agencies.

13-008 RESERVED

13-009 RESERVED

13-010 GENERAL LICENSE: USE OF FOREIGN APPROVED PACKAGE

13-010.01 A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.12.

13-010.02 Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the U.S. Nuclear Regulatory Commission as satisfying the applicable provisions of 10 CFR 71, subpart H.

13-010.03 This general license applies only to international shipments.

13-010.04 This general license applies only to a licensee who:

1. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and
2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of 180 NAC 13. With respect to the quality assurance provision of 180 NAC 7-021, the licensee is exempt from design, construction, and fabrication considerations.

13-011 GENERAL LICENSE: FISSILE MATERIAL

13-011.01 A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with 180 NAC 13-011. The fissile material need not be contained in a package which meets the standards of 10 CFR 71 subparts E and F; however the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

13-011.02 The general license applies only to a licensee who has a quality assurance program approved by the Department.

13-011.03 The general license applies only when a package's contents:

1. Contains less than a Type A quantity of fissile material; and
2. Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

13-011.04 The general license applies only to packages containing fissile material that are labeled with a CSI which:

1. Has been determined in accordance with 180 NAC 13-011.05;
2. Has a value less than or equal to 10; and
3. For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

13-011.05 CSI determination:

1. The value for the CSI must be greater than or equal to the number calculated by the following equation:
   The calculated CSI must be rounded up to the first decimal place;

$$CSI = 10\left[\frac{\text{grams of } ^{235}U}{X} + \frac{\text{grams of } ^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right];$$

2. The values of X, Y, and Z used in the CSI equation must be taken from Table 13 -1 or Table 13-2, as appropriate;
3. If Table 13-2 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and
4. Table 13-1 values for X, Y., and Z must be used to determine the CSI if:

   a. Uranium-233 is present in the package;
   b. The mass of the plutonium exceeds 1% of the mass of uranium-235;
   c. The uranium is unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or
   d. Substances having a moderating effectiveness (that is, an average hydrogen density greater that H_2O (for example, certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

TABLE 13-1
Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per 180 NAC 13-011.05

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density

		greater than H_2O[a] (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

[a] When mixtures of moderating substances are present, the lower mass limits must be used if more than 15% of the moderating substance has an average hydrogen density greater than H_2O.

TABLE 13-2 - Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per 180 NAC 13-011

Uranium enrichment in weight percent of uranium-235 not exceeding	Fissile material mass of uranium-235 U(X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180

2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

13-012 GENERAL LICENSE: PLUTONIUM-BERYLLIUM SPECIAL FORM MATERIAL

13-012.01 A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this subsection. This material need not be contained in package which meets the standards of 10 CFR 71 subpart E and F; however the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 40 CFR 173.417(a).

13-012.02 This general license applies only when all of the following requirements are met:

1. The package contains no more than a Type A quantity of radioactive material; and
2. Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

13-012.03 The general license applies only to a licensee who has a quality assurance program approved by the Department.

13-012.04 The general license applies only to packages labeled with a CSI which:

1. Has been determined per 180 NAC 13-012.05;
2. Has a value less than or equal to 100; and
3. For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

13-012.05 CSI determination:

1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$\text{CSI} = 10 \left[\frac{\text{grams of } ^{239}\text{Pu} + \text{grams of } ^{241}\text{Pu}}{24} \right] \text{; and}$$

2. The calculated CSI must be rounded up to the first decimal place.

OPERATING CONTROLS AND PROCEDURES

13-013 ASSUMPTIONS AS TO UNKNOWN PROPERTIES

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee must package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

13-014 PRELIMINARY DETERMINATIONS: Prior to the first use of any packaging for the shipment of licensed material:

13-014.01 The licensee must ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects which could significantly reduce the effectiveness of the packaging;

13-014.02 Where the maximum normal operating pressure will exceed 35 kilopascal (5 lbf/in^2) gauge, the licensee must test the containment system at an internal pressure at least 50% higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

13-014.03 The licensee must determine that the packaging has been fabricated in accordance with the design approved by the NRC; and

13-014.04 The licensee must conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the NRC.

13-015 ROUTINE DETERMINATIONS: Prior to each shipment of licensed material, the licensee must ensure that the package with its contents satisfies the applicable requirements of 180 NAC 13-015 and of the licensee. The licensee must determine that:

13-015.01 The package is proper for the contents to be shipped;

13-015.02 The package is in unimpaired physical condition except for superficial defects such as marks or dents;

13-015.03 Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

13-015.04 Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

13-015.05 Any pressure relief device is operable and set in accordance with written procedures;

13-015.06 The package has been loaded and closed in accordance with written procedures;

13-015.07 For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

13-015.08 Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

13-015.09 The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in 180 NAC 13-015.0~~8~~9, item (1), the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in TABLE 13-3 of 180 NAC 13-015 at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in TABLE 13-3.

1. In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in 180 NAC 13-015.0 ~~8~~9. The levels at the beginning of transport must not exceed the levels in 180 NAC 13-015.0 ~~8~~9;

13-015.10 External radiation levels around the package and around the vehicle, if applicable, will not exceed 2 mSv/h (200 mrem/hr) at any point on the external surface of the package at any time during transportation. The transport index must not exceed 10.

13-015.11 For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in 180 NAC 13-015.09 but must not exceed any of the following:

1. 2 mSv/h (200 mrem/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/hr);

    a. The shipment is made in a closed transport vehicle,
    b. Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and
    c. There are no loading or unloading operations between the beginning and end of the transportation.

2. 2 mSv/h (200 mrem/hr) at any point on the outer surface of the vehicle, including the upper and top and underside of the vehicle, or, in the case of a flat-bed style vehicle, with a personnel barrier*, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load [or enclosure, if used], and on the lower external surface of the vehicle[3] ;

3. 0.1 mSv/h (10 mrem/hr) at any point 2 meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and

4. 0.02 mSv/h (2 mrem/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with 180 NAC 10-003; and

13-015.12 For shipments made under the provisions of 180 NAC 13-015.11, the shipper must provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

13-015.13 The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increase radiation levels or radiation exposures to transport workers or member of the general public.

13-015.14 A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 185 degrees Fahrenheit (85 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures must not exceed these limits at any time during transportation.

13-015.15 A package may not incorporate a feature intended to allow continuous venting during transport.

TABLE 13-3
Removable External Radioactive Contamination Wipe Limits

Contaminant	Maximum Permissible Limits		
	Bq/cm^2	$\mu Ci/cm^2$	dpm/cm^2

[3]A flat-bed style vehicle with a personnel barrier must have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 2 mSv/h (200 mrem/hr) at the surface.*

Beta and gamma emitteers and low toxicity alpha emitters	0.41	1.0 E-5	22
All other alpha emitting radionuclides	0.04	1.0 E-6	2.2

13-016 AIR TRANSPORT OF PLUTONIUM

13-016.01 Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Section or included indirectly by citation of the DOT regulations, as may be applicable, the licensee must assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

1. The plutonium is contained in a medical device designed for individual human application; or

2. The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Appendix 13-A, Table A-2, in which the radioactivity is essentially uniformly distributed; or

3. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 180 NAC 13-005; or

4. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.

13-016.02 Nothing in 180 NAC 13-016.01 is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

13-016.03 For a shipment of plutonium by air which is subject to 180 NAC 13-016.01, item 4, the licensee must, through special arrangement with the carrier, require compliance with 49 CFR 175.704, the DOT regulations applicable to the air transport of plutonium.

13-017 OPENING INSTRUCTIONS: Before delivery of a package to a carrier for transport, the licensee must ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 180 NAC 4-038.

13-018 SHIPMENT RECORDS: Each licensee must maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under 180 NAC 13-004, showing, where applicable:

1. Identification of the packaging by model number and serial number;
2. Verification that the packaging, as shipped, has no significant defects;
3. Volume and identification of coolant;

4. Type and quantity of licensed material in each package, and the total quantity of each shipment;
5. Date of the shipment;
6. Name and address of the transferee;
7. Address to which the shipment was made; and
8. Results of the determinations required by 180 NAC 13-015 and by the conditions of the package approval.

13-019 REPORTS The licensee must report to the Department within 30 days:

1. Any instance in which there is significant reduction in the effectiveness of any packaging during use;
2. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence; or
3. Instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

13-020 ADVANCE NOTIFICATION OF TRANSPORT OF NUCLEAR WASTE

13-020.01 As specified in 180 NAC 13-020.02, 13-20.03 and 13-020.04:

1. Each licensee must provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across `the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.
2. After the effective date of these regulations, each licensee must provide advance notification to the Tribal official of participating Tribes referenced in 180 NAC 13-020.03, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

~~Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee must provide advance notification of such transport to the governor, or governor's designee, of each state within or through which the waste will be transported.[4]~~

13-020.02 Advance notification is also required in 180 NAC 13 for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

1. The nuclear waste is required to be in Type B packaging for transportation;

~~[4]A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, NRC, Washington, D.C. 20555. The list will be published annually in the Federal register on or about June 30 to reflect any changes in information.~~

2. The nuclear waste is being transported into, within, or through, a state enroute to a disposal facility or to a collection point for transport to a disposal facility; and
3. The quantity of licensed material in a single package exceeds:

   a. 3000 times the A_1 value of the radionuclides as specified in Appendix 13-A, Table I for special form radioactive material;
   b. 3000 times the A_2 value of the radionuclides as specified in Appendix 13-A, Table I for normal form radioactive material; or
   c. 1000 TBq (27,000 Ci).

13-020.03 Each advance notification required by 180 NAC 13-020.01 must contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;
2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);
3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;
4. The seven-day period during which arrival of the shipment at state boundaries or Tribal reservation boundaries is estimated to occur;
5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and
6. A point of contact with a telephone number for current shipment information.

13-020.04 Procedures for submitting advance notification:

1. The notification required by 180 NAC 13-020.01 must be made in writing to:

   a. The office of each appropriate governor, or governor's designee;
   b. The office of each appropriate Tribal official or Tribal official's designee and
   c. To the U.S. Nuclear Regulatory Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response.

2. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

3. A notification delivered by any other means than mail must reach the office of the governor, or governor's designee, or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. ~~A copy of the notification must be retained by the licensee for three years.~~

   a. A list of names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the *Federal Register* on June 30, 1995 (60 FR 34306).

b. The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the *Federal Register* on or about June 30th to reflect any changes in information.

c. A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

d. The licensee must retain a copy of the notification as a record for 3 years.

13-020.05 Revision Notice: A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with 180 NAC 13-020, will not be met, must telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. ~~The licensee must notify each appropriate governor, or governor's designee, and the Department of any changes to schedule information provided pursuant to 180 NAC 13-020.01. Such notification must be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states.~~The licensee must maintain for ~~one~~three years a record of the name of the individual contacted.

13-020.06 Cancellation Notice

1. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent must send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and the Director, Division of Security Policy, Office of Nuclear Security and Incident Response. ~~Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, must send a cancellation notice, identifying the advance notification that is being canceled, to the governor, or governor's designee, of each appropriate state and to the Department.~~ A copy of the notice must be retained by the licensee for three years
2. The licensee must state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee must retain a copy of the notice as a record for three years.

QUALITY ASSURANCE

13-021 QUALITY ASSURANCE REQUIREMENTS

13-021.01 Unless otherwise authorized by the Department, each licensee, certificate holder and applicant for a CoC must establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

13-021.02 The licensee, certificate holder and applicant for a CoC must identify the material and components to be covered by the quality assurance program.

13-021.03 Each licensee, certificate holder and applicant for a CoC must document the quality assurance program by written procedures or instructions and must carry out the program in accordance with those procedures throughout the period during which packaging is used.

13-021.04 Prior to the use of any package for the shipment of radioactive material, each licensee, certificate holder and applicant for a CoC must obtain approval by the Department of its quality assurance program.

13-021.05 The licensee, certificate holder and applicant for a CoC must maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material must be maintained for a period of three years after shipment.

13-021.06 The licensee, certificate holder and applicant for a CoC must maintain a program for transport container inspection and maintenance limited to radiographic exposure devices, source changer, or packages transporting these devices and meeting the requirements of 180 NAC 5-011 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements.

13-021.07 Handling, storage, and shipping control: The licensee, certificate holder, and applicant for a CoC must establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

13-021.08 Inspection, test, and operating status:

1. The licensee, certificate holder, and applicant for a CoC must establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.
2. The licensee must establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

13-021.09 Nonconforming materials, parts, or components: The licensee, certificate holder, and applicant for a CoC must establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for

identification, documentation, segregation, disposition, and notification to affected organization. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

13-021.10 Corrective Actions: The licensee, certificate holder, and applicant for a CoC must establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are prompt identified and corrected. In the case of significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

13-021.11 Quality assurance records: The licensee, certificate holder, and applicant for a CoC must maintain sufficient written records to describe the activities affecting quality. The records must include the instruction, procedures, and drawings to prescribe quality assurance activities and must include closely related specifications such as required qualification of personnel, procedures, and equipment. The records must include the instructions or procedures, which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC must retain these records for three years beyond the date which the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instruction is superseded, the licensee, certificate holder, and applicant for a CoC must retain the superseded material for three years after it is superseded.

13-021.12 Audits: The licensee, certificate holder, and applicant for a CoC must carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

13-021.13 The licensee, certificate holder, and applicant for a CoC ~~mstl~~must base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

1. The impact of malfunction or failure of the item to safety;
2. The design and fabrication complexity or uniqueness of the item;
3. The need for special controls and surveillance over processes and equipment;
4. The degree to which functional compliance can be demonstrated by inspection or test; and
5. The quality history and degree of standardization of the item

13-021.14 The licensee, certificate holder, and applicant for a CoC must provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC must review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program must review regularly the status and adequacy of that part of the quality assurance program they are executing.

DETERMINATION OF A_1 AND A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II.
a. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A_1 and A_2 values contained in Table A-3 may be used. Otherwise the licensee must obtain prior Department approval of the A_1 and A_2 values for radionuclides not listed in Table A-1, before shipping the material.
b. For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee must obtain prior Department approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.
c. The licensee must submit requests for prior approval, described under paragraphs II.a. and II.b. of this Appendix, to the Department, in accordance with 180 NAC 1-012.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter radionuclide has a half-life either longer than 10 days, or longer than that of the parent radionuclide, must be considered as a single radionuclide, and the activity to be taken into account, and the A_1 and A_2 value to be applied must be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides must be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i, and $A_1(i)$ is the A_1 value for radionuclide I.

b. For normal form radioactive material, the maximum quantity transported in a Type A package is a follows:

$$\sum B(i)/A_{(2)}i \leq 1$$

where B(i) is the activity of radionuclide i, and A_2(i) is the A_2 value for radionuclide i.

c. Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_{1 \text{ for mixture}} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide I in the mixture, and A_2(i) is the appropriate A_1 value for radionuclide I.

d. Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

$$A_{2 \text{ for mixture}} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and A_2(i) is the appropriate A_2 value for radionuclide I.

e. The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

Where f(i) is the fraction of activity concentration of radionuclide I in the mixture, and [A] is the activity concentration for exempt material containing radionuclide I.

f. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limits for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and A is the activity limit for exempt consignments for radionuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195	Gold (79)	$1.0X10^{1}$	$2.7X10^{2}$	6.0	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Ba-133		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	9.4	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	8.1	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{-3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	1.9	$5.2X10^{1}$
Bi-210		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$
Bk-247	Berkelium (97)	8.0	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	8.1	$6.1X10^{1}$	$1.6X10^{3}$
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6
Cf-252 (h)		$5.0X10^{-2}$	1.35	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	4.0	$1.1X10^{2}$	4.0	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	3.2	$8.7X10^{1}$
Cu-64	Copper (29)	6.0	$1.6X10^{2}$	1.0	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	8.1	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short lived)		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long lived)		7×10^{-1}	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192 (c)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-81	Krypton (36)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		8.0	$2.2X10^{2}$	8.0	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		9.0	$2.4X10^{2}$	9.0	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	1.1
Mo-99 (a) (i)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{7}$	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	8.8	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	6.0	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0x10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^{1}$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	5.4	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	5.2	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	1.4	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-1}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
U-230 (medium lung absorption) (a)(e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0x10^{1}$	$1.1X10^{3}$	$2.0x10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0x10^{1}$	$1.1X10^{3}$	$6.0x10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less)(g)		Unlimited	Unlimited	Unlimited	Unlimited	§ 173.434	§ 173.434
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	§ 173.434	§ 173.434
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$

APPENDIX 13-A, TABLE A-1 - A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (79)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$
Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

NOTES:

(a) A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days.

(b) The values of A_1 and/or A_2 in Curies (Ci) are approximate and for infomraiton only; the regulatory standard units are Terabecque (TBq), (see Appendix 13-A – Determination of A_1 and/or A_2, Section 1)

(c) The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

(d) These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

(e) These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

(f) These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

(g) These values apply to unirradiated uranium only.

(h) A_1 = 0.1 TBq (2.7 Ci) and A_2 = 0.001 TBq (0.027 Ci) for Cf-252 for domestic use.

(i) A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225 (a)	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227 (a)		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211 (a)	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-131 (a)	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253 (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247 (a)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152 m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52 (a)	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60 (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Gd-146 (a)	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68 (a)	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172 (a)	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194 (a)	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135 (a)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189 (a)	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-81	Krypton (36)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28 (a)	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99 (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230 (a)	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103 (a)	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m (a)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188 (a)	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103 (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113 (a)	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m (a)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126 (a)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82 (a)	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m (a)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m (a)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m (a)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132 (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b),(d)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-7}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-6}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less)(g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX 13-A, TABLE A-2 - EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Yb-169	Ytterbium (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

NOTES:

(a) [Reserved]

(b) Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207

Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

(c) [Reserved]

(d) These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

(e) These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

(f) These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

(g) These values apply to unirradiated uranium only.

TABLE -A-3: GENERAL VALUES FOR A_1 AND A_2

CONTENTS	A_1		A_2		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	TBq	Ci	TBq	Ci				
Only beta- or gamma-emitting nuclides are known to be present	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{-1}	2.7×10^{-10}	1×10^{-4}	2.7×10^{-7}
Only alpha-emitting nuclides are known to be present.	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
No relevant data are available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

TABLE A-4: ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment*-weight % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8 E-8	5.0 E-7
0.72	2.6 E-8	7.1 E-7
1.0	2.8 E-8	7.6 E-7
1.5	3.7 E-8	1.0 E-6
5.0	1.0 E-7	2.7 E-6
10.0	1.8 E-7	4.8 E-6
20.0	3.7 E-7	1.0 E-5
35.0	7.4 E-7	2.0 E-5
50.0	9.3 E-7	2.5 E-5
90.0	2.2 E-6	5.8 E-5
93.0	2.6 E-6	7.0 E-5
95.0	3.4 E-6	9.1 E-5

* The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

ATTACHMENT 13-1

39 CFR Part 111, §111.1

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[Code of Federal Regulations]
[Title 39, Volume 1]
[Revised as of January 1, 2008]
From the U.S. Government Printing Office via GPO Access
[CITE: 39CFR111.1]

[Page 25]

TITLE 39--POSTAL SERVICE

CHAPTER I--UNITED STATES POSTAL SERVICE

PART 111_GENERAL INFORMATION ON POSTAL SERVICE--Table of Contents

Sec. 111.1 Mailing Standards of the United States Postal Service, Domestic Mail Manual; incorporated by reference of regulations governing domestic mail services.

Sec.

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001-3011, 3201-3219, 3403-3406, 3621, 3626, 3632, 3633, and 5001.

Source: 44 FR 39852, July 6, 1979, unless otherwise noted.

Section 552(a) of title 5, U.S.C., relating to the public information requirements of the Administrative Procedure Act, provides in pertinent part that ``* * * matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.'' In conformity with that provision, and with 39 U.S.C. section 410(b)(1), and as provided in this part, the U.S. Postal Service hereby incorporates by reference in this part, the Mailing Standards of the United States Postal Service, Domestic Mail Manual, a loose-leaf document published and maintained by the Postal Service.

[62 FR 14827, Mar. 28, 1997, as amended at 69 FR 59139, Oct. 4, 2004; 70 FR 14535, Mar. 23, 2005]

TITLE 180 CONTROL OF RADIATION

CHAPTER 14 RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING AND SUBSURFACE TRACER STUDIES

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at: http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 14 RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING AND SUBSURFACE TRACER STUDIES:

14-001 SCOPE AND AUTHORITY

14-001.01 180 NAC 14 establishes radiation safety requirements for persons using sources of radiation in these operations. 180 NAC 14 applies to all licensees who use radioactive material including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

14-001.02 The provisions and requirements of 180 NAC 14 are in addition to, and not in substitution for, other requirements of these regulations. In particular, the provisions of 180 NAC 1, 2, 3, 4, 10, 13, 15 17 and 18 apply to applicants and licensees subject to this Chapter.

14-001.03 40 CFR as published July 1, 2002 and referred throughout this Chapter is herein incorporated by reference and available for viewing at the Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

14-001.04 American National Standard Institute (ANSI) ANSI N43.6 and United States of America Standard Institute (USASI) USASI N 5.10-1968 as referred to in this Chapter are herein incorporated by reference and available for viewing at the Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

14-002 DEFINITIONS: As used in this Chapter, the following definitions apply:

Energy compensation source (ECS) means a small sealed source, with an activity not exceeding 3.7 MBq (100 microcuries), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

Field station means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

Fresh water aquifer means a geologic formation that is capable of yielding fresh water to a well or spring, except those aquifers exempted pursuant to 40 CFR 122.35.

Injection tool means a device used for controlled subsurface injection of radioactive tracer material.

Irretrievable well logging source means any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

Logging assistant means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 180 NAC 14-0~~19~~20.

Logging supervisor means an individual who uses radioactive material or provides personal supervision in the use of radioactive material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the regulations and the conditions of the license.

Logging tool means a device used subsurface to perform well logging.

Personal supervision means guidance and instruction by a logging supervisor, who is physically present at a temporary jobsite, who is in personal contact with logging assistants, and who can give immediate assistance.

Radioactive marker means radioactive material used for depth determination or direction orientation. This term includes radioactive collar markers and radioactive iron nails.

Safety review means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

Source holder means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.

Subsurface tracer study means the release of unsealed radioactive material or a substance labeled with radioactive material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

Surface casing for protecting fresh water aquifers means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

Temporary jobsite means a place where radioactive materials are present for the purpose of performing well logging or subsurface tracer studies.

Tritium neutron generator target source means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

Uranium sinker bar means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

Well means a drilled hole in which well logging may be performed. "Well" includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

Well logging means all operations involving the lowering and raising of measuring devices or tools which contain radioactive material or are used to detect radioactive materials in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

14-003 SPECIFIC LICENSES FOR WELL LOGGING

14-003.01 The Department will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements:

1. The applicant must satisfy the general requirements specified in 180 NAC 3-011 for radioactive material, in 180 NAC 3-015 for source material and any special requirements contained in 180 NAC 14.

2. The applicant must develop a program for training logging supervisors and logging assistants and submit to the Department a description of this program which specifies the:

    a. Initial training;
    b. On-the-job training;
    c. Annual safety reviews provided by the licensee;
    d. Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Department's regulations and licensing requirements and the applicant's operating and emergency procedures; and
    e. Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

3. The applicant must submit to the Department written operating and emergency procedures as described in 180 NAC 14-018 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

4. The applicant must establish and submit to the Department its program for annual inspections of the job performance of each logging supervisor to ensure that the Department's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for 3 years after each annual internal inspection.

5. The applicant must submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

6. If an applicant wants to perform leak testing of sealed sources, the applicant must identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant must establish procedures to be followed and submit a description of these procedures to the Department. The description must include the:

a. Instruments to be used;
b. Methods of performing the analysis; and
c. Pertinent experience of the person who will analyze the wipe samples.

14-00~~3~~4 AGREEMENT WITH WELL OWNER OR OPERATOR

14-00~~3~~4.01 A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements.

1. If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;
2. A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;
3. The radiation monitoring required in 180 NAC 14-021.01 will be performed;
4. If the environment, any equipment, or personnel are contaminated with radioactive material, they must be decontaminated before release from the site or release for unrestricted use; and
5. If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

   a. Each irretrievable well logging source must be immobilized and sealed in place with a cement plug.
   b. A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations and
   c. A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm (7 inches) square and 3 mm (1/8 inch) thick. The plaque must contain:

      (1) The word "Caution";
      (2) The radiation symbol (the color requirement in 180 NAC 4-033.01 need not be met);
      (3) The date the source was abandoned;
      (4) The name of the well owner or well operator as appropriate;
      (5) The well name and well identification number(s) or other designation;

(6) An identification of the sealed source(s) by radionuclide and quantity;
(7) The depth of the source and depth to the top of the plug; and
(8) An appropriate warning such as "DO NOT RE-ENTER THIS WELL".

d. If a radioactive source is classified as irretrievably lost in any well or test hole, the licensee must, within 15 days, file with the Register of Deeds of the County in which the well or test hole is located, a map of the location, including the legal description where the source was irretrievably lost, and a statement identifying the type and quantity of the radioactive source. Certified copies of the filing must be submitted to the Department within 30 days of the filing.

14-0034.02 The licensee must retain a copy of the written agreement for three years after the completion of the well logging operation.

14-004.03 If a radioactive source is irretrievably lost in a fresh water aquifer or down a liquefied petroleum products storage cavity, then a drilling safety zone must be established by the Department upon review of the geology and hydrology of the site. All wells and storage cavities in the drilling safety zone must be abandoned and no fluids may be removed except upon approval by the Department. In addition of the notice requirements in 180 NAC 14-0034.01, item 5, within 15 days after receipt of notice of the establishment of a drilling safety zone by the Department, the licensee must prepare a map of the drilling safety zone indicating the type and quantity of radioactive source, and the map must be filed with the Register of Deeds of any County which forms a portion of the drilling safety zone. Certified copies of the filing must be submitted to the Department within 30 days after the filing.

14-0034.04 A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee must still otherwise meet the requirements in 180 NAC 14-004.01, item 1 through item 5.

EQUIPMENT

14-0045 LABELS, SECURITY AND TRANSPORTATION PRECAUTIONS

14-0045.01 Labels

1. The licensee may not use a source, source holder, or logging tool that contains radioactive material unless the smallest component that is transported as a separate piece of equipment with the radioactive material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in 180 NAC 4-033.01, without the conventional color requirements, and the wording:

CAUTION[1]
RADIOACTIVE MATERIAL

2. The licensee may not use a container to store radioactive material unless the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in and the wording:

CAUTION[2]
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)

3. The licensee may not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 180 NAC 13.

14-0045.02 Security, Precautions During Storage and Transportation

1. The licensee must store each source containing radioactive material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of radioactive material from storage by unauthorized personnel. The licensee must store radioactive material in a manner that will minimize danger from explosion or fire.
2. The licensee must lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the radioactive material from the vehicle.

14-0056 RADIATION SURVEY INSTRUMENTS

14-0056.01 The licensee must keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by 180 NAC 14 and by 180 NAC 4. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.001 mSv (0.1 mrem) per hour through at least 0.5 mSV (50 mrem) per hour.

14-0056.02 The licensee must have available additional calibrated and operable radiation survey instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.

14-0056.03 The licensee must have each radiation survey instrument required under 180 NAC 14-0056.01 calibrated:

[1]Or "Danger".

[2]Ibid. p. 4

1. At intervals not to exceed six months and after instrument servicing;
2. For linear scale instruments, at two points located approximately 1/3 and 2/3 of full scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at approximate points;
3. So that an accuracy within plus or minus 20% of the calibration standard can be demonstrated on each scale; and
4. At energies and radiation levels appropriate for use.

14-0056.04 The licensee must retain calibration records for a period of three years after the date of calibration for inspection by the Department.

14-0067 LEAK TESTING OF SEALED SOURCES

14-0067.01 Requirements: Each licensee using sealed sources of radioactive material must have the sources tested for leakage. Records of leak test results must be kept in units of microcuries and maintained for inspection by the Department.

14-0067.02 Method of Testing: The wipe of a sealed source must be performed using a leak test kit or method approved by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person approved by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

14-0067.03 Testing Frequency

1. Each sealed source (except an energy compensation source (ECS) must be tested at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested.
2. Each ECS that is not exempt from testing in accordance with 180 NAC 14-007.05 must be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the ECS may not be used until tested.

14-0067.04 Removal of Leaking Source from Service

1. If the test conducted pursuant to 180 NAC 14-0067.01 and 14-0067.02 reveals the presence of 185 Bq (0.005 microcuries) or more of removable radioactive material, the licensee must remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State licensee that is authorized to perform these functions. The licensee must check the

equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State licensee that is authorized to perform these functions.

2. The licensee must submit a report to the Department within five days of receiving the test results. The report must describe the equipment involved in the leak test, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

14-0067.05 Exemptions from Testing Requirements: The following sealed sources are exempt from the periodic leak test requirements set out in 180 NAC 14-007.01 through 14-007.04:

1. Hydrogen-3 (tritium) sources;
2. Sources containing radioactive material with a half-life of 30 days or less;
3. Sealed sources containing radioactive material in gaseous form;
4. Sources of beta- or gamma- emitting radioactive material with an activity of 3.7 MBq (100 microcuries) or less; and
5. Sources of alpha- or neutron- emitting radioactive material with an activity of 0.37 MBq (10 microcuries) or less.

14-0078 PHYSICAL INVENTORY: Each licensee must conduct a quarterly physical inventory to account for all radioactive material received and possessed under the license. The licensee must retain records of the inventory for three years from the date of the inventory for inspection by the Department. The inventory must indicate the quantity and kind of radioactive material, the location of the radioactive material, the date of the inventory, and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

14-0089 RECORDS OF MATERIAL USE

14-0089.01 Each licensee must maintain records for each use of radioactive material showing:

1. The make, model number, and a serial number or a description of each sealed source used;
2. In the case of unsealed radioactive material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer materials;
3. The identity of the logging supervisor who is responsible for the radioactive material and the identity of logging assistants present; and
4. The location and date of use of the radioactive material.

14-0089.02 The licensee must make the records required by 180 NAC 14-0089.01 available for inspection by the Department. The licensee must retain the records for three years from the date of the recorded event.

14-0090 DESIGN, PERFORMANCE CRITERIA FOR SEALED SOURCES

14-0~~09~~10.01 A licensee may use a sealed source for use in well logging applications if:

1. The sealed source is doubly encapsulated;
2. The sealed source contains radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and
3. Meets the requirements of 180 NAC 14-0~~09~~10.02, 14-010.03 or 14-0~~09~~10.04.

14-0~~09~~10.02 For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources", or the requirements in 180 NAC 14-0~~09~~10.03 and 14-0~~09~~10.04.

14-0~~09~~10.03 For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources - Classification."

14-0~~09~~10.04 For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if:

1. The sealed source's prototype has been tested and found to maintain its integrity
   after each of the following tests:

   a. Temperature. The test source must be held at -40°C (-40°F) for 20 minutes, 600°C (1112°F) for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600°C (1112°F) to 20°C (68°F) within 15 seconds.
   b. Impact Test. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.
   c. Vibration Test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.
   d. Puncture Test. A 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.
   e. Pressure Test. The test source must be subjected to an external pressure of 1.695E+7 pascals (24,600 pounds per square inch absolute).

14-0~~09~~10.05 The requirements in 180 NAC 14-0~~09~~10.01, 14-0~~09~~10.02, 14-0~~09~~10.03 and 14-0~~09~~10.04 do not apply to sealed sources that contain radioactive material in gaseous form.

14-0~~09~~10.06 The requirements in 180 NAC 14-0~~09~~10.01, 14-0~~09~~10.02, 14-0~~09~~10.03 and 14-0~~09~~10.04 do not apply to energy compensation sources (ECS). ECSs must be registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

14-0~~10~~11 INSPECTION MAINTENANCE AND OPENING OF A SOURCE OR SOURCE HOLDER

14-0~~10~~11.01 Each licensee must visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired and a record must be made listing: the date of check, name of inspector, equipment involved, defects found, and repairs made. These records must be retained for three years after the defect is found.

14-0~~10~~11.02 Each licensee must conduct, at intervals not to exceed six months, a program of visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations performed, any defects found, and any actions taken to correct the defects. These records must be retained for three years after the defect is found.

14-0~~10~~11.03 Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure pursuant to 180 NAC 14-018 has been developed by the licensee and approved by the Department based upon compliance with 180 NAC 4 and 10.

14-0~~10~~11.04 If a sealed source is stuck in the source holder, the licensee may not perform any operation on the source holder, such as drilling, cutting, or chiseling, unless the licensee is specifically approved by the Department; approval is based upon training and experience of the licensee and upon compliance with 180 NAC 4 and 10.

14-0~~10~~11.05 The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State.

14-0~~11~~12 SUBSURFACE TRACER STUDIES

14-0~~11~~12.01 The licensee must require all personnel handling radioactive tracer material to use protective gloves and, if required by the licensee, other protective clothing and equipment. The licensee must take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

14-0~~11~~12.02 A licensee may not knowingly inject radioactive material into fresh water aquifers.

14-0~~12~~13 URANIUM SINKER BARS: The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words "CAUTION - RADIOACTIVE - DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND".

14-0~~13~~14 USE OF A SEALED SOURCE

14-0~~13~~14.01 In a Well with a Surface Casing: No sealed source may be used in any well unless the well is cased pursuant to the rules and regulations of the Nebraska Oil and Gas Conservation Commission Title 267 Chapter 3, 012.01 through 012.03 and 012.09 and Chapter 4, 006.01B, except as pursuant to 14-014.02.

14-0~~13~~14.02 In a Well without a Surface Casing: The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State.

14-0~~14~~15 ENERGY COMPENSATION SOURCE: The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 3.7 MBq (100 microcuries):

14-0~~14~~15.01 For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 180 NAC 14-00~~6~~7,14-00~~7~~8 and 14-00~~8~~9.

14-0~~14~~15.02 For well logging applications without the surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 180 NAC 14-00~~3~~4, 14-00~~6~~7, 14-00~~7~~8, 14-00~~8~~9, 14-0~~13~~14, and 14-0~~26~~27.

14-0~~15~~16 TRITIUM NEUTRON GENERATOR TARGET SOURCE

14-0~~15~~16.01 Use of a tritium neutron generator target source, containing quantities not exceeding 1,110 MBq (30 curies) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of 180 NAC 14 except 180 NAC 14-00~~3~~4, 14-0~~9~~10 and 14-0~~26~~27.

14-0~~15~~16.02 Use of a tritium neutron generator target source, containing quantities exceeding 1,110 MBq (30 curies) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of 180 NAC 14 except 180 NAC 14-0~~0~~910.

RADIATION SAFETY REQUIREMENTS

14-0~~16~~17 TRAINING AND EXPERIENCE QUALIFICATION REQUIREMENTS FOR WELL LOGGING PERSONNEL

14-0~~16~~17.01 Radiation Safety Officer:

1. A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering;
2. Qualified well logger or six weeks on-the-job training under an authorized user; and
3. Forty hours of formal instruction in:

    a. Principles and practices of radiation protection;
    b. Radioactivity measurements standardization and monitoring techniques and instruments;
    c. Mathematics and calculations basic to the use of and measurement of radioactivity;
    d. Biological effects of radiation, and
    e. Operating and emergency procedures and federal and state radiation control regulations.

14-0~~16~~17.02 The licensee must not permit an individual to act as a logging supervisor until that person:

1. Has completed forty hours of formal training in the subjects outlined in 180 NAC 14-0~~16~~17.06;
2. Has received copies of, and instruction in:

    a. 180 NAC 4, 10, and 14;
    b. The license under which the logging supervisor will perform well logging; and
    c. The licensee's operating and emergency procedures required by 180 NAC 14-0~~18~~19;

3. Has completed six weeks of on-the-job training under a logging supervisor and demonstrated competence in the use of radioactive materials, remote handling tools, and radiation survey instruments by a field evaluation; and
4. Has demonstrated understanding of the requirements in 180 NAC 14-0~~16~~17.02 and 14-0~~16~~17.02, items 1 and 2 by successfully completing a written test.

14-0~~16~~17.03 The licensee must not permit an individual to act as a logging assistant until that person:

1. Has received instruction in applicable parts of 180 NAC 4, and 10;
2. Has received copies of, and instruction in, the licensee's operating and emergency procedures required by 180 NAC 14-0~~17~~18;
3. Has demonstrated understanding of the materials listed in 180 NAC 14-0~~16~~17.03 item 1 and 2 by successfully completing the test; and
4. Has received instruction in the use of radioactive materials, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

14-0~~16~~17.04 The licensee must provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

14-0~~16~~17.05 The licensee must maintain a record on each logging supervisor's and logging assistant's training and annual safety review. The training records must include copies of written tests and dates of oral tests. The training records must be retained for three years following the termination of employment. Records of annual safety reviews must list the topics discussed and be retained for three years.

14-0~~16~~17.06 The licensee must include the following subjects in the training required in 180 NAC 14-0~~16~~17.02:

1. Fundamentals of radiation safety including:

   a. Characteristics of radiation;
   b. Units of radiation dose and quantity of radioactivity;
   c. Hazards of exposure to radiation;
   d. Levels of radiation from radioactive material;
   e. Methods of controlling radiation dose (time, distance, and shielding); and
   f. Radiation safety practices, including prevention of contamination, and methods of decontamination.

2. Radiation detection instruments including:

   a. Use, operation, calibration, and limitations of radiation survey instruments;
   b. Survey techniques; and
   c. Use of personnel monitoring equipment;

3. Equipment to be used including:

   a. Operation of equipment, including source handling equipment and remote handling tools;
   b. Storage, control, and disposal of radioactive material; and
   c. Maintenance of equipment.

4. The requirements of pertinent regulations. And
5. Case histories of accidents in well logging.

14-0~~17~~18 OPERATING AND EMERGENCY PROCEDURES: Each licensee must develop and follow written operating and emergency procedures that cover:

1. The handling and use of radioactive materials including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;
2. The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

3. Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 180 NAC 14-0~~19~~20.02 through 14-0~~19~~20.05;
4. Minimizing personnel exposure including exposures from inhalation and ingestion of radioactive tracer materials;
5. Methods and occasions for locking and securing stored radioactive materials;
6. Personnel monitoring and the use of personnel monitoring equipment;
7. Transportation of sources of radiation to field stations or temporary jobsites, packaging of sources of radiation for transport in vehicles, placarding of vehicles when needed, and physically securing sources of radiation in transport vehicles during transportation to prevent accidental loss, tampering or unauthorized removal;
8. Picking up, receiving, and opening packages containing radioactive materials, in accordance with 180 NAC 4-038;
9. For the use of tracers, decontamination of the environment, equipment, and personnel;
10. Maintenance of records generated by logging personnel at temporary jobsites;
11. The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by 180 NAC 14-0~~10~~11;
12. Actions to be taken if a sealed source is lodged in a well;
13. Notifying proper persons in the event of an accident; and
14. Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination, to minimize inhalation and ingestion of radioactive materials, and actions to obtain suitable radiation survey instruments as required by 180 NAC 14-00~~5~~6.02.

14-0~~18~~19 PERSONNEL MONITORING

14-0~~18~~19.01 The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of licensed radioactive materials, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters at least quarterly. After replacement, each personnel dosimeter must be promptly processed.

14-0~~18~~19.02 The licensee must provide bioassay services to individuals using radioactive materials in subsurface tracer studies if required by the license.

14-0~~18~~19.03 The licensee must retain records of personnel dosimeters required by 14-0~~18~~19.01 and bioassay results for inspection until the Department authorizes disposition of records.

14-0~~19~~20 RADIATION SURVEYS

14-0~~19~~20.01 The licensee must make radiation surveys, including but not limited to the surveys required under 180 NAC 14-0~~19~~20.02 through 14-0~~19~~20.05, of each area where radioactive materials are used and stored.

14-0~~19~~20.02 Before transporting radioactive materials, the licensee must make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the radioactive materials.

14-0~~19~~20.03 If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee must confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

14-0~~19~~20.04 If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of sealed source could be damaged by the operation, the licensee must conduct a radiation survey, including a contamination survey, during and after the operation.

14-0~~19~~20.05 The licensee must make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

14-0~~19~~20.06 The results of surveys required under 180 NAC 14-0~~19~~20.01 through 14-0~~19~~20.05 must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey instrument used, and the location of the survey. The licensee must retain records of survey for inspection by the Department for three years after they are made.

14-0~~20~~21 RADIOACTIVE CONTAMINATION CONTROL

14-0~~20~~21.01 If the licensee detects evidence that a sealed source has ruptured or radioactive materials have caused contamination, the licensee may initiate immediately the emergency procedures required by 180 NAC 14-017.

14-0~~20~~21.02 If contamination results from the use of radioactive material in well logging, the licensee must decontaminate all work areas, equipment, and unrestricted areas.

14-0~~20~~21.03 During efforts to recover a sealed source lodged in the well, the licensee must continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

PRECAUTIONARY PROCEDURES IN LOGGING AND SUBSURFACE TRACER

14-0~~21~~22 HANDLING TOOLS: The licensee must provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

14-0~~22~~23 PARTICLE ACCELERATORS: No licensee or registrant must permit above-ground testing of particle accelerators, designed for use in well logging, which results in the production of

radiation, except in areas or facilities controlled or shielded so that the requirements of 180 NAC 4-005 and 4-013, as appropriate, are met.

SECURITY, RECORDS, NOTIFICATIONS

14-0~~23~~24 SECURITY

14-0~~23~~24.01 A logging supervisor must be physically present at a temporary jobsite whenever radioactive material is being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

14-0~~23~~24.02 During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor must maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined 180 NAC 1-002.

14-0~~24~~25 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS: Each licensee must maintain the following documents and records at the field station:

1. A copy of 180 NAC 4, 10 and 14;
2. The license authorizing the use of radioactive material;
3. Operating and emergency procedures required by 180 NAC 14-0~~17~~18;
4. The record of radiation survey instrument calibrations required by 180 NAC 14-00~~5~~6;
5. The record of leak tests required by 180 NAC 14-00~~6~~7;
6. Physical inventory records required by 180 NAC 14-00~~7~~8;
7. Utilization records required by 180 NAC 14-00~~8~~9;
8. Records of inspection and maintenance required by 180 NAC 14-0~~10~~11;
9. Training records required by 180 NAC 14-0~~16~~17; and
10. Survey records required by 180 NAC 14-0~~19~~20.

14-0~~25~~26 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOBSITES: Each licensee conducting operations at a temporary jobsite must maintain the following documents and records at the temporary jobsite until the well logging operation is completed:

1. Operating and emergency procedures required by 180 NAC 14-0~~17~~18;
2. Evidence of latest calibration of the radiation survey instruments in use at the site required by 180 NAC 14-00~~5~~6;
3. Latest survey records required by 180 NAC 14-0~~19~~20.02, 14-0~~19~~20.03 and 14-0~~19~~20.05;
4. The shipping papers for the transportation of radioactive materials required by 180 NAC 13-005; and
5. When operating under reciprocity pursuant to 180 NAC 3-028, a copy of the U.S. Nuclear Regulatory Commission or Agreement State License authorizing use of radioactive materials.

14-02~~26~~27 NOTIFICATION OF INCIDENTS AND LOST SOURCES; ABANDONMENT PROCEDURES FOR IRRETRIEVABLE SOURCES

14-02~~26~~27.01 The licensee must immediately notify the Department by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. The letter must designate the well or other location, describe the magnitude and extent of the escape of radioactive materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

14-02~~26~~27.02 The licensee must notify the Department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by 180 NAC 4-057, 4-058, 4-059 and 180 NAC 3-026.

14-02~~26~~27.03 If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee must:

1. Notify the appropriate Department by telephone of the circumstances that resulted in the inability to retrieve the source and
   a. Obtain Department approval to implement abandonment procedures; or
   b. That the licensee implemented abandonment before receiving Department approval because the licensee believed there was an immediate threat to public health and safety; and
2. Advise the well owner or operator, as appropriate, of the abandonment procedures under 180 NAC 14-00~~3~~4.01 or 14-00~~3~~4.03; and
3. Either ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.

14-02~~26~~27.04 The licensee must, within 30 days after a sealed source has been classified as irretrievable, make a report in writing to the Department. The report must contain the following information:

1. Date of occurrence;
2. A description of the irretrievable well logging source involved including the radionuclide and its quantity, chemical, and physical form;
3. Surface location and identification of the well;
4. Results of efforts to immobilize and seal the source in place;
5. A brief description of the attempted recovery effort;
6. Depth of the source;
7. Depth of the top of the cement plug;
8. Depth of the well; and
9. The immediate threat to public health and safety justification for implementing abandonment if prior to Department approval was not obtained in accordance with 180 NAC 14-02~~26~~27.03, item 1.b.
10. Any other information, such as a warning statement, contained on the permanent identification plaque.

TITLE 180 CONTROL OF RADIATION

CHAPTER 15 TRAINING AND EXPERIENCE REQUIRMENTS FOR USE OF RADIATION SOURCES

TITLE 180 CONTROL OF RADIATION

CHAPTER 15 TRAINING AND EXPERIENCE REQUIREMENTS FOR USE OF RADIATION SOURCES

15-001 SCOPE AND AUTHORITY

15-001.01 180 NAC 15 establishes the training and experience requirements of personnel in 180 NAC 3, 5, 6, 8, 9, 12 and 20.

15-001.02 It establishes the criteria which courses of instruction must possess prior to being approved by the Department for the certification training programs.

15-001.03 The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

15-002 DEFINITIONS: As used in 180 NAC 15, the following definitions apply.

Experience means active participation in events or activities, leading to accumulation of knowledge.

Formal Training means training or education, including either didactic or clinical practicum or both, which has a specified objective, planned activities for students, and suitable methods for measuring student attainment, and which is offered, sponsored, or approved by an organization or institution which is able to meet or enforce these criteria.

15-003 RESERVED

15-004 RESERVED

15-005 RESERVED

15-006 RESERVED

15-007 RESERVED

15-008 RESERVED

15-009 RESERVED

15-010 RESERVED

15-011 RECENTNESS OF TRAINING: The training and experience specified in 180 NAC 15 must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

15-012 RESERVED

15-013 MINIMUM QUALIFICATIONS FOR RADIOLOGICAL MEDICAL PHYSICIST, RADIOLOGICAL HEALTH PHYSICIST AND QUALIFIED EXPERT

15-013.01 Radiological Medical Physicist means a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. This person must have training and experience in the clinical applications of radiation physics. This person must have at least the following:

1. Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Roentgen Ray and Gamma Ray Physics, X-Ray and Radium Physics; or Radiological Physics; or the American Board of Medical Physics in Radiation Oncology Physics or the Canadian College of Medical Physics. Certification must be in the specialty the individual will be clinically practicing, or

2. Holds a Master's or Doctor's Degree in physics, medical physics, other physical science, engineering, applied mathematics, nuclear physics, biophysics, radiological physics, or health physics and has completed one year of full time training in medical physics and an additional year of full time work experience under the supervision of a Radiological Medical Physicist that meets the requirements of 15-013.01, item 1 at a medical institution. Full time training and full time work experience must be in the specialty the individual will be clinically practicing.

15-013.02 Radiological Health Physicist with reference to radiation protection, means a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons having relevant certification from the American Board of Radiology or American Board of Health Physics, or those having equivalent qualifications). With reference to shielding design, a person having particular knowledge and training in the field of radiation shielding. This person must have at least the following:

1. Is certified by the American Board of Health Physics or the American Board of Radiology in Therapeutic Radiological Physics, Roentgen Ray

and Gamma Ray Physics, X-Ray and Radium Physics, or Radiological Physics, Diagnostic Radiologic Physics; or the American Board of Medical Physics, or the Canadian College of Medical Physics; or

2. A Master's or a Doctor's degree in a physical or natural science or equivalent, biophysics, radiological physics or health physics, plus one year of full time experience in radiation protection and measurements, or

3. A Bachelor's Degree in a physical or natural science or equivalent, plus three years of full time training and experience in radiation protection and measurements and a written statement from a radiological health physicist as defined in 180 NAC 15-013.02, items 1 or 2 that two years of training and experience in radiation protection and measurements were obtained under his/her supervision.

15-013.03 Qualified Expert means an individual who has demonstrated to the satisfaction of the Department that s/he possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. This person must have at least the following:

1. A Bachelor's Degree in a physical or natural science, and one year of experience in radiation protection and measurements, or
2. A Certificate or an Associate Degree from an accredited radiological technology school and one year of experience in radiation protection and measurements.

15-014 RESERVED

15-015 TRAINING AND EXPERIENCE REQUIREMENTS FOR PERSONNEL FOR INSTITUTIONAL BROAD SCOPE TYPE LICENSE A, B, AND C LISTED IN 180 NAC 3-013

15-015.01 The minimum qualifications are:

1. Radiation Safety Officer

   a. A college degree at the bachelor level, in physical or biological sciences or in engineering plus four years work experience in health physics, radiological health or another field equivalent to the above fields; or

   b. A master's degree of graduate work in health physics or radiological health with two years of work experience in health physics or radiological health.

2. Authorized User

   a. A college degree at the bachelor level, or equivalent training or experience, in the physical or biological sciences or in engineering; and

b. At least 40 hours of formal instruction in:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity; and
(4) Biological effects of radiation; and

c. One-Hundred and Sixty hours experience in the safe handling of radioactive material.

15-016 PERSONNEL TRAINING AND EXPERIENCE REQUIREMENTS FOR LICENSEE'S IN AN EDUCATIONAL INSTITUTION OTHER THAN BROAD SCOPE LICENSES

15-016.01 Radiation Safety Officer and/or Authorized User:

1. A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and

2. Forty hours of formal instruction in:

a. Radiation physics and instrumentation;
b. Radiation protection;
c. Mathematics pertaining to the use and measurement of radioactivity, and
d. Biological effects of radiation; and

3. Demonstrate an understanding of institution radiation safety policy and procedures and Title 180 or their equivalent.

15-017 TRAINING AND EXPERIENCE REQUIREMENTS FOR LABORATORY AND INDUSTRIAL USE OF RADIOACTIVE MATERIAL PERSONNEL

15-017.01 For Millicurie Quantities:

1. Radiation Safety Officer and/or Authorized User:

a. A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and

(1) Forty hours of formal instruction in:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity; and
(d) Biological effects of radiation; and

(2) Demonstrate an understanding of operating and emergency procedures and Title 180 or their equivalent.

15-017.02 For Microcurie Quantities:

1. Radiation Safety Officer and/or Authorized User:

a. Forty hours of formal instruction in:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity; and
(4) Biological effects of radiation; and

b. Demonstrate an understanding of operating and emergency procedures and Title 180 or their equivalent.

15-018 PERSONNEL TRAINING AND EXPERIENCE REQUIREMENTS FOR LICENSES TO MANUFACTURE OR INTRODUCTION OF RADIOACTIVE MATERIAL INTO MANUFACTURED PRODUCTS AND DEVICES SPECIFIED IN 180 NAC 3-014.05, ~~1 through~~ 3-014.06, 3-014.09, and 3-014.12 and 3-014.13

15-018.01 Radiation Safety Officer and/or Authorized User:

1. A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and
2. Forty hours of formal instruction in:

a. Radiation physics and instrumentation;
b. Radiation protection;
c. Mathematics pertaining to the use and measurement of radioactivity;
d. Biological effects of radiation; and

3. Demonstrate an understanding of company radiation safety policy and procedures and Title 180 or their equivalent.

15-019 PERSONNEL TRAINING AND EXPERIENCE REQUIREMENTS FOR LICENSES TO MANUFACTURE AND INTRODUCE RADIOACTIVE MATERIAL INTO RADIOPHARMACEUTICALS AS SPECIFIED IN 180 NAC 3-014.08

15-019.01 Radiation Safety Officer and/or Authorized User:

1. A registered pharmacist;
2. Basic radioisotope handling techniques of 200 hours, including:

a. Radiation physics and instrumentation;
b. Radiation protection;
c. Mathematics pertaining to the use and measurement of radioactivity;
d. Biological effects of radiation; and
e. Radiopharmaceutical chemistry.

3. Three-hundred hours experience as a radiopharmaceutical chemist.

15-020 RESERVED

15-021 RESERVED

15-022 RESERVED

15-023 RESERVED

15-024 RESERVED

15-025 TRAINING AND EXPERIENCE REQUIREMENTS FOR PARTICLE ACCELERATORS PERSONNEL NON HUMAN USE

15-025.01 Radiation Safety Officer or Supervisor must have a Bachelor of Science Degree plus one year experience in the use and operation of particle accelerators which includes forty hours instruction as specified for particle accelerator operators.

15-025.02 Operators must have 40 hours instruction in subject matter listed below and three months experience, the first one month on-the-job training must be under direct supervision.

1. Forty Hours instruction of Particle Accelerator Operators

   a. All operators must be instructed in the fundamentals of radiation.

      (1) Characteristics of radiation.
      (2) Units of radiation dose (sievert/rem).
      (3) Biological effects of radiation.
      (4) Levels of radiation from particle accelerators.
      (5) Methods used to prevent radiation exposure at the specific facility to be operated:

         (a) Shielding
         (b) Interlock system
         (c) Safety rules
         (d) Radiation monitoring equipment

2. All operators must:

a. Be instructed on the use and care of personnel monitoring equipment employed at the facility.
b. Be familiar with the location and use of all operating controls.
c. Be familiar with the requirements of pertinent State regulations.
d. Be familiar with the registrant's written operating and emergency procedures.
e. Receive at least one month of full time or equivalent on-the-job training before assuming operational responsibility.

15-026 TRAINING AND EXPERIENCE FOR SELF-SHIELDED IRRADIATORS

1. Authorized User:

a. ~~Forty~~Eight hours of formal instruction in:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of ~~radioactivity~~ radiation; and
(4) Biological effects of radiation; and

b. Demonstrate an understanding of operating and emergency procedures and Title 180 or their equivalent.

15-027 TRAINING AND EXPERIENCE REQUIREMENTS FOR INDUSTRIAL GAUGE PERSONNEL

15-027.01 Radiation Safety Officer and/or Authorized ~~Licensed~~ User: Demonstrate competency in use, maintenance and transfer of device by satisfactory completion of eight hour course provided by the manufacturer of the device or any Department accepted course.

15-028 RESERVED ~~15-028 TRAINING AND EXPERIENCE REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT PERSONNEL~~

~~15-028.01 At least 20 hours of instruction in the fundamentals of:~~

~~1. Radiation physics and instrumentation;~~
~~2. Radiation protection;~~
~~3. Radiation units of measurement;~~
~~4. Biological effects of radiation; and~~
~~5. Equipment operation~~

~~a. Operation of analytical x-ray equipment;~~
~~b. Safety devices;~~
~~c. Labeling;~~
~~d. Registrant's operations and emergency procedures; and~~

~~e. Case histories of analytical x-ray accidents.~~

15-029 TRAINING AND EXPERIENCE REQUIREMENTS FOR GAS CHROMATOGRAPH PERSONNEL

15-029.01 Radiation Safety Officer and/or Authorized User: Has received and is competent in operating procedures and manufacturer's instructions.

15-030 RESERVED

15-031 RESERVED

15-032 TRAINING AND EXPERIENCE REQUIREMENTS FOR MANAGEMENT OF RADIOACTIVE WASTE PERSONNEL

15-032.01 Radiation Safety Officer (RSO)

1. The RSO must have experience in applied radiation protection at nuclear facilities or waste disposal sites dealing with radiation protection problems. The individual should be familiar with the design features and operations of LLW sites that affect the potential for exposures of site personnel to radiation. In addition, the RSO should have the technical competence to establish radiation protection programs and the supervisory capability to direct the work of radiation protection technicians.

2. The RSO should have a bachelor's degree in science or engineering (or equivalent), including formal training in radiation protection. Minimum acceptable substitutes for a bachelor's degree are a high school diploma or its equivalent and one of the following: (1) four years of formal schooling in science or engineering, (2) four years of applied experience at a nuclear facility in the area of radiation protection, or (3) any combination of the above totaling four years, and

3. The RSO should have at least three years of experience in radiation protection, one year of which should be at a LLW disposal site. If the RSO does not have a bachelor's degree, then a total of seven years experience is recommended. A master's degree and doctor's degree may be considered equivalent to one and two years experience, respectively, if the course work is related to radiation protection.

15-032.02 Radiation Protection Technician

1. The senior radiation protection technician should have three years of working experience in radiation protection of which one year should be from an LLW disposal site. The technician should possess a high degree of manual dexterity and ability, and should be capable of learning and applying basic skills.

2. Individuals in training or apprentice positions should not be considered technicians, but should be permitted to perform work for which qualification has been demonstrated. The classification of radiation protection technicians should be as follows:

   a. In training (minimal experience) - apprentice technician.
   b. 0-3 years experience - technician.
   c. Greater than three years experience - senior technician.

   However, time alone is not enough. Any training and advancement program should also require technicians to pass written and oral examinations before advancing to different technician levels.

15-032.03 Radiation Protection Training Instructor

1. At the time of appointment to the instructor position, the responsible individual must have experience in applied radiation at nuclear facilities dealing with the radiation protection problems and programs similar to those at LLW disposal sites. The individual should be familiar with the design features and operations of LLW sites that affect the potential for exposure of site personnel to radiation.

2. The instructor should have an associate's degree in science or engineering (or equivalent), including formal training in radiation protection. Minimum acceptable substitutes for an associate degree are a high school diploma or its equivalent and one of the following: (1) two years of formal schooling in science or engineering, (2) two years of applied experience at a nuclear facility in the area of radiation protection, or (3) any combination of the above totaling two years. The instructor should have one year of experience in radiation protection at an LLW disposal site. If the instructor does not have an associate's degree, then a total of three years experience is recommended.

15-032.04 General Employee: Information on the LLW site's radiation protection policy and program should be presented to all new employees during the general employee orientation training. The orientation training should consist of classroom instruction and may be supplemented by other training methods. Written material covering the basic topics of the training should be distributed to the new employees for future reference. Visitor and contractor personnel should be given the same training, if it is expected that they may encounter radioactive material or radiation levels above background. It is recommended that the classroom instruction phase of this training be at least eight hours in length.

15-032.05 Radiation Worker: Personnel who work in a radiation area are termed radiation workers and their radiation worker training must be received prior to entering or beginning work in a radiation area. The classroom instruction phase of this training must be at least twenty hours in length.

15-033 TRAINING AND EXPERIENCE REQUIREMENTS FOR INSTALLATION AND/OR SERVICING OF RADIATION GENERATING EQUIPMENT AND ASSOCIATED RADIATION GENERATING EQUIPMENT AS SUPPLIED BY THE EMPLOYER

15-033.01 A minimum of eight hours of formal course work or as approved by the Department should be completed and include the following:

1. Radiation physics and instrumentation
2. Radiation protection
3. Mathematics pertaining to the use and measurement of radiation~~radioactivity~~
4. Biological effects of radiation

15-033.02 On-the-job training should include hands-on experience installing and/or servicing radiation generating equipment and associated radiation generating equipment components. On-the-job training must be for six months under the supervision of an individual who has completed the training in 180 NAC 15-033.01.

~~15-034 RESERVED~~

TITLE 180 CONTROL OF RADIATION

CHAPTER 19 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

SPECIFIC LICENSING REQUIREMENTS

DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

OPERATION OF IRRADIATORS

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TITLE 180 CONTROL OF RADIATION

CHAPTER 19 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

19-001 SCOPE AND AUTHORITY

19-001.01 180 NAC 19 contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. 180 NAC 19 also contains radiation safety requirements for operating irradiators. The requirements of 180 NAC 19 are in addition to other requirements of Title 180. In particular, the provisions of 180 NAC 1, 3, 4, 10, 13, 17 and 18 apply to applications and licenses subject to this 180 NAC 19. Nothing in 180 NAC 19 relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§71-3501 to 71-3520.

19-001.02 180 NAC 19 applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type.

19-001.03 180 NAC 19 does not apply to self contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

19-001.04 American Concrete Institute Standard ACI 318-89 “Building Code Requirements for Reinforced Concrete,” Chapter 21 “Special Provisions for Seismic Design” as referred to in this Chapter is herein incorporated by reference and available for viewing at the Department of Health and Human Services, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

19-002 DEFINITIONS: As used in 180 NAC 19, the following definitions apply:

Annually means either (1) at intervals not to exceed one year or (2) once per year, at about the same time each year (plus or minus one month).

Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device are not accessible to personnel.

Irradiator operator means an individual who has successfully completed the training and testing described in 180 NAC 19-018 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any ~~byproduct~~radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the ~~byproduct~~radioactive material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the U.S. Geological Survey.

Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

SPECIFIC LICENSING REQUIREMENTS

19-003 APPLICATION FOR A SPECIFIC LICENSE: A person, as defined in 180 NAC 1-002, may file an application for a specific license authorizing the use of sealed sources in an irradiator on Form NRH-5, "Application for Material License" in 180 NAC 3. Each application for a license, must be accompanied by the fee prescribed in 180 NAC 18-005. The application and a copy must be sent to:

Department of Health and Human Services
Division of Public Health
Radiological Health
P.O. Box 95026
301 Centennial Mall South
Lincoln, NE 68509-5026

19-004 SPECIFIC LICENSES FOR IRRADIATORS: The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in 180 NAC 19.

19-004.01 The applicant must satisfy the general requirements specified in 180 NAC 3-011, items 1 thru 4 and the requirements contained in 180 NAC 19.

19-004.02 The application must describe the training provided to irradiator operators including:

1. Classroom training;
2. On-the-job or simulator training;
3. Safety reviews;
4. Means employed by the applicant to test each operator's understanding of the Department's regulations and licensing requirements and the irradiator operating and emergency procedures; and
5. Minimum training and experience of personnel who may provide training.

19-004.03 The application must include an outline of the written operating and emergency procedures listed in 180 NAC 19-019 that describes the radiation safety aspects of the procedures.

19-004.04 The application must describe the organizational structure for managing the irradiator, specifically, the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

19-004.05 The application must include a description of the access control systems required by 180 NAC 19-008, the radiation monitors required by 180 NAC 19-011, the method of detecting leaking sources required by 180 NAC 19-022 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

19-004.06 If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant must establish procedures for leak testing and submit a description of these procedures to the Department. The description must include the:

1. Instruments to be used;
2. Methods of performing the analysis; and
3. Pertinent experience of the individual who analyzes the samples.

19-004.07 If licensee personnel are to load or unload sources, the applicant must describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading of its facility, the loading or unloading must be done by an organization specifically authorized by the Department, U.S. Nuclear Regulatory Commission or an Agreement State to load or unload irradiator sources.

19-004.08 The applicant must describe the inspection and maintenance checks including the frequency of the checks required by 180 NAC 19-023.

19-005 START OF CONSTRUCTION: The applicant may not begin construction of a new irradiator prior to the submission to the Department of both an application for a license for the irradiator and the fee required by 180 NAC 18-005. As used in 180 NAC 19, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of site, site surveys or soil testing, site preparation, site evacuation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of license with respect to the requirements of the Nebraska Radiation Control Act, as amended, and rules, regulations, and orders issued under the Act.

19-006 APPLICATION FOR EXEMPTIONS: In addition to the exemption in 180 NAC 1-003.01, any application for a license or for amendment of a license authorizing use of teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of 180 NAC 19. The Department will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

19-007 PERFORMANCE CRITERIA FOR SEALED SOURCES

19-007.01 Requirements: Sealed sources installed after October 30, 1996:

1. Must have a certificate of registration issued under the U. S. Nuclear Regulatory Commission or an Agreement State for evaluation of radiation safety information about its product.
2. Must be doubly encapsulated;
3. Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;
4. Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in 180 NAC 19-007.02 through 19-007.07

19-007.02 Temperature: The test source must be held at -40° celsius for 20 minutes, 600° celsius for one hour, and then be subjected to a thermal shock test with a temperature drop from 600° celsius to 20° celsius within 15 seconds.

19-007.03 Pressure: The test source must be twice subjected for at least five minutes to an external pressure (absolute) of two million newtons per square meter.

19-007.04 Impact: A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

19-007.05 Vibration: The test source must be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

19-007.06 Puncture: A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of one meter onto the test source.

19-007.07 Bend: If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of two thousand newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

19-008 ACCESS CONTROL

19-008.01 Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded

position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

19-008.02 In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual must be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

19-008.03 A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in 180 NAC19-008.02. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

19-008.04 Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

19-008.05 Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

19-008.06 Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

19-008.07 Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL(S) “or ”DANGER, RADIOACTIVE MATERIAL(S)“ or Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

19-008.08 If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if

shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

19-008.09 Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

19-009 SHIELDING

19-009.01 The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over any area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.

19-009.02 The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in the fully shielded position.

19-009.03 The radiation dose rate at 1 meter from the shield of a dry-source storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

19-010 FIRE PROTECTION

19-010.01 The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

19-010.02 The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

19-011 RADIATION MONITORS

19-011.01 Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this 180 NAC 19-011.01.

19-011.02 Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

19-012 CONTROL OF SOURCE MOVEMENT

19-012.01 The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

19-012.02 The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

19-012.03 The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

19-012.04 Each control for a panoramic irradiator must be clearly marked as to its function.

19-013 IRRADIATOR POOLS

19-013.01 For licenses initially issued after October 30, 1996, irradiators pools must either:

1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pools; or
2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee must have a method to safely store the sources during repairs of the pool.

19-013.02 For licenses initially issued after October 30, 1996, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

19-013.03 A means must be provided to replenish water losses from the pool.

19-013.04 A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

19-013.05 Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens (ohms) per centimeter or less and with a clarity so that the sources can be seen clearly.

19-013.06 A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

19-013.07 If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

19-014 SOURCE RACK PROTECTION: If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

19-015 POWER FAILURES

19-015.01 If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

19-015.02 The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

19-015.03 During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

19-016 DESIGN REQUIREMENTS: Irradiators whose construction begins after October 30, 1996, must meet the design requirements of 180 NAC 19-016.

19-016.01 Shielding: For panoramic irradiators, the licensee must design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 180 NAC 19-009. If the irradiator will use more than 2 $x10^{17}$ becquerels (5 million curies) of activity, the licensee must evaluate the effects of heating of the shielding walls by the irradiator sources.

19-016.02 Foundations: For panoramic irradiators, the licensee must design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

19-016.03 Pool integrity: For pool irradiators, the licensee must design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 180 NAC 19-013.02, and that metal components are metallurgically compatible with other components in the pool.

19-016.04 Water handling system: For pool irradiators, the licensee must verify that the design of the water purification system is adequate to meet the requirements of 180 NAC 19-013.05. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

19-016.05 Radiation monitors: For all irradiators, the licensee must evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 180 NAC 19-011.01. The licensee must verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under 180 NAC 19-022.02, the licensee must verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

19-016.06 Source rack: For pool irradiators, the licensee must verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee must determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee must review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

19-016.07 Access control: For panoramic irradiators, the licensee must verify from the design and logic diagram that the access control system will meet the requirements of 180 NAC 19-008.

19-016.08 Fire protection: For panoramic irradiators, the licensee must verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect

fires and that the detectors are protected from mechanical and radiation damage. The licensee must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

19-016.09 Source return: For panoramic irradiators, the licensee must verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

19-016.10 Seismic: For panoramic irradiators to be built in seismic areas, the licensee must design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

19-016.11 Wiring: For panoramic irradiators, the licensee must verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

19-017 CONSTRUCTION MONITORING AND ACCEPTANCE TESTING: The requirements of 180 NAC 19-017 must be met for irradiators whose construction begins after October 30, 1996. The requirements must be met prior to loading sources.

19-017.01 Shielding: For panoramic irradiators, the licensee must monitor the construction of the shielding to verify that the construction meets design specifications and generally accepted building code requirement for reinforced concrete.

19-017.02 Foundations: For panoramic irradiators, the licensee must monitor the construction of the foundations to verify that their construction meets design specifications.

19-017.03 Pool integrity: For pool irradiators, the licensee must verify that the pool meets design specifications and must test the integrity of the pool. The licensee must verify that outlets and pipes meet the requirements of 180 NAC 19-013.02.

19-017.04 Water handling system: For pool irradiators, the licensee must verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

19-017.05 Radiation monitors: For all irradiators, the licensee must verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 180 NAC 19-011.01. For pool irradiators, the licensee must verify the proper operation of the radiation monitors and the related alarm if used to meet 180 NAC 19-022.02. For underwater irradiators, the licensee must verify the proper operation of the over-the-pool monitors, alarms, and interlocks required by 180 NAC 19-011.02.

19-017.06 Source rack: For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee must observe and test the operation of the conveyor system to assure that the requirements in 180 NAC 19-014 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

19-017.07 Access control: For panoramic irradiators, the licensee must test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

19-017.08 Fire protection: For panoramic irradiators, the licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing systems.

19-017.09 Source return: For panoramic irradiators, the licensee must demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

19-017.10 Computer systems: For panoramic irradiators that use a computer system to control the access control system, the licensee must verify that the access control system will operate properly if offsite power is lost and must verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

19-017.11 Wiring: For panoramic irradiators, the licensee must verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

OPERATION OF IRRADIATORS

19-018 TRAINING

19-018.01 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

1. The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Department dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how a irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);
2. The requirements of 180 NAC 10 and 180 NAC 19 that are relevant to the irradiator;

3. The operation of the irradiator;
4. Those operating and emergency procedures listed in 180 NAC 19-019 that the individual is responsible for performing; and
5. Case histories of accidents or problems involving irradiators.

19-018.02 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individuals responsible for performing and other operations necessary to safely operate the irradiator without supervision.

19-018.03 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual must also demonstrate the ability to perform those portions of the operating and emergency procedures that s/he is to perform.

19-018.04 The licensee must conduct safety reviews for irradiator operators at least annually. The licensee must give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

1. Changes in operating and emergency procedures since the last review, if any;
2. Changes in regulations and license conditions since the last review, if any;
3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
4. Relevant results of inspections of operator safety performance;
5. Relevant results of the facility's inspection and maintenance checks; and
6. A drill to practice an emergency or abnormal event procedure.

19-018.05 The licensee must evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee must discuss the results of the evaluation with the operator and must instruct the operator on how to correct any mistakes or deficiencies observed.

19-018.06 Individuals that will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, must be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 180 NAC 19-019 that they are expected to perform or comply with, and their proper response to alarms required in 180 NAC 19. Tests may be oral.

19-018.07 Individuals who must be prepared to respond to alarms required by 180 NAC 19-008.02, 19-008.09, 19-010.01, 19-011.01, 19-011.02 and 19-022.02 must be trained and tested on how to respond. Each individual must be retested at least once a year. Tests may be oral.

19-019 OPERA~~R~~TING AND EMERGENCY PROCEDURES

19-019.01 The licensee must have and follow written operating procedures for:

1. Operation of the irradiator, including entering and leaving the radiation room;
2. Use of personnel dosimeters;
3. Surveying the shielding of panoramic irradiators;
4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
5. Leak testing of sources;
6. Inspection and maintenance checks required by 180 NAC 19-023;
7. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
8. Inspection of movable shielding required by 180 NAC 19-008.08, if applicable.

19-019.02 The licensee must have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

1. Sources stuck in the unshielded position;
2. Personnel overexposures;
3. A radiation alarm from the product exit portal monitor or pool monitor;
4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
6. A prolonged loss of electrical power;
7. A fire alarm or explosion in the radiation room;
8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
10. The jamming of automatic conveyor systems.

19-019.03 The licensee may revise operating and emergency procedures without Department approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility,
2. The revisions are consistent with the outline or summary of procedures submitted with the license application,
3. The revisions have been reviewed and approved by the radiation safety officer; and
4. The users or operators are instructed and tested on the revised procedures before they are put into use.

19-020 PERSONNEL MONITORING

19-020.01 Irradiator operators must wear either a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited for high energy photons in the normal and accident dose ranges (see 180 NAC 4-021.03). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly and other dosimeters must be processed at least quarterly.

19-020.02 Other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ±30% of the true radiation dose.

19-021 RADIATION SURVEYS

19-021.01 A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modifications to the radiation room shielding or structure that might increase dose rates.

19-021.02 If the radiation levels specified in 180 NAC 19-009 are exceeded, the facility must be modified to comply with the requirements in 180 NAC 19-009.

19-021.03 Portable radiation survey meters must be calibrated at least annually to an accuracy of ± 20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

19-021.04 Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 180 NAC 4, Table 2, Column 2 or Table 3 of Appendix 4-B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

19-021.05 Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

19-022 DETECTION OF LEAKING SOURCES

19-022.01 Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Department, U.S. Nuclear Regulatory Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Department, U.S. Nuclear Regulatory Commission or an Agreement State to perform the test.

19-022.02 For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

19-022.03 If a leaking source is detected, the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by the Department, U. S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. The licensee must promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee must arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or product are found, the licensee must arrange to have them decontaminated or disposed of by the Department, U.S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee must arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in 180 NAC 4, Table 2, Column 2. Appendix 4-B. (See 180 NAC 3-026 for reporting requirements.)

19-023 INSPECTION AND MAINTENANCE

19-023.01 The licensee must perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by 180 NAC 19-008.
2. Functioning of the source position indicator required by 180 NAC 19-012.02.
3. Operability of the radiation monitor for radioactive contamination in pool water required by 180 NAC 19-022.02 using a radiation check source, if applicable.
4. Operability of the over-pool radiation monitor at underwater irradiators as required by 180 NAC 19-011.02.
5. Operability of the product exit monitor required by 180 NAC 19-011.01.
6. Operability of the emergency source return control required by 180 NAC 19-012.03.
7. Leak-tightness of systems through which pool water circulates (visual inspection).
8. Operability of the heat and smoke detectors and extinguisher system required by 180 NAC 19-010 (but without turning extinguishers on).
9. Operability of the means of pool water replenishment required by 180 NAC 19-013.03.
10. Operability of the indicators of high and low pool water levels required by 180 NAC 19-013.04.
11. Operability of the intrusion alarm required by 180 NAC 19-008.09, if applicable.
12. Functioning and wear of the systems, mechanisms, and cables used to raise and lower sources.
13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 180 NAC 19-014.
14. Amount of water added to the pool to determine if the pool is leaking.
15. Electrical wiring on required safety systems for radiation damage.
16. Pool water conductivity measurements and analysis as required by 180 NAC 19-024.02.

19-023.02 Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

19-024 POOL WATER PURITY

19-024.01 Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee must take prompt actions to lower the pool water conductivity and must take corrective actions to prevent future recurrences.

19-024.02 The licensee must measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

19-025 ATTENDANCE DURING OPERATION

19-025.01 Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, must be present onsite;

1. Whenever the irradiator is operated using an automatic product conveyor system; and
2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

19-025.02 At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in 180 NAC 19-018.07 must be onsite.

19-025.03 At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 180 NAC 19-018.06 and 19-018.07. Static irradiations may be performed without a person present at the facility.

19-026 ENTERING AND LEAVING THE RADIATION ROOM

19-026.01 Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator must use a survey meter to determine that the source has returned to its fully shielded position. The operator must check the functioning of the survey meter with a radiation check source prior to entry.

19-026.02 Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator must:

1. Visually inspect the entire radiation room to verify that no one else is in it; and
2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

19-026.03 During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 180 NAC 19-011.02 is operating with backup power.

19-027 IRRADIATION OF EXPLOSIVE OR FLAMMABLE MATERIALS

19-027.01 Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

19-027.02 Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior

written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

RECORDS

19-028 RECORDS AND RETENTION PERIODS: The licensee must maintain the following records at the irradiator for the periods specified.

19-028.01 A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents not superseded.

19-028.02 Records of each individual's training, tests, and safety reviews provided to meet the requirements of 180 NAC 19-018.01 thru 19-018.04, 19-018.06 and 19-018.07 until three years after the individual terminates work.

19-028.03 Records of the annual evaluations of the safety performance of irradiator operators required by 180 NAC 19-018.05 for three years after the evaluation.

19-028.04 A copy of the current operating and emergency procedures required by 19-019 until superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 180 NAC 19-019.03, item three retained for three years from the date of the change.

19-028.05 Evaluations of personnel dosimeters required by 180 NAC 19-020 must be retained until the Department terminates the license.

19-028.06 Records of radiation surveys required by 180 NAC 19-021 for three years from the date of the survey.

19-028.07 Records of radiation survey meter calibrations required by 180 NAC 19-021 and pool water conductivity meter calibrations required by 180 NAC 19-024.02 until three years from the date of calibration.

19-028.08 Records of the results of leak tests required by 180 NAC 19-022.01 and the results of contamination checks required by 180 NAC 19-022.02 for three years from the date of each test.

19-028.09 Records of inspection and maintenance checks required by 180 NAC 19-023 for three years.

19-028.10 Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

19-028.11 Records of the receipt, transfer and disposal, of all licensed sealed sources as required by 180 NAC 3-025 and 3-030.

19-028.12 Records on the design checks required by 180 NAC 19-016 and the construction control checks as required by 180 NAC 19-017 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

19-028.13 Records related to decommissioning of the irradiator as required by 180 NAC 3-018.07.

19-029 REPORTS

19-029.01 In addition to the reporting requirements in other parts of Department regulations, the licensee must report the following events if not reported under of parts of Department regulations:

1. Source stuck in an unshielded position.
2. Any fire or explosion in a radiation room.
3. Damage to the source racks.
4. Failure of the cable or drive mechanism used to move the source racks.
5. Inoperability of the access control system.
6. Detection of radiation source by the product exit monitor.
7. Detection of radioactive contamination attributable to licensed radioactive material.
8. Structural damage to the pool liner or walls.
9. Abnormal water loss or leakage from the source storage pool.
10. Pool water conductivity exceeding 100 microsiemens (ohms) per centimeter.

19-029.02 The report must include a telephone report within 24 hours as described in 180 NAC 3-026.03, item 1 and a written report within 30 days as described in 180 NAC 3-026.03, item 2.

TITLE 180 CONTROL OF RADIATION

CHAPTER 20 THERAPEUTIC RADIATION MACHINES FOR HUMAN USE

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TITLE 180 CONTROL OF RADIATION

CHAPTER 20 THERAPEUTIC RADIATION MACHINES FOR HUMAN USE

20-001 SCOPE AND AUTHORITY

20-001.01 180 NAC 20 provides special requirements for therapeutic radiation machines. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

20-001.02 The requirements of this 180 NAC 20 are in addition to, and not in substitution for applicable requirements in 180 NAC 1, 2, 3, 4, 6, 10, 15, 17 and 18.

20-002 DEFINITIONS: As used in 180 NAC 20, the following definitions apply:

Absorbed dose rate means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible surface means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

Added filtration means any filtration which is in addition to the inherent filtration.

Air kerma (K) means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE, where dE is the sum of the initial kinetic energies of all ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

Barrier (See “Protective barrier”).

Beam axis means the axis of rotation of the beam limiting device.

Beam-limiting device means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimension of the useful beam.

Beam monitoring system means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Beam scattering foil means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Bent beam linear accelerator means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Changeable filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

Contact therapy system means a therapeutic machine with a short target to skin distance (TSD), usually less then 5 centimeters.

~~Contact therapy system means a therapeutic machine with a short target to skin distance (TSD), usually less then 5 centimeters.~~

Conventional Simulator means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

Detector (See Radiation detector).

Dose monitor unit (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

Electronic brachytherapy means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

Electronic brachytherapy device means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

Electronic brachytherapy source means the x-ray tube component used in an electronic brachytherapy device.

External beam radiation therapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening filter means a filter used to homogenize the absorbed dose rate over the radiation field.

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 180 NAC 20-006.

Gantry means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

Half-value layer (HVL) means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

Intensity Modulated Radiation Therapy (IMRT) means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

Interlock means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Interruption of irradiation means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Irradiation means the exposure of a living being or matter to ionizing radiation.

Isocenter means the center of the sphere though which the useful beam axis passes while the gantry moves through it's full range of motions.

Kilovolt (kVp)[kilo electron volt (keV)] means the energy equal to theat acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

Lead equivalent means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

Leakage radiation means radiation emanating from the radiation therapy system except for the useful beam.

Light field means that area illuminated by light, simulating the radiation field.

mA means milliampere.

Megavolt (MV) [mega electron volt (MeV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note current convention is to use MV for photons and MeV for electrons.]

Misadministration means an event that meets the criteria in 180 NAC 20-005.02. ~~means the administration of a Therapeutic Particle Accelerator Dose:~~

~~1. Involving the wrong patient or wrong treatment site;~~
~~2. When the treatment consists of three or fewer fractions and the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 10% of the total prescribed dose;~~
~~3. When the calculated weekly administered dose is 30% or more greater than the weekly prescribed dose; or~~
~~4. When the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 20% of the total prescribed dose.~~

Mobile Electronic Brachytherapy Service means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record

Monitor unit (MU) (See "Dose monitor unit").

Moving beam radiation therapy means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

Nominal treatment distance means:

a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

b. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance must be that specified by the manufacturer.

Patient means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Periodic quality assurance check means a procedure which is performed to ensure that a previous calibration continues to be valid.

Phantom means an object behaving in essentially the same manner as tissue, with respect to the absorption or scattering of the ionizing radiation in question.

Practical range of electrons corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" [Medical Physics 18(1): 73-109, Jan/Feb. 1991] and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

Prescribed dose means the total dose and dose per fraction as documented in the written directive. The prescribed dose is a estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

Primary dose monitoring system means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier see "Protective barrier".

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the

useful beam.

b. "Secondary protective barrier" means the material which attenuates stray radiation.

Radiation detector means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation field see "Useful beam".

Radiation head means the structure from which the useful beam emerges.

Radiological Medical Physicist means an individual qualified in accordance with 180 NAC 15-013.01.

Redundant beam monitoring system means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

Scattered radiation means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

Secondary dose monitoring system means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Secondary protective barrier see "Protective barrier".

Shadow tray means a device attached to the radiation head to support auxiliary beam blocking material.

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Simulator (radiation therapy simulation system) means any x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. [See: Conventional Simulator and Virtual Simulator.]

Source means the region and/or material from which the radiation emanates.

Source-skin distance (SSD) see "Target-skin distance".

Stationary beam radiation therapy means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray radiation means the sum of leakage and scattered radiation.

Target means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

Target-skin distance (TSD) means the distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.

Tenth-value layer (TVL) means the thickness of a specified material which attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

Termination of irradiation means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Therapeutic radiation machine means x-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these regulations, therapeutic radiation machine includes, but in not limited to devices used to administer used to administer electronic brachytherapy. ~~For the purpose of these regulations, devices used to administer electronic brachytherapy must also be considered therapeutic radiation machines.~~

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

Virtual Simulator means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

Virtual source means a point from which radiation appears to originate.

Wedge filter means a filter which effects continuous change in transmission over all or a part of the useful beam.

Written directive means an order in writing for the administration of radiation to a specific patient or human research subject, as specified in 180 NAC 20-005.01.

X-ray tube means any electron tube which is designed to be used primarily for the production of ~~X~~x-rays.

20-003 GENERAL ADMINISTRATIVE REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

20-003.01 Administrative Controls: The registrant will be responsible for directing the operation of the therapeutic radiation machines that have been registered with the Department. The registrant or the registrant's agent will ensure that the requirements of 180 NAC 20 are met in the operation of the therapeutic radiation machine(s).

20-003.02 A therapeutic radiation machine that does not meet the provisions of these regulations can not be used for irradiation of patients.

20-003.03 Training for External Beam Radiation Therapy Users: The registrant of any therapeutic radiation machine subject to 180 NAC 20.006 or 20.007 must require the user to be a physician who is licensed in the State of Nebraska and who:

1. Is certified in:

   a. Radiology (combined diagnostic and therapeutic radiology program), therapeutic radiology or radiation oncology ~~onocology~~, by the American Board of Radiology; or
   b. Radiation oncology by the American Osteopathic Board of Radiology; or
   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

   a. To satisfy the requirement for instruction, the classroom and laboratory training must include:

      (1) Radiation physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of ionization radiation; and
      (4) Radiation biology.

   b. To satisfy the requirement for supervised work experience, training must be under the supervision of an individual meeting the requirements of 180 NAC 20-003.03 and must include:

      (1) Review of the full calibration measurements and periodic quality assurance checks;
      (2) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
      (3) Using administrative controls to prevent misadministrations;
      (4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit

or console; and

(5) Checking and using radiation survey meters.

c. To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an individual meeting the requirements of 180 NAC 20-003.03. The supervised clinical experience must include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
(2) Selecting proper dose and how it is to be administered;
(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and
(4) Post-administration follow-up and review of case histories.

d. Notwithstanding the requirements of 180 NAC 20-003.03, item 1 and 2, the registrant for any therapeutic radiation machine subject to 180 NAC 20-006 may also submit the training of the prospective authorized user physician for Department review on a case-by-case basis.

e. A physician must not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Department.

20-003.04 Training for Radiological Medical Physicist: The registrant for any therapeutic radiation machine subject to 20 NAC 20-006 or 20-007 must require the individual to meet the training requirements of 180 NAC 15-013.01.

20-003.05 Qualifications of Operators:

1. Individuals who will be operating a therapeutic radiation machine for medical use must be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists must submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.[1/]

[1/] "Standards for Accredited Educational Program in Radiologic Sciences – Effective January 1, 2002", Joint Review Committee on Education in Radiologic Technology, January 1996; Revised 2001.

2. The names and training of all personnel currently operating a therapeutic radiation machine must be kept on file at the facility. Information on former operators must be retained for a period of at least two (2) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

20-003.06 Written safety procedures and rules must be developed by a Radiological Medical Physicist and must be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator must be able to demonstrate familiarity with these rules.

20-003.07 Individuals must not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

20-003.08 All individuals associated with the operation of a therapeutic radiation machine must be instructed in and must comply with the provisions of the registrant's quality management program. In addition to the requirements of 180 NAC 20, these individuals are also subject to the requirements of 180 NAC 4-005, 4-009 and 4-021.

20-003.09 Information and Maintenance Record and Associated Information: The registrant must maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Department:

1. Report of acceptance testing;
2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 180 NAC 20, as well as the name(s) of person(s) who performed such activities;
3. Records of maintenance and/or modifications performed on the therapeutic radiation machine, as well as the name(s) of person(s) who performed such services;
4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

20-003.10 Records Retention: All records required by 180 NAC 20 must be retained until disposal is authorized by the Department unless another retention period is specifically authorized in 180 NAC 20. All required records must be retained in an active file from the time of generation, until at least the next Department inspection. Any required record generated prior to the last Department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Department authorizes final disposal.

20-003.11 Visiting Authorized User. Notwithstanding the provisions of 180 NAC 20-003.07, a registrant may permit any physician to act as a visiting authorized user under

the term of the registrant's Certificate of Registration for up to sixty (60) days per calendar year under the following conditions:

1. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee (where applicable); and
2. The visiting authorized user meets the requirements established for authorized user(s) in 180 NAC 20-003.03, item 1 and 2; and
3. The registrant must maintain copies of the written permission required in 180 NAC 20-003.11, item 1i and documentation that the visiting authorized user met the requirements of 180 NAC 20-003.03, item 2 for five (5) years from the date of the last visit.

20-004 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

20-004.01 Protection Surveys

20-004.01A The registrant must ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with 180 NAC 20-008. The radiation protection survey must be performed by, or under the direction of, a Radiological Medical Physicist and must verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with and without a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 180 NAC 4-005.01; and
2. Radiation levels in unrestricted areas do not exceed the limits specified in Parts 180 NAC 4-013.01 and 180 NAC 4-013.02.

20-004.01B In addition to the requirements of 180 NAC 20-004.01A, a radiation protection survey must also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;
2. After making any change in the location of the therapeutic radiation machine within the treatment room;
3. After relocating the therapeutic radiation machine; or
4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

~~20-004.01C The survey record must also include:~~

~~1. The date of the measurements;~~
~~2. The reason the survey is required;~~
~~3. The manufacturer's name;~~
~~4. Model number and serial number of the therapeutic radiation machine;~~

~~5. The instrument(s) used to measure radiation levels;~~
~~6. Plan of the areas surrounding the treatment room that were surveyed;~~
~~7. The measured dose rate at several points in each area expressed in microsieverts or millirems per hour;~~
~~8. The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and~~
~~9. The signature of the individual responsible for conducting the survey;~~

20-004.01C The survey record must indicate all instances where the facility, in the opinion of the Radiological Medical Physicist or a qualified expert, is in violation of applicable regulations. The survey record must also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

20-004.01D If the results of the surveys required by 180 NAC 20-004.01, A or B indicate any radiation levels in excess of the respective limit specified in 180 NAC 20-004.01A., the registrant must lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or
2. Until the registrant has received a specific exemption from the Department.

20-004.02 Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program If the survey required by 180 NAC 20-004.01 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 180 NAC 4-013.01 and 4-013.02, before beginning the treatment program the registrant must:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 180 NAC 4-013.01 and 4-013.02;
2. Perform the survey required by 180 NAC 20-004.01 again; and
3. Include in the report required by 180 NAC 20-004.04 the results of the initial survey, a description of the modification made to comply with 180 NAC 20-004.02A., and the results of the second survey; or
4. Request and receive a registration amendment under 180 NAC 4-013.04 that authorizes radiation levels in unrestricted areas greater than those permitted by 180 NAC 4-013.01 and 4-013.02.

20-004.03 Dosimetry Equipment

20-004.03A The registrant must have a calibrated dosimetry system available for use. The system must have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration must have been performed within the previous 24 months and after any servicing that may have affected system calibration. An independent survey must be conducted by a qualified expert or Radiological Medical Physicist other than the person performing the original survey prior to the equipment being used except as described in 180 NAC 20-004.01D.

1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system must have been calibrated for Cobalt-60;
2. For beams with energies equal to or less than 1 MV (1 MeV), ~~20.004.03B The~~the dosimetry system must have been calibrated at an energy (energy range) appropriate for the radiation being measured;

20-004.03B~~C~~ The registrant must have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 180 NAC 20-004.03A. This comparison will have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 180 NAC 20-004.03A.

20-004.03C~~D~~ The registrant must maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record must include:

1. The date;
2. The model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 180 NAC 20-004.03A and B; the correction factors that were determined;
3. The names of the individuals who performed the calibration, intercomparison, or comparison; and
4. Evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Radiological Medical Physicist.

20-004.04 Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for any therapeutic radiation machine subject to 180 NAC 20-006 or 20-007 must furnish a copy of the records required in 180 NAC 20-004.01 and 20-004.02. to the Department within thirty (30) days following completion of the action that initiated the record requirement

20-005 QUALITY MANAGEMENT PROGRAM: Each registrant or applicant subject to 180 NAC 20-006 or 20-007 must develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the user.

20-005.01 Scope and Applicability: The quality management program must address, as

a minimum the following specific objectives:

1. Written Directives

   a. A written directive must be dated and signed by a user prior to the administration of radiation. If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.
   b. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and the number of fractions.
   c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.
   d. The registrant must retain a copy of the written directive for three years.

2. Procedures for Administration: The registrant must develop, implement, and maintain written procedures to provide high confidence that:

   a. Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
   b. Each administration is in accordance with the written directive;
   c. Therapeutic radiation machine final plans ~~External beam radiation therapy final plans~~ of treatment and related calculations are in accordance with the respective written directives by:

      (1) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive;
      (2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

   d. Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and
   e. The registrant retains a copy of the procedures for administration for the duration of the registration.

20-005.02 Reports and Notifications of Misadministrations

20-005.03A A registrant must report any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

20-005.02~~A~~B Other than events that result from intervention by a patient or human research subject, a registrant must report any event in which the administration of an external beam radiation dose:

1. Involving the wrong patient, wrong treatment modality, or wrong treatment site; or
~~2. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose; or~~
2.~~3.~~ When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30%; or
3.~~4.~~ When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

20-005.02~~B~~C The registrant must notify the Department by telephone ~~nor~~not later than the next business day after the discovery of a misadministration.

20-005.02~~C~~D The registrant must submit a written report to the Department within 30 days after the discovery of a misadministration. The written report must include:

1. The registrant's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the administration;
6. Actions, ~~it~~if any, that have been taken, or are planned to prevent recurrence;
7. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

20-005.02~~D~~E The report may not contain the individual's name or any other information that could lead to the identification of the individual.

20-005.02~~E~~F The registrant must provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that s/he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant must make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of 180 NAC 20-005.02E, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant must inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the registrant upon request. The

registrant must provide such a written description if requested.

20-005.02~~F~~G Aside from the notification requirement, nothing in this subsection affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relative or guardians.

20-005.02~~G~~H The registrant must retain a record of misadministration in accordance with 180 NAC 20-005.03. A copy of the record required must be provided to the referring physician if other than the registrant within 15 days after discovery of the misadministration.

20-005.03 Records of Misadministrations: A registrant must retain a record of misadministration reported in accordance with 180 NAC 20-005.02 for three years. The record must contain the following:

1. The registrant's name and the names of the individuals involved ;
2. The identification number, if one has been assigned, of the individual who is the subject of the misadministration;
3. A brief description of the event; why it occurred; the effect, if any, on the individual;
4. The actions, if any, taken or planned to prevent recurrence; and
5. Whether the registrant notified the individual (or the individual's responsible relative or guardian), and, if not, whether such failure to notify was based on guidance from the referring physician.

20-006 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 kV.[2]

20-006.01 Leakage Radiation: When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate must not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 0-50 kV Systems The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly must not exceed 1 mGy (100 mrad) in any one hour.

2. >50 and <500 kV Systems The leakage air kerma rate measured at a distance of 1 meter from the target in any direction must not exceed 1 cGy (1 rad) in any 1 hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly must not exceed 30 cGy (30 rad) per hour.

[2/] "Standards for Accredited Educational Program in Radiologic Sciences – Effective January 1, 2002", Joint Review Committee on Education in Radiologic Technology, January 1996; Revised 2001.

3. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 180 NAC 20-006.01, items 1. and 2. for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.

20-006.02 Permanent Beam Limiting Devices: Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

20-006.03 Adjustable or Removable Beam Limiting Devices

1. All adjustable or removable beam limiting devices, diaphragms, cones or blocks must not transmit more than 5% of the useful beam for the most penetrating beam used;
2. When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light beam.

20-006.04 Filter System: The filter system must be so designed that:

1. Filters can not be accidentally displaced at any possible tube orientation;
2. For equipment installed after July 11, 2009~~ the effective date of these regulations~~, an interlock system prevents irradiation if the proper filter is not in place;
3. The air kerma rate escaping from the filter slot does not exceed 1 cGy (1 rad) per hour at 1 meter under any operating conditions; and
4. Each filter is marked as to its material of construction and its thickness.

20-006.05 Tube Immobilization

1. The x-ray tube must be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and
2. The tube housing assembly must be capable of being immobilized for stationary portal treatments.

20-006.06 Source Marking: The tube housing assembly must be marked so that it is possible to determine the location of the source to within 5 millimeters, and such marking must be readily accessible for use during calibration procedures.

20-006.07 Beam Block: Contact therapy tube housing assemblies must have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

20-006.08 Timer: A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.

1. A timer, with a display, must be provided at the treatment control panel. The

timer must have a pre-set time selector and an elapsed time or time remaining indicator;

2 The timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it will be necessary to reset the elapsed time indicator;

3. The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
4. The timer must permit accurate pre-setting and determination of exposure times as short as 1 second;
5. The timer must not permit an exposure if set at zero;
6. The timer must not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
7. The timer must be accurate to within 1% of the selected value or 1 second, whichever is greater.

20-006.09 Control Panel Functions: The control panel, in addition to the displays required by other provisions in 180 NAC 20-006, must have:

1. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
2. An indication of whether x-rays are being produced;
3. A means for indicating x-ray tube potential and current;
4. The means for terminating an exposure at any time;
5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
6. For therapeutic radiation machines installed after July 11, 2009~~the effective date of these regulations~~, a positive display of specific filter(s) in the beam.

20-006.10 Multiple Tubes: When a control panel may energize more than one x-ray tube:

1. It must be possible to activate only one x-ray tube at any time;
2. There must be an indication at the control panel identifying which x-ray tube is activated; and
3. There must be an indication at the tube housing assembly when that tube is energized.

20-006.11 Target-to-Skin Distance (TSD): There must be a means of determining the central axis TSD to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.

20-006.12 Shutters: Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam must be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter must be controlled by the operator from the control panel. An indication of shutter position must appear at the control panel.

20-006.13 Low Filtration X-ray Tubes: Each therapeutic radiation machine equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and must be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

20-006.14 Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV: In addition to shielding adequate to meet requirements of 180 NAC 20-009, the treatment room must meet the following design requirements:

1. Aural Communication: Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel;

2. Viewing Systems: Provision must be made to permit continuous observation of the patient during irradiation and the viewing system must be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational.

20-006.15 Additional Requirements: Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV must meet the following additional requirements:

1. All protective barriers must be fixed except for entrance doors or beam interceptors;
2. The control panel must be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks must be provided such that all entrance doors, including doors to any interior booths, must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
4. When any door referred to in 180 NAC 20-006.15, item 3. is opened while the X-ray tube is activated, the air kerma rate at a distance of 1 meter from the source must be reduced to less than 1 mGy (100 mrad) per hour.

20-006.16 Full Calibration Measurements

20-006.16A Full calibration of a therapeutic radiation machine subject to 180 NAC 20-006 must be performed by, or under the direct supervision of, a Radiological Medical Physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
2. At intervals not exceeding one year; and
3. Before medical use under the following conditions:

a. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled; and
b. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

4. Notwithstanding the requirements of 180 NAC 20-006.16A.3:

a. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
b. If the repair, replacement or modification does not affect all energies, full calibration must be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 180 NAC 20-006.16A.3.a.

20-006.16B To satisfy the requirement of 180 NAC 20-006.16A, full calibration must include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

~~1. The calibration must be performed in accordance with the protocol published by the American Association of Physicist in Medicine, or a user submitted protocol having the prior approval of the Department, before the system is first used for irradiation of patients and thereafter at time intervals which do no exceed one year and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.~~
~~2. An independent verification by a third party medical physicist other than the person performing the calibration.~~

20-006.16C The registrant must maintain a record of each calibration for the duration of the registration. The record must include:

1. The date of the calibration;
2. The manufacturer's name,
3. Model number, and serial number for the therapeutic radiation machine if applicable;
4. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
5. The signature of the Radiological Medical Physicist responsible for performing the calibration.

20-006.17 Periodic Quality Assurance Checks

20-006.17A Periodic quality assurance checks must be performed on therapeutic radiation machines subject to 180 NAC 20-006, which are capable of operation at greater than or equal to 50 kV.

20-006.17B To satisfy the requirement of 180 NAC 20-006.17A, quality assurance checks must meet the following requirements:

1. The registrant must perform quality assurance checks in accordance with written procedures established by the Radiological Medical Physicist.; and
2. The quality assurance check procedures must specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures must specify that the quality assurance check will be performed during the calibration specified in 180 NAC 20-006.16A. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 180 NAC 20-006.16A, must be stated.

20-006.17C The cause for a parameter exceeding a tolerance set by the Radiological Medical Physicist must be investigated and corrected before the system is used for patient irradiation.

20-006.17D Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiological Medical Physicist's quality assurance check procedures, the system must be recalibrated as required in 180 NAC 20-006.16A.

20-006.17E The registrant must use the dosimetry system described in 180 NAC 20-004.03B, to make the quality assurance check required in 180 NAC 20-006.17B.

20-006.17F The registrant must have the Radiological Medical Physicist review and sign the results of each radiation output quality assurance check within 1 month of the date that the check was performed.

20-006.17G The registrant must ensure that quality assurance checks of therapeutic radiation machines subject to 180 NAC 20-006 are performed at intervals not to exceed 1 month.

20-006.17H Notwithstanding the requirements of 180 NAC 20-006.17F and G, the registrant must ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 180 NAC 20-006.17F and G have been performed within the 30 day period immediately prior to said administration.

20-006.17I To satisfy the requirement of 180 NAC 20-006.17B, safety quality assurance checks must ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. The "BEAM-ON" and termination switches;
3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;
4. Viewing systems; and
5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

20-006.17J The registrant must maintain a record of each quality assurance check required by 180 NAC 20-006.17A and G for three years. The record must include:

1. The date of the quality assurance check;
2. The manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name;
3. The manufacture's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
4. The signature of the individual who performed the periodic quality assurance check.

20-006.18 Operating Procedures

20-006.18A The therapeutic radiation machine must not be used for irradiation of patients unless the requirements of 180 NAC 20-006.16 and 20-006.17. have been met.

20-006.18B Therapeutic radiation machines must not be left unattended unless secured pursuant to 180 NAC 20-006.09 item 5.

20-006.18C When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used.

20-006.18D The tube housing assembly must not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder must wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV.

20-006.18E A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.

20-006.18F No individual other than the patient must be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room must be protected by a barrier sufficient to meet the requirements of 180 NAC 4-005.

20-006.18G Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 180 NAC 20-005 must possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) must be operable and calibrated in accordance with 180 NAC 20-008.

20-007 THERAPEUTIC RADIATION MACHINES – PHOTON THERAPY SYSTEMS (500 kV AND ABOVE) AND ELECTRON THERAPY SYTEMS (500 keV and ABOVE)

Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 180 NAC 20-007must possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) must be operable and calibrated in accordance with 180 NAC 20-008.

20-007.01 Leakage Radiation Outside the Maximum Useful Beam In Photon and Electron Modes

20-007.01A The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), must not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

20-007.01B Except for the area defined in 180 NAC 20-007.01A, the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window must not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters.

20-007.01C For equipment manufactured after the effective date of these regulations, the neutron absorbed dose outside the useful beam must be in compliance with International Electrotechnical Commission (IEC) Documents 60601-2-1, 2007-3 Third ~~Addition~~ Edition and ~~not exceed manufacturer's specifications.~~

20-007.01D For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 180 NAC 20-007.01A through C for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.

20-007.02 Leakage Radiation Through Beam Limiting Devices

20-007.02A Photon Radiation: All adjustable or interchangeable beam limiting devices must attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) must not exceed 2% of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm^2 ~~10 centimeter by 10 centimeter~~ radiation field, or maximum available field size if less than 100 cm^2;

20-007.02B Electron Radiation: All adjustable or interchangeable electron applicators must attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance must not exceed:

1. A maximum of 2% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line 7 centimeters outside the periphery of the useful beam; and
2. A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line 2 centimeters outside the periphery of the useful beam.

20-007.03 Measurement of Leakage Radiation

20-007.03A Photon Radiation: Measurements of leakage radiation through the beam limiting devices must be made with the beam limiting devices closed and any residual aperture blocked by at least two- tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector of area not exceeding 10 square centimeters;

20-007.03B Electron Radiation: Measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding 1 square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements must be made using 1 centimeter of water equivalent build up material.

20-007.04 Filters/Wedges

20-007.04A Each wedge filter that is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor must be redetermined;

20-007.04B If the absorbed dose rate information required by 180 NAC 20-007.01

relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter must be removable only by the use of tools;

20-007.04C For equipment installed after July 11, 2009 ~~the effective date of these regulations~~ which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

1. Irradiation must not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
2. An interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;
3. A display must be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and
4. An interlock must be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

20-007.05 Stray Radiation in the Useful Beam: For equipment installed after the effective date of these regulations, the registrant must determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with Internation Electrotecnical Commission (IEC) Document 60601-2-1, 2007-3, 3rd edition. ~~Do not exceed manufactures specification.~~

20-007.06 Beam Monitors: All therapeutic radiation machines subject to 180 NAC 20-007 must be provided with redundant beam monitoring systems. The sensors for these systems must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

20-007.06A Equipment installed after July 11, 2009 ~~the effective date of these regulations~~ must be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

20-007.06B Equipment installed on or before July 11, 2009 ~~the effective date of these regulations~~ must be provided with at least one radiation detector. This detector must be incorporated into a useful beam monitoring system;

20-007.06C The detector and the system into which that detector is incorporated must meet the following requirements:

1. Each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning;
2. Each detector must form part of a beam monitoring system from whose

readings in dose monitor units the absorbed dose at a reference point can be calculated;

3. Each beam monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation; and
4. For equipment installed after July 11, 2009 ~~the effective date of these regulations~~, the design of the beam monitoring systems must ensure that the:

    a. Malfunctioning of one system must not affect the correct functioning of the other system(s); and
    b. Failure of either system must terminate irradiation or prevent the initiation of radiation.

5. Each beam monitoring system must have a legible display at the treatment control panel. For equipment installed after July 11, 2009 ~~the effective date of these regulations~~, each display must:

    a. Maintain a reading until intentionally reset;
    b. Have only one scale and no electrical or mechanical scale multiplying factors;
    c. Utilize a design such that increasing dose is displayed by increasing numbers; and
    d. In the event of power failure, the beam monitoring information required in 180 NAC 20-007.06C5.c. displayed at the control panel at the time of failure must be retrievable in at least one system for a 20 minute period of time.

20-007.07 Beam Symmetry

20-007.07A Bent-beam linear accelerators with beam flattening filter(s) subject to 180 NAC 20-007 must be provided with auxiliary device(s) to monitor beam symmetry;

20-007.07B The device(s) referenced in 180 NAC 20-007.07A must be able to detect field asymmetry greater than 10%; and

20-007.07C The device(s) referenced in 180 NAC 20-007.07A must be configured to terminate irradiation if the specifications in 180 NAC 20-007.07B can not be maintained.

20-007.08 Selection and Display of Dose Monitor Units

20-007.08A Irradiation must not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel,

20-007.08B The pre-selected number of dose monitor units will be displayed at the treatment control panel until reset manually for the next irradiation,

20-007.08C After termination of irradiation, it will be necessary to reset the dosimeter

display before subsequent treatment can be initiated; and

20-007.08D For equipment installed after July 11, 2009 ~~the effective date of these regulations~~ after termination of irradiation, it will be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

20-007.09 Air Kerma Rate/Absorbed Dose Rate: For equipment installed after July 11, 2009 ~~the effective date of these regulations~~, a system must be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in 180 NAC 20-007.06 may form part of this system. In addition:

1. The dose monitor unit rate must be displayed at the treatment control panel;

2. If the equipment can deliver, under any conditions, an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device must be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated must be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device must be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

4. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the maximum value(s) specified in 180 NAC 20-007.09, item 2 and 3, for the specified operating conditions. Records of these maximum value(s) must be maintained at the installation for inspection by the Department.

20-007.10 Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy

20-007.10A Each primary system must terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

20-007.10B If the original design of the equipment included a secondary dose monitoring system, that system must be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

20-007.10C For equipment installed after July 11, 2009 ~~the effective date of these regulations~~, an indicator on the control panel must show which monitoring system has

terminated irradiation.

20-007.11 Termination of Irradiation: It must be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

20-007.12 Interruption of Irradiation: If a therapeutic radiation machine has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it must be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements must be automatically terminated.

20-007.13 Timer: A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.

1. A timer must be provided which has a display at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator.
2. The timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it will be necessary to reset the elapsed time indicator.
3. The timer must terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

20-007.14 Selection of Radiation Type: Equipment capable of both x-ray therapy and electron therapy must meet the following additional requirements:

1. Irradiation must not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
2. The radiation type selected must be displayed at the treatment control panel before and during irradiation;
3. An interlock system must be provided to ensure that the equipment can principally emit only the radiation type that has been selected;
4. An interlock system must be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;
5. An interlock system must be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
6. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

20-007.15 Selection of Energy: Equipment capable of generating radiation beams of different energies must meet the following requirements:

1. Irradiation will not be possible until a selection of energy has been made at the treatment control panel;
2. The nominal energy value selected must be displayed at the treatment control

panel until reset manually for the next irradiation. After termination of irradiation, it will be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

3. Irradiation will not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.
4. For equipment manufactured after the effective date of these regulations, the selection of energy must be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1, 2007-3, third edition.

20-007.16 Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy: Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the following requirements:

1. Irradiation will not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
2. The mode of operation must be displayed at the treatment control panel;
3. An interlock system must be provided to ensure that the equipment can operate only in the mode that has been selected;
4. An interlock system must be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
5. Moving beam radiation therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment installed after July 11, 2009 ~~the effective date of these regulations~~:

    a. An interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20% from the selected value;

    b. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than 5% from the dose monitor unit value selected;

    c. An interlock must be provided to prevent motion of more than 5 degrees or 1 cm beyond the selected limits during moving beam radiation therapy;

    d. An interlock must be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

    e. Moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitor system terminates the irradiation in moving beam

radiation therapy, the termination of irradiation must be as required by 180 NAC 20-007.10; and

7. For equipment installed after July 11, 2009 ~~the effective date of these regulations~~, an interlock system must be provided to terminate irradiation if movement:

   a. Occurs during stationary beam radiation therapy; or
   b. Does not start or stop during moving beam radiation therapy unless such stoppage is a pre-planned function.

20-007.17 Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV: In addition to shielding adequate to meet requirements of 180 NAC 20-009, the following design requirements include:

1. Protective Barriers: All protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors;

2. Control Panel: In addition to other requirements specified in 180 NAC 20, the control panel must also:

   a. Be located outside the treatment room;
   b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
   c. Provide an indication of whether radiation is being produced; and
   d. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.

3. Viewing Systems: Windows, mirrors, closed-circuit television or an equivalent viewing system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational;

4. Aural Communications: Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine must not be used for irradiation of patients unless continuous two-way aural communication is possible;

5. Room Entrances: Treatment room entrances must be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

6. Entrance Interlocks: Interlocks must be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

7. Beam Interceptor Interlocks: If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 180 NAC 4-013.01 and 4-013.02, interlocks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

8. Emergency Cutoff Switches: At least one emergency power cutoff switch must be located in the radiation therapy room and must terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 180 NAC 20-007.11. All emergency power cutoff switches must include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch. ~~All emergency cutoff switches must be labled.~~

9. Safety Interlocks: All safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; ~~all interlocks and visible or audible alarms must be tested for proper operation at intervals not to exceed three months~~ and

10. Surveys for Residual Radiation: Surveys for residual activity must be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

20-007.18 Radiological Medical Physicist Support

20-007.18A The services of a Radiological Medical Physicist is required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiological Medical Physicist must be responsible for:

1. Full calibration(s) required by 180 NAC 20-007.20 and protection surveys required by 180 NAC 20-004.01.;
2. Supervision and review of dosimetry;
3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
4. Quality assurance, including quality assurance check review required by 180 NAC 20-007.21E.;
5. Consultation with the user in treatment planning, as needed; and
6. Perform calculations/assessments regarding misadministrations.

20-007.18B If the Radiological Medical Physicist is not a full-time employee of the registrant, the operating procedures required by 180 NAC 20-007.19F must also specifically address how the Radiological Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the

Radiological Medical Physicist can be contacted.

20-007.19 Operating Procedures

20-007.19A No individual, other than the patient, must be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

20-007.19B Therapeutic radiation machines must not be made available for medical use unless the requirements of 180 NAC 20-004.01, 20-007.20 and 20-007.21 have been met;

20-007.19C Therapeutic radiation machines, when not in operation, must be secured to prevent unauthorized use;

20-007.19D When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field.

20-007.19E If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used; and

20-007.19F A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.

20-007.20 Acceptance Testing, Commissioning and Full Calibration Measurements

20-007.20A Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 180 NAC 20-007 must be performed by, or under the supervision of, a Radiological Medical Physicist.

20-007.20B Acceptance testing and commissioning must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" ~~or~~and manufactures specifications and must be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

20-007.20C Full calibration must include measurement of all applicable parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46," prepared by Committee Task Group 40 and must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" prepared by Radiation Therapy Task Group 45. Although it must not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) must be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in Table II. ~~Full calibrations must include:~~

~~1. The calibration of systems subject to 180 NAC 20 must be performed in accordance with the protocol published by the American Association of Physicist in Medicine, or a user submitted protocol having the prior approval of the Department, before the system is first used for irradiation~~

~~of patients and thereafter at time intervals which do no exceed one year and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.~~

~~2. An independent verification of equipment radiation output by a third party medical physicist other than the person performing the calibration.~~

20-007.20D The Radiological Medical Physicist must perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities must require measurements for only those modes and/or energies that are not within their acceptable range; and

2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements must be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 180 NAC 20-007.20D.1.

20-007.20E The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number and serial number for the therapeutic radiation machine;
3. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
4. The signature of the Radiological Medical Physicist responsible for performing the calibration.

20-007.21 Periodic Quality Assurance Checks

20-007.21A Periodic quality assurance checks must be performed on all therapeutic radiation machines subject to 180 NAC 20-007 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46," Report of AAPM Radiation Therapy Committee Task Group 40; or other procedure.

20-007.21B To satisfy the requirement of 180 NAC 20-007.21A, quality assurance checks must include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" ~~or a user submitted protocol having the prior approval of the Department~~.

Representative sampling must include all applicable referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

20-007.21C The registrant must use a dosimetry system that has been intercompared within the previous 12 months with the dosimtry systems described in 180 NAC 20-004.03A to make the periodic quality assurance checks required in 180 NAC 20-007.21B;

20-007.21D The registrant must perform periodic quality assurance checks required by 180 NAC 20-007.21A in accordance with written procedures established by the Radiological Medical Physicist;

20-007.21E The registrant must review the results of each periodic radiation output check according to the following procedures:

1. The user and Radiological Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine must not be made available for subsequent medical use until the Radiological Medical Physicist has determined that all parameters are within their acceptable tolerances;
2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check must be reviewed and signed by either the authorized user or Radiological Medical Physiscist within 3 treatment days; and
3. The Radiological Medical Physicist must review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

20-007.21F Therapeutic radiation machines subject to 180 NAC 20-007 must have applicable safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46" prepared by ~~Report of~~ AAPM Radiation Therapy Committee Task Group 40" ~~or a user submitted protocol having the prior approval of the Department~~ performed at intervals not to exceed 1 week;

20-007.21G To satisfy the requirement of 180 NAC 20-007.21F, safety quality assurance checks must ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. Proper operation of the "BEAM-ON", interrupt and termination switches;
3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
4. Viewing systems;
5. Electrically operated treatment room door(s) from inside and outside the treatment room.

20-007.21H The registrant must promptly repair any system identified in 180 NAC 20-007.21G. that is not operating properly; and

20-007.21I The registrant must maintain a record of each quality assurance check required by 180 NAC 20-007.021A and G for 3 years. The record must include:

1. The date of the quality assurance check;
2. The manufacturer's name, model number, and serial number of the therapeutic radiation machine;
3. The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
4. The signature of the individual who performed the periodic quality assurance check.

20-007.21J Quality Assurance Checks for IMRT must:

1. Include commissioning and testing of the treatment planning and delivery systems,routine quality assurance of the delivery system, and patient-specific validation of treatment plans; [3/] and
2. Be performed in accordance with "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82"; and
3. Be performed in accordance with the manufacturer's contractual specifications.

20-008 CALIBRATION OF SURVEY INSTRUMENTS

20-008.01 The registrant must ensure that the survey instruments used to show compliance with 180 NAC 20 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

20-008.02 To satisfy the requirements of 180 NAC 20-008.01, the registrant must:

1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);
2. Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

20-008.03 To satisfy the requirements of 180 NAC 20-008.02, the registrant must:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and
2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20% if a correction factor or graph is conspicuously attached to the instrument.

20-008.04 The registrant must retain a record of each calibration required in 180 NAC 20-008.01 for three years. The record must include:

3 IMRT is a rapidly evolving modality and the QA program must also evolve to handle new issues that arise

1. A description of the calibration procedure; and
2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

20-008.05 The registrant may obtain the services of individuals licensed by the Department, the U. S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations that contain information required by 180 NAC 20-008.04 must be maintained by the registrant.

20-009 SHIELDING AND SAFETY DESIGN REQUIREMENTS

20-009.01 Each therapeutic radiation machine subject to 180 NAC 20-006 or 20-007 must be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 180 NAC 4-005 and 4-013.

20-009.02 Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy must be submitted for Department approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix 20-A.

20-010 QUALITY ASSURANCE FOR RADIATION THERAPY SIMULATION SYSTEMS

20-010.01 Quality assurance for a conventional or virtual simulator must include acceptance testing and periodic verification of system performance; and

20-010.02 Be performed in accordance with "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No.40: AAPM Report No. 46" for a conventional simulator; or

20-010.03 Be performed in accordance with "Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83" for a virtual simulator.

20-011 ELECTRONIC BRACHYTHERAPY

20-011.01 Applicability: Electronic brachytherapy devices must be subject to the requirements of 180 NAC 20-011, and must be exempt for the requirements of 180 NAC 20-006.

20-011.01A An electronic brachytherapy device that does not meet the requirements of 180 NAC 20-11 must not be used for irradiation of patients; and

20-011.01B An electronic brachytherapy device must only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

20-011.02 Possession of Survey Instrument(s) Each facility location authorized to use an electronic brachytherapy device in accordance with 180 NAC 20-11 must possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) must be operable and calibrated in accordance with 180 NAC 20-008 for the applicable electronic brachytherapy source energy.

20-011.03 Facility Design Requirements for Electronic Brachytherapy Devices: In addition to shielding adequate to meet requirements of 180 NAC 20-009, the treatment room must meet the following design requirements:

20-011.03A If applicable, provision must be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.

20-011.03B Access to the treatment room must be controlled by a door at each entrance.

20-011.03C Each treatment room must have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device must not be used for patient irradiation unless the patient can be observed.

20-011.03D For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room must be available, either as a portable shield and/or as localized shielded material around the treatment site.

20-011.03E For electronic brachytherapy devices capable of operating at greater than 150 kV: [4]/

1. The control panel must be located outside the treatment room; and
2. Electrical interlocks must be provided for all door(s) to the treatment room that will:

   a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
   b. Cause the source to be shielded when an entrance door is opened; and
   c. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

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20-011.04 Electrical Safety for Electronic Brachytherapy Devices

20-011.04A The high voltage transformer must be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

20-011.04B The high voltage transformer must be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

20-011.04C The high voltage transformer must have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

20-011.04D Equipment manufactured after the effective date of these regulations must be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

1. IEC 60601-1:
2. IEC 60601-1-2:2001;
3. IEC 60601-2-8; and
4. IEC 60601-2-17:.

20-011.05 Control Panel Functions: The control panel, in addition to the displays required by other provisions in 180 NAC 20-011 must:

20-011.05A Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

20-011.05B Provide an indication of whether x-rays are being produced;

20-011.05C Provide a means for indicating electronic brachytherapy source potential and current;

1. Provide the means for terminating an exposure at any time; and
2. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

20-011.06 Timer: A suitable irradiation control device (timer) must be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

20-011.06A A timer must be provided at the treatment control panel. The timer must indicate planed setting and the time elapsed or remaining;

20-011.06B The timer must not permit an exposure if set at zero;

20-011.06C The timer must be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator;

20-011.06D The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

20-011.06E The timer must permit setting of exposure times as short as 0.1 second; and

20-011.06F The timer must be accurate to within one (1) percent of the selected value or 0.1 second, whichever is greater.

20-011.07 Qualified Medical Physicist Support

20-011.07A The services of a Qualified Medical Physicist must be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist must be responsible for:

1. Evaluation of the output from the electronic brachytherapy source;
2. Generation of the necessary dosimetric information;
3. Supervision and review of treatment calculations prior to initial treatment of any treatment site;
4. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in 20-011.11;
5. Consultation with the authorized user in treatment planning, as needed; and
6. Performing calculations/assessments regarding patient treatments that may constitute a misadministration.

20-011.07B If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by 20-011.08 must also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

20-011.08 Operating Procedures

20-011.08A Only individuals approved by the authorized user, Radiation Safety Officer, or Qualified Medical Physicist must be present in the treatment room during treatment;

20-011.08B Electronic brachytherapy devices must not be made available for medical use unless the requirements of 180 NAC 20-004.01, 20-011.09 and 20-011.10 have been met;

20-011.08C The electronic brachytherapy device must be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

20-011.08D During operation, the electronic brachytherapy device operator must monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam;

20-011.08E If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used;

20-011.08F Written procedures must be developed, implemented, and maintained for responding to an abnormal situation. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
2. The names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

20-011.08F A copy of the current operating and emergency procedures must be physically located at the electronic brachytherapy device control console[5];

20-011.08G Instructions must be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and

20-011.08H The Radiation Safety Officer, or his/her designee, and an authorized user must be notified as soon as possible if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist must inform the manufacturer of the event.

20-011.09 Safety Precautions for Electronic Brachytherapy Devices

20-11.09A A Qualified Medical Physicist must determine which persons in the treatment room require monitoring when the beam is energized;

20-011.09B An authorized user and a Qualified Medical Physicist must be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

20-011.09C A Qualified Medical Physicist and either an authorized user or a physician or electronic brachytherapy device operator, under the supervision of an

5 If the control console is integral to the electronic brachytherapy device, the required procedures must be kept where the operator is located during electronic brachytherapy device operation.

authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, must be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

20-011.09D When shielding is required by 180 NAC 20-011.03D, the electronic brachytherapy device operator must use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist must designate shield locations sufficient to meet the requirements of 180 NAC 4-005 for any individual, other than the patient, in the treatment room; and

20-011.09E All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist must approve any deviation from this requirement and must designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

20-011.10 Electronic Brachytherapy Source Calibration Measurements

20-011.10A Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to 180 NAC 20-011 must be performed by, or under the direct supervision of, a Qualified Medical Physicist;

20-011.10B Calibration of the electronic brachytherapy source output must be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

20-011.10C Calibration of the electronic brachytherapy source output must utilize a dosimetry system described in 180 NAC 20-011.04C;

20-011.10D Calibration of the electronic brachytherapy source output must include, as applicable, determination of:

1. The output within two percent (2 %) of the expected value, if applicable, or determination of the output if there is no expected value;
2. Timer accuracy and linearity over the typical range of use;
3. Proper operation of back-up exposure control devices;
4. Evaluation that the relative dose distribution about the source is within five percent (5 %) of that expected; and
5. Source positioning accuracy to within one (1) millimeter within the applicator;

20-011.10E Calibration of the x-ray source output required by 180 NAC 20-011.10A through F must be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol must be followed.

20-011.10F The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for it's electronic brachytherapy source; the model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

20-011.11 Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

20-011.11A Quality assurance checks must be performed on each electronic brachytherapy device subject to 180 NAC 20-011:

1. At the beginning of each day of use;
2. Each time the device is moved to a new room or site[6]; and
3. After each x-ray tube installation.

20-011.11B The registrant must perform periodic quality assurance checks required by 180 NAC 20-011.11A in accordance with procedures established by the Qualified Medical Physicist;

20-011.11C To satisfy the requirements of 180 NAC 20-011.11A, radiation output quality assurance checks must include as a minimum:

1. Verification that output of the electronic brachytherapy source falls within three percent (3 %) of expected values, as appropriate for the device, as determined by:

   a. Output as a function of time, or
   b. Output as a function of setting on a monitor chamber.

2. Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by 180 NAC 20-011.10; and
3. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one (1) mm; and

20-011.11D The registrant must use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in 180 NAC 20-004.03A to make the quality assurance checks required in 180 NAC 20-011.03;

6 *Site* is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer. See 180 NAC 20-011.14 for additional clarification.

20-011.11E The registrant must review the results of each radiation output quality assurance check according to the following procedures:

1. An authorized user and Qualified Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device must not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;
2. If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check must be reviewed and signed by either the authorized user or Qualified Medical Physicist within two (2) days; and
3. The Qualified Medical Physicist must review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

20-011.11F To satisfy the requirements of 180 NAC 20-011.11A, safety device quality assurance checks must,at a minimum, assure:

1. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
2. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
3. Proper operation of radiation monitors, if applicable;
4. The integrity of all cables, catheters or parts of the device that carry high voltages; and
5. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
6. If the results of the safety device quality assurance checks required in 180 NAC 20-011.11F, indicate the malfunction of any system, a registrant must secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.
7. The registrant must maintain a record of each quality assurance check required by 180 NAC 20-011.11C and G in an auditable form for three (3) years.

    a, The record must include:

        (1) The date of the quality assurance check;
        (2) The manufacturer's name, model number and serial number for the electronic brachytherapy device;
        (3) The name and signature of the individual who performed the periodic quality assurance check and the name and
        (4) Signature of the Qualified Medical Physicist who reviewed the quality assurance check;

b. For radiation output quality assurance checks required by 180 NAC 20-011.11, item 3, the record must also include:

(1) The unique identifier for the electronic brachytherapy source and the manufacturer's name;
(2) Model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

20-011.12 Therapy-Related Computer Systems: The registrant must perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol must be followed.

20-011.12A Acceptance testing must be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing must include, as applicable, verification of:

1 The source-specific input parameters required by the dose calculation algorithm;
2. The accuracy of dose, dwell time, and treatment time calculations at representative points;
3. The accuracy of isodose plots and graphic displays;
4. The accuracy of the software used to determine radiation source positions from radiographic images; and
5. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

20-011.12B The position indicators in the applicator must be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

20-011.12C Prior to each patient treatment regimen, the parameters for the treatment must be evaluated and approved by the authorized user and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

20-011.13 Training.

20-011.13A A registrant must provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in 180 NAC 20-

011.08. If the interval between patients exceeds one year, retraining of the individuals must be provided.

20-011.13B In addition to the requirements of 180 NAC 20-003.03 for therapeutic radiation machine authorized users and 180 NAC 20-003.04 for Qualified Medical Physicists, these individuals must also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training must be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol must be followed. The training must include, but not be limited to:

1. Device-specific radiation safety requirements;
2. Device operation;
3. Clinical use for the types of use approved by the FDA;
4. Emergency procedures, including an emergency drill; and
5 The registrant's Quality Assurance Program.

20-011.13C A registrant must retain a record of individuals receiving instruction required by 180 NAC 20-011.13A and B for three (3) years. The record must include:

1. A list of the topics covered,
2. The date of the instruction,
3. The name(s) of the attendee(s), and
4. The name(s) of the individual(s) who provided the instruction.

20-011.14 Mobile Electronic Brachytherapy Service: A registrant providing mobile electronic brachytherapy service must, as a minimum:

20-011.14A Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.

20-011.14B Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

20-011.14C Perform, at each location on each day of use, all of the required quality assurance checks specified in 180 NAC 20-011.11 to assure proper operation of the device.

20-012 OTHER USES OF ELECTRONICALLY PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE

20-012.01 A person must not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

20-012.01A The applicant or registrant has, at a minimum, provided the Department with:

1. A detailed description of the device and its intended application(s);
2. Facility design requirements, including shielding and access control;
3. Documentation of appropriate training for authorized user physician(s) and qualified medical physicist(s)
4. Methodology for measurement of dosages to be administered to patients or human research subjects;
5. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety
6. Radiation safety precautions and instructions; and
7. Other information requested by the Department in its review of the application; and

20-012.01B The applicant or registrant has received written approval from the Department to utilize the device in accordance with the regulations and specific conditions the Department considers necessary for the medical use of the device.

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APPENDIX 20-A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. All Therapeutic Radiation Machines

A. Basic facility information including: name and telephone number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam must have primary barriers.

C. Secondary barriers must be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic Radiation Machines up to 150 Kv (photons only)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV will submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

B. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth must be noted on the plan and the operator's station at the control panel must be behind a protective barrier sufficient to ensure compliance with 180 NAC 4-005;

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest

area(s) where it is likely that individuals may be present; and

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility:

1. If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

2. Submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic Radiation Machines Over 150 kV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV and/or electrons must submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [i.e.: photon, electron]. The target to isocenter distance must be specified;

B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze;

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [i.e.: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and expected radiation

exposure in both restricted and unrestricted areas; and

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron Shielding

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities that are capable of operating above 10 MV must submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material;

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility:

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the results obtained with the software. ~~Submit quality control sample calculations to verify the result obtained with the software.~~

D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of

X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

~~B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).~~

B.~~C.~~ NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

C. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).

D. NCRP Report 151, “Structural Shielding Design and Evaluation for Megavoltage X and Gamma-Ray Radiotherapy Facilities. (2006).

TITLE 180 CONTROL OF RADIATION

CHAPTER 21 DENTAL RADIOGRAPHIC EQUIPMENT

FORM(S)

Form NRH-3 Notice to Employees
Form NRH-4 Application for Registration of Radiation Generating Equipment
Form NRH-21 Dental Interim Inspection Form
Form NRH 21A Equipment List
Form NRH-21B – Equipment Performance Evaluation

~~ATTTACHMENTS~~

~~Attachment Number 21-1 21 CFR 56~~
~~Attachment Number 21-2 21 CFR 1020.30 and 1020.31~~
~~Attachment Number 21-3 45 CFR 46~~

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

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TITLE 180 CONTROL OF RADIATION

CHAPTER 21 DENTAL RADIOGRAPHIC EQUIPMENT

21-001 SCOPE AND AUTHORITY:

21-001.01 180 NAC 21 applies to all persons who receive, possess, use, transfer, own, or acquire any dental radiographic equipment. Persons that receive, possess, use, transfer, own or acquire dental computed tomography, dental fluoroscopic equipment, rotating anode tube radiation generating equipment or other radiation generating equipment will need to refer to 180 NAC 1, 2, 4, 6, 9, 10, 15, 17, 18, and 20.

21-001.02 180 NAC 21 establishes the following:

1. The registration of dental radiation generating equipment.
2. The standards for protection against ionizing radiation resulting from activities conducted pursuant to registrations issued by the Department.
3. The requirements to control the receipt, possession, use, transfer, and disposal of dental radiation generating equipment by any person so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in 180 NAC 21. However, nothing in 180 NAC 21 will be construed as limiting actions that may be necessary to protect health and safety.
4. Requirements for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the practice of dentistry.
5. The requirements for notices, instructions and reports by dental registrants to individuals engaged in activities under a registration and options available to such individuals in connection with Department inspections of registrants to ascertain compliance with the provisions of the Act and regulations, orders issued there under regarding radiological working conditions.
6. Specific record keeping requirements and general provisions for records and reports.

7. The training and experience requirements of dental personnel.
8. The conduct of proceedings under the Radiation Control Act, the administrative procedures of the Department and the Formal Hearing Procedures of the Department of Health and Human Services, for the issuing, denying, renewing, transferring, amending, suspending, revoking of any registration and for determining compliance with or granting of exemptions from Department rule, order, or condition of registration; for assessing administrative penalties; and for determining content of other Department orders. Proceedings held under the Radiation Control Act will be governed by the Rules of Practice and Procedure of the Department of Health and Human Services, 184 NAC 1.
9. Establishes the fees for registration, other regulatory services and provide for their payment.

21-001.03 The use of x-ray equipment for the intentional exposure of individuals for dental diagnosis or treatment will be by or under the supervision of one licensed to practice dental healing arts in Nebraska. The registrant will assure that the requirements of 180 NAC 21 are met in the operation of such dental radiation generating equipment.

21-001.04 The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Rev. Stat. §§ 71-3501 to 71-3520.

21-001.05 Part 21 Code of Federal Regulations (CFR) as published on April 1, ~~2004~~2014 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

21-002 DEFINITIONS: As used in 180 NAC 21, these terms have the definitions set forth below:

Absorbed dose means the energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE and dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI Unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Act means Radiation Control Act Neb. Rev. Stat. §§ 71-3501 to 71-3520.

Adult means an individual 18 or more years of age.

Air Kerma see [Kerma]

Applicant means a person seeking a certificate of registration or a person's certification to use radiation sources issued under the provisions of the Act and these rules.

As low as is reasonably achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and registered sources of radiation in the public interest.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

Background radiation means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the registrant. Background radiation does not include sources of radiation from radioactive materials regulated by the Department.

Barrier ~~({~~[See “Protective barrier”]~~)~~.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Beam quality (diagnostic x-ray) is a term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kVp and filtration.

Certificate of Registration means a document issued pursuant to the Act and rules promulgated thereunder.

Certified equipment means equipment that has been certified in accordance with Title 21, Code of Federal Regulations.

CFR means Code of Federal Regulations.

Civil penalty means any monetary penalty levied on a licensee or registrant because of violations of statutes, rules, regulations, licenses or registration certificates, but does not include criminal penalties.

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

Continuous pressure switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.

Declared pregnant woman means a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Deep dose equivalent (DDE) (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

Deliberate misconduct means an intentional act or omission by a person that (a) would intentionally cause a licensee, registrant, or applicant for a license or registration to be in violation of any rule, regulation, or order of or any term, condition or limitation of any license or registration issued by the Department under the Radiation Control Act or (b) constitutes an intentional violation of a requirement, procedure, instruction, contract, purchase order, or policy under the Radiation Control Act of a licensee, a registrant, an applicant for a license or registration, or contractor or subcontractor of a licensee, registrant, or applicant for a license or registration.

Dental healing arts means diagnosis, treatment, prescribing, or operation for any disease, pain, deformity, deficiency, injury, or physical condition of the teeth or jaws or adjacent structures.

Dental radiographic equipment is radiation generating equipment that is specifically used for making dental radiographs of the human teeth or tissues or the oral cavity. Dental radiographic equipment does not include dental tomography, dental computed tomography, cone beam dental computed tomography, dental fluoroscopic equipment, rotating anode tube radiation generating equipment or other radiation generating equipment.

Dentist means an individual who holds a current Nebraska license to practice dentistry.

Department means the Department of Health and Human Services.

Diagnostic source assembly means the tube housing assembly with a beam limiting device attached.

Director means Director of the Division of Public Health.

Discipline means the imposition by the Department of a sanction, including revocation, suspension, limitation, condition, or civil penalty.

Dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of 180 NAC 21, radiation dose is an equivalent term.

Dose equivalent (H_t) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

Dose limits means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, limits is an equivalent term.

Embryo/fetus means the developing human organism from conception until the time of birth.

Enforcement Conference is a meeting held by the Department with registrant management to discuss safety, safeguards, or environmental problems; the registrant's compliance with regulatory, or registration condition requirements; a registrant's proposed corrective measures (including, but not limited to, schedules for implementation); and enforcement options available to the Department.

Entrance exposure means the exposure expressed in roentgens (R), measured in air with the specified technique, calculated or adjusted to represent the exposure at the point where the center of the useful beam enters the patient.

Exposure means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg).

Exposure rate means the exposure per unit of time, such as roentgen per minute (R/min) or milliroentgen per hour (mR/h).

Extremity means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to preferentially absorb selected radiations.

Gray (Gy) means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray [1 Gy=1 rad].. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Hearing is a proceeding to examine an application or other matter before the Department in order to receive information or to adjudicate rights, duties, or privileges.

Hearing Examiner means a person selected by the Director of the Division of Public Health to conduct hearings.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" must mean the preselected portion of the device.

Individual means any human being.

Individual monitoring means the assessment of dose equivalent by the use of individual monitoring devices or by the use of survey data.

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, termoluminescence dosimeters (TLD's), and pocket ionization chambers. For the purposes of these regulations, personnel dosimeter and dosimeter are equivalent terms.

Inspection means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department. The registrant is notified of any items of noncompliance and/or recommendation of the Department.

Interim inspection means an examination by the Department of information submitted by the registrant on a form provided by the Department.

Kerma means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged participles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

kV means kilovolts.

kVp ~~{~~[See Peak tube potential]~~}~~.

Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation means radiation emanating from the diagnostic source assembly except for:

1. The useful beam; and
2. Radiation produced when the exposure switch or timer is not activated.

Lens dose equivalent(LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

Limits ~~([~~ See Dose limits ~~])~~

Member of the public means any individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Mobile services means the utilization of radiation generating equipment in temporary locations for limited time periods. The radiation generating equipment may be fixed inside a mobile van or transported to temporary locations.

Mobile x-ray equipment ~~({~~[See X-ray equipment]~~})~~.

Monitoring means the measurement of radiation to evaluate potential exposures and doses. For the purposes of 180 NAC 21 radiation monitoring and radiation protection monitoring are equivalent terms.

Notice of Violation is a written statement of one or more infringements of a legally binding requirement. The notice normally requires the registrant to provide a written statement describing:

1. Corrective steps taken by the registrant, and the results achieved;
2. Corrective steps to be taken to prevent recurrence; and
3. The projected date for achieving full compliance.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from sources of radiation, whether in the possession of the registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Title 180, from voluntary participation in medical research programs, or as a member of the public.

Order means a specific directive contained in a legal document issued by the Department.

Party is a person designated as such by the Hearing Examiner. A party may consist of the following:

1. The Department;
2. An applicant/registrant; and
3. Any person affected.

Patient means an individual subjected to dental healing arts examination, diagnosis, or treatment.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Person means any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

Personnel dosimeter ~~{~~[See Individual monitoring devices]~~}~~.

Personnel monitoring equipment ~~{~~[See Individual monitoring devices]~~}~~.

PID [See Position indicating device]

Position indicating device (PID) means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Portable x-ray equipment ~~{~~[See X-ray equipment]~~}~~.

Preliminary Report is a document prepared by the Department containing:

1. A statement of facts on which the Department bases the conclusion that a violation has occurred;
2. Recommendations that an administrative penalty be imposed on the person charged; and
3. Recommendations for the amount of that proposed penalty.

Primary protective barrier ~~{~~[See Protective barrier]~~}~~.

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

Primary protective barrier means the material, excluding filters, placed in the useful beam;

Secondary protective barrier means a barrier sufficient to attenuate the stray radiation to the required degree.

Public dose means the dose received by a member of the public from exposure to sources of radiation released by a registrant, or to any other source of radiation under the control of a registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Title 180, or from voluntary participation in medical research programs.

Public Hearing means a proceeding which will be open to the public, for the purpose of hearing testimony or receiving written statements from any person who chooses to offer information on the subject matter set for hearing, conducted after notice to the public of the time, date, and place of the hearing.

Rad means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

Radiation means ionizing and nonionizing radiation as follows:

(a) Ionizing radiation means gamma rays, x-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other atomic or nuclear particles or rays, but does not include sound or radiowaves or visible, infrared, or ultraviolet light; and
(b) Nonionizing radiation means (i) any electromagnetic radiation which can be generated during the operations of electronic products to such energy density levels as to present a biological hazard to occupational and public health and safety and the environment, other than ionizing electromagnetic radiation, and (ii) any sonic, ultrasonic, or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and to such energy density levels as to present a biological hazard to occupational and public health and safety, and the environment.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation Dose ~~{~~[See "Dose]~~}~~

Radiation generating equipment means any manufactured product or device, component part of such a product or device, or machine or system which during operation can generate or emit radiation except devices which emit radiation only from radioactive material. Radiation generating equipment in 180 NAC 21 refers to only dental radiographic equipment.

Radiation Safety Officer (RSO) means an individual who has the knowledge of and the authority and responsibility to apply appropriate radiation protection regulations, and practices, who is specifically named on a certificate of registration, and who is the primary contact with the Department.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Registrant means any person who is registered with the Department and is legally obligated to register with the Department pursuant to Title 180 or the Act.

Registration means registration with the department pursuant to the Radiation Control Act and in accordance with the regulations adopted by the Department.

Rem means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

Restricted area means an area, access to which is limited by the registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction. ~~(See "Direct scattered radiation").~~

Secondary protective barrier ~~({~~[See "Protective barrier"]~~})~~.

Severity level means a classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety or the environment.

Shallow dose equivalent (SDE) (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeters ($7mg/cm^2$).

SI means the abbreviation for the International System of Units.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

Sources of radiation means any radioactive material, any radiation-generating equipment or any device or equipment emitting or capable of emitting radiation or radioactive material.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Source-to-skin distance means the distance from the source to the skin of the patient.

Special Units means the conventional units historically used by registrants, i.e. rad (absorbed dose), and rem (dose equivalent).

Stationary x-ray equipment ~~({~~[See X-ray equipment]~~})~~.

Stray radiation means the sum of leakage and scattered radiation.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or disposal or radiation generating equipment.

When appropriate, such evaluation includes, but is not limited to, tests, physical examinations of location of equipment or radiation generating equipment, and measurements of levels of radiation present, and evaluation of administrative and/or engineered controls.

Technique Chart means the chart that provides all necessary generator control settings and geometry needed to make clinical radiographs.

Technique factors means the conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
3. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Total effective dose equivalent (TEDE) means the sum of the dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Traceable to a national standard indicates that a quantity or a measurement has been compared to a national standard, for example, the National Institute of Standards and Technology, directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Unrestricted area means an area, access to which is neither limited nor controlled by the registrant. For purposes of these regulations, uncontrolled area is an equivalent term.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Violation means an infringement of any rule, registration condition, order of the Department, or any provision of the Act.

Whole body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

Worker means an individual engaged in work under a registration issued by the Department and controlled by a registrant, but does not include the registrant.

X-ray exposure control means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timer and back-up timers.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the focus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays, including but not limited to an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system must be considered integral parts of the system.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

Year means the period of time beginning in January used to determine compliance with the provisions of Title 180. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

21-003 EXEMPTIONS

21-003.01 General Provision: The Department may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of 180 NAC 21 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

21-003.02 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (5 μSv) per hour at 5 cm from any accessible surface of such equipment. The production, testing or factory servicing of such equipment will not be exempt.

21-003.03 Dental radiation generating equipment while in transit or storage incident thereto are exempt from the requirements of 180 NAC 21. This exemption does not apply to the providers of dental radiation generating equipment for mobile services. Facilities that have placed all dental radiation generating equipment in storage, including storage in place, and have notified the Department in writing, are exempt from the requirements of 180 NAC 21. This exemption is void if any radiation machine is energized resulting in the production of radiation.

21-003.04 Inoperable dental radiation generating equipment is exempt from the requirements of 180 NAC 21. For the purpose of 180 NAC 21, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

21-003.05 Financial institutions that take possession of dental radiation generating equipment as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in 180 NAC 21 to the extent that they demonstrate that the radiation machine is operable for the sole purpose of selling, leasing or transferring.

21-003.06 No individual monitoring will be required for personnel operating only dental radiation generating equipment for dental diagnostic purposes.

21-003.07 Individuals who are sole practitioners and sole operators and the only occupationally exposed individual are exempt from the requirements of 180 NAC 21-007.03, 21-007.04C and 21-007.05B and C.

21-004 GENERAL PROVISIONS

21-004.01 Communications

1. All communications and reports concerning 180 NAC 21, and applications filed thereunder, should be addressed to the Department at its office:

   Department of Health and Human Services
   Division of Public Health
   Radiological Health
   301 Centennial Mall South
   P.O. Box 95026
   Lincoln, Nebraska 68509-5026

2. Documents received by the Department will be deemed to have been received on the date of the postmark, telegram, FAX, or electronic media transmission.

21-004.02 Discrimination Prohibited: The Department must not exclude any person on the ground of sex from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity registered by this Department. This provision will be enforced through provisions established, with respect to racial and other discrimination, under the Nebraska Fair Employment Act. This remedy is not exclusive,

however, and will not prejudice or cut off any other legal remedies available to a discriminate.

21-004.03 Citizenship Attestation: All applicants and renewals for registration or licensure must: Attest that the applicant is a citizen of the United States or a qualified alien under the Federal Immigration and Nationality Act, for the purpose of complying with Neb. Rev. Stat. §§Stat. 4-108 through 4-114. The applicant must provide his/her immigration status and alien number, and agree to provide a copy of his/her United States Citizenship and Immigration Services (USCIS) documentation upon request. If a corporation or other separate legal entity, this section does not apply.

21-005 FEES

21-005.01 Initial Application Fee: Each application for a Certificate of Registration will be accompanied by a non-refundable fee as specified in 180 NAC 21-005.05. No application will be accepted for filing or processing prior to full fee payment or the application will be returned to the applicant.

21-005.02 Annual Fee for Certification of Registration: A non-refundable fee as specified in 180 NAC 21-005.05 must be paid in full each year on or before the last day of the expiration anniversary month of the certificate of registration.[1]

21-005.03 An Application for Amendment: If a new piece of equipment is purchased during the year an additional fee will be prorated as follows:

1. The prorated costs will be based on monthly intervals and will be charged from the first day of the month the amendment is effective until the end of the current billing period.
2. The Department will bill the registrant the additional fee.

The replacement of part(s) for an existing radiation machine or replacement of an existing machine will not result in an additional fee.

21-005.04 Reciprocity Fees: Each application for reciprocal recognition of an out-of-state registration must be accompanied by the applicable annual fee, provided that no such fee has been submitted within 12 months of the date of commencement of the proposed activity.

21-005.05 Initial Application and Annual Fees

Dental Radiation Generating Equipment	Fee Per Unit
1. Dental Diagnostic	$70.00
2. Reciprocity (Registration of out-of-state radiation	

[1]Example: If the certificate of registration expires on June 30, 2007, annual fees are due on or before June 30, of each year.

Generating equipment brought into Nebraska for
Temporary use). $70.00

21-005.06 Method of Payment: Fee payments will be made payable to: Nebraska Department of Health and Human Services

Send to: Department of Health and Human Services
Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026.

21-005.07 Failure to Pay Prescribed Fees

21-005.07A In any case where the Department finds that an applicant for a certificate of registration has failed to pay the fee, the Department will not process that application until the fee is paid.

21-005.07B In any case where the Department finds that a registrant has failed to pay a fee by the due date, the Department may implement the appropriate compliance procedures.

21-006 REGISTRATION OF DENTAL RADIATION GENERATING EQUIPMENT:

21-006.01 Application for Registration: Each person having dental radiation generating equipment must:

1. Apply for registration of such facility with the Department within 30 days following the commencement of the operation of a dental radiation generating equipment facility. Application for registration must be completed on form NRH-4 furnished by the Department and must contain all the information required by the form NRH-4 and accompanying instructions.
2. Designate on the application form an individual to be responsible for radiation protection. A radiation safety officer will be designated on the application form. The radiation safety officer will carry out the responsibilities of 180 NAC 21-007.01B. ~~The dental radiation generating equipment of the applicant must be operated by personnel per Nebraska Practice of Dentistry~~ Neb. Rev. Stat. ~~§§ 71-183.01 (9) and 71-193.17 and in such a manner as to minimize danger to public health and safety~~
3. An application for use of a dental radiation generating equipment must be signed by the applicant and the radiation safety officer if the radiation safety officer is someone other than the applicant.
4. The Department may at any time after the filing of the original application require further statements in order to enable the Department to determine whether the certification of registration should be issued or denied.
5. An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities. If an application includes a request for an additional authorization other than use of a dental

radiation machine, compliance with other applicable chapters of Title 180 NAC will be required.

6. Each application for a certificate of registration will be accompanied by the fee prescribed in 180 NAC 21-005.
7. The applicant's proposed dental radiation generating equipment, facilities, and operating and safety procedures must be adequate to minimize danger to occupational and public health and safety.
8. Each registrant must prohibit any person from furnishing radiation generating equipment servicing or services as described in 180 NAC 2-005.04 to his/her radiation generating equipment facility until such person provides evidence that s/he has been registered with the Department as a provider of services in accordance with 180 NAC 2-005.

21-006.02 Issuance of Certificate of Registration

21-006.02A Upon a determination that an applicant meets the requirements of the regulations, the Department will issue a Certificate of Registration.

21-006.02B The Department may incorporate in the Certificate of Registration at the time of registration or thereafter by rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of dental radiation generating equipment, radiation source servicing, radiation measurements and/or services it deems appropriate or necessary in order to:

1. Minimize danger to occupational and public health and safety;
2. Require additional records and the keeping of additional records as may be appropriate or necessary; and
3. Prevent loss or theft of dental radiation generating equipment subject to 180 NAC 21.

21-006.03 Specific Terms and Conditions of Certificates of Registration

21-006.03A Each certificate of registration issued in accordance to 180 NAC 21 will be subject to the applicable provisions of the Nebraska Radiation Control Act, Neb. Rev. Stat. §§ 71-3501 to 17-3520 now or hereafter in effect, and to the applicable rules and order of the Department.

21-006.03B No certificate of registration issued or granted under 180 NAC 21 will be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the Department authorizes the transfer in writing.

21-006.03C Each person registered by the Department for dental radiation generating equipment use in accordance with 180 NAC 21 will confine use and possession of the dental radiation generating equipment registered to the locations and purposes authorized in the certificate of registration.

21-006.03D The registrant is responsible for complying with 180 NAC 21 and the conditions of the Certificate of Registration.

21-006.04 Responsibilities of the Registrant

21-006.04A The registrant will notify the Department in writing within 30 days of any change which would render the information contained in the application for registration no longer accurate.

21-006.04B The following criteria applies to the loaner dental radiation generating equipment and dental radiation generating equipment used for clinical trial evaluations:

1. Dental radiation generating equipment used for clinical trial evaluations and loaner or demonstration dental radiation generating equipment may be used for up to 60 days without adding the dental radiation generating equipment to an existing certificate of registration. If the use period will exceed 60 days, the facility will be required to add the dental radiation generating equipment to their certificate of registration and a fee will be assessed. Dental radiation generating equipment must be registered in accordance with 180 NAC 21-006.

2. No fees will be assessed for the operation of dental radiation generating equipment for clinical trial evaluations or loaner or demonstration dental radiation generating equipment used for a period of 60 days or less at a facility with a current certificate of registration.

21-006.04C The following applies to voluntary or involuntary petitions for bankruptcy:

1. Each registrant will notify the Department, in writing, immediately following the filing of voluntary or involuntary petition for bankruptcy.
2. The notification specified in 180 NAC 21-006.04C, item 1. will include the bankruptcy court in which the petition for bankruptcy was filed; and the date of the filing of the petition.
3. A copy of the “petition for bankruptcy” must be submitted to the Department along with the written notification.

21-006.04D Receipt, transfer, and disposal of dental radiation generating equipment. The registrant will ensure that records of receipt, transfer, and disposal of dental radiation generating equipment are made and/or maintained for each unit of dental radiation generating equipment. Records or receipt, transfer, and disposal of dental radiation generating equipment will include the following:

1. Manufacturer’s name and model and serial number from the control panel; and
2. Date of the receipt, transfer, and disposal.

21-006.04E Approval not implied: No person, in any advertisement, will refer to the fact that s/he or his/her facility is registered with the Department pursuant to the provision of 180 NAC 21-006, and no person will state or imply that any activity under such registration has been approved by the Department.

21-006.04F Inventory

21-006.04F1 Each registrant will annually inventory all dental radiation generating equipment possessed. The inventory will include the manufacturer's name, model, and serial number of the control panel and will be made and maintained for inspection by the Department in accordance with 180 NAC 21-009.01.

21-006.04F2 Notification is required within 30 days of any change of dental radiation generating equipment inventory. This includes installation or removal and the disposition of any equipment disposed of or transferred. The assembler's notification of installation may be accepted in lieu of notification by the registrant. This does not relieve the registrant of the responsibility to assure that proper notification has been made.

21-006.05 Expiration of Certificates of Registration

21-006.05A Except as provided by 180 NAC 21-006.07B, each certificate of registration will expire annually on the anniversary of the date issued. Expiration does not relieve the registrant of the requirements of 180 NAC 21.

21-006.05B If a registrant does not renew the certificate of registration per 180 NAC 21-006.01, the registrant will on or before the expiration date on the certificate of registration:

1. Terminate use of all dental radiation generating equipment;
2. Submit a record of disposition of the dental radiation generating equipment; and
3. Pay any outstanding fees per 180 NAC 21-005.

21-006.06 Termination of Certificates of Registration: When a registrant decides to terminate all activities involving dental radiation generating equipment authorized under the certification of registration, the registrant must notify the Department immediately and:

1. Request termination of the certificate of registration in writing;
2. Submit a record of disposition of the dental radiation generating equipment; and
3. Pay any outstanding fee per 180 NAC 21-005.

21-006.07 Renewal of Certificate of Registration

21-006.07A Application for renewal of registration will be filed in accordance with 180 NAC 21-006.01.

21-006.07B In any case in which a registrant has filed an application in proper form for renewal, the existing certificate of registration will not expire until the application has been finally determined by the Department.

21-006.08 Reciprocal Recognition of Out-of State Certificate of Registration: Whenever any radiation generating equipment which is registered in another state or by the federal government is to be brought into the State, it must be registered by this Department.

21-006.09 Application for Registration of Mobile Services Used in Dentistry: In addition to the requirements of 180 NAC 21-006.01, each applicant will apply for and receive authorization for mobile services before beginning mobile service operation. The following will be submitted:

1. An established main location where the equipment, records, etc. will be maintained for inspection. This will be a street address, not a post office box number.
2. A sketch or description of the normal configuration of each dental radiation generating equipment unit's use, including the operator's position and any ancillary personnel's location during exposure. If a mobile van is used with a fixed dental radiation generating equipment unit inside, furnish the floor plan indicating protective shielding and the operator's location.
3. A current copy of the applicant's operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the general public.

21-007 REQUIREMENTS

21-007.01 Administrative Controls

21-007.01A Registrant: The registrant must be responsible for directing the operation of the x-ray system(s) under his/her administrative control. The registrant or the registrant's agent must assure that the requirements listed as follows are met in the operation of the x-ray system(s):

1. An x-ray system which does not meet the provisions of Title 180 must not be operated for diagnostic purposes.
2. Registrants must assure that individuals who will operate dental x-ray systems are authorized under Neb. Rev. Stat. §38-11~~30~~15 to practice dentistry,~~ and~~ or 38-1131 to practice as dental hygienists or ~~and~~ § 38-1135 to practice as a dental assistant. ~~s who meet the requirements of Neb. Rev. Stat. § 38-1135.~~
3. A technique chart relevant to the particular x-ray machine must be provided or electronically displayed in the vicinity of the control panel and used by all operators.
4. Individuals must not be exposed to the useful beam except for dental healing arts purposes and unless the exposure has been ordered by a dentist. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing arts purpose.

21-007.01B Radiation safety officers responsibilities are:

1. Preparing operating and safety procedures and keeping them updated;
2. Informing this Department of lost or stolen dental radiation generating equipment or overexposures;
3. Knowing policies and procedures;
4. Stopping unsafe practices;
5. Keeping records;
6. Training employees; and
7. ~~Making~~ Insuring sure that 180 NAC 21 is followed.

21-007.01C Information and Maintenance Record and Associated Information: The registrant must maintain the following information for each x-ray system for inspection by the Department:

1. Model and serial numbers of all certifiable components, and user's manuals for those components;
2. Tube rating charts and cooling curves;
3. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and
4. A copy of all correspondence with this Department regarding that x-ray system.

21-007.01D The registrant must maintain control of registered dental radiation generating equipment that are in an unrestricted area and that are not in storage.

21-007.02 ALARA: The registrant must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

21-007.03 Operating and Safety Procedures:

21-007.03A Each registrant must have and implement written operating and safety procedures. These procedures must be made available to each individual operating a dental radiation generating machine, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. These procedures must include, but are not limited to, the following procedures as applicable:

1. Use of a technique chart in accordance with 180 NAC 21-007.01A, item 3
2. Radiation dose requirements in accordance with 180 NAC 21-007.04A and B
3. Holding of patients or film in accordance with 180 NAC 21-007.09B and E
4. Film processing program in accordance with 180 NAC 21-007.12 and/or 180 NAC 21-007.13
5. Posting notices to worker in accordance with 180 NAC 21-007.05B

6. Instructions to workers in accordance with 180 NAC 21-007.04C
7. Notification and reports to individuals in accordance with 180 NAC 21-008.02D
8. Ordering x-ray exams in accordance with 180 NAC 21-007.01A, item 4

21-007.03B The registrant must at intervals not to exceed 12 months, review the operating and safety procedures.

21-007.04 Personnel Requirements

21-007.04A Occupational limits

21-007.04A1 The registrant must control the occupational dose to individual adults to the following dose limits:

1. An annual limit, total effective dose equivalent being equal to 0.05 Sv (5 rem).

2. The annual limits to the lens of the eye, to the skin of the whole body, and to skin of the extremities which are:

   a. An lens dose equivalent of 0.15 Sv (15 rem), and
   b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

21-007.04A2 The registrant must ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem).

1. The registrant must make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 180 NAC 21-007.04A2.[2]
2. If by the time the woman declares pregnancy to the registrant, the dose equivalent to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the registrant must be deemed to be in compliance with 180 NAC 21-007.04A2 if the additional dose to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

21-007.04A3 Occupational Dose Limits for Minors: The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in 180 NAC 21-007.04A1.

[2]The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 116 "Limitation of Exposure to Ionizing Radiation" (March 31, 1993) that no more than 0.5 mSv (0.05 rem) to the embryo\fetus be received in any one month.

21-007.04A4 The assigned deep dose equivalent and shallow dose equivalent must be for the portion of the body receiving the highest exposure.

21-007.04A5 The deep dose equivalent, lens-dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

21-007.04A6 The registrant must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

21-007.04B Dose limits for individual members of the public

21-007.04B1 Each registrant must conduct operations so that:

1. The total effective dose equivalent to individual members of the public from exposure to radiation from radiation generating machines does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in authorized medical research programs; and
2. The dose in any unrestricted area from external exposure to radiation from radiation generating equipment does not exceed 0.02 mSv (0.002 rem) in any one hour.

21-007.04B2 If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

21-007.04B3 The Department may impose additional restrictions on radiation levels in unrestricted areas.

21-007.04C Instruction to workers:The registrant must provide instructions to radiation workers prior to beginning initial work in restricted areas. These instructions will include the following:

1. Precautions or procedures to minimize exposure;
2. The applicable provisions of Department requirements and certificates of registration for the protection of personnel from exposures to radiation occurring in such areas; and
3. The radiation worker's responsibility to report promptly to the registrant any condition that may constitute, lead to, or cause a violation of Department requirements or certificate of registration conditions, or unnecessary exposure to radiation.

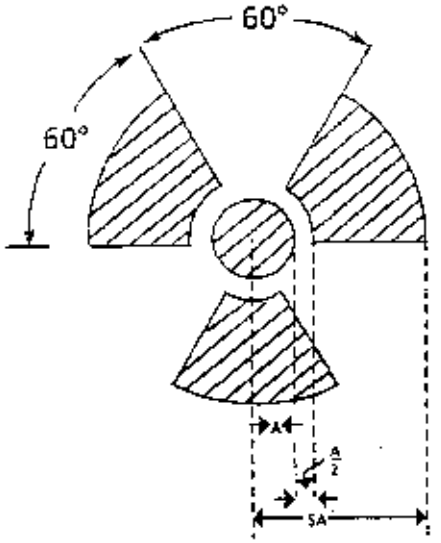
21-007.05 Facility Requirements

21-007.05A Caution Signs

21-007.05A1 Standard Radiation Symbol: Unless otherwise authorized by the Department, the symbol prescribed by 180 NAC 21-007.05 must use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



21-007.05A2 Exception to Color Requirements for Standard Radiation Symbol: Notwithstanding the requirements of 180 NAC 21-007.05A1, registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

21-007.05A3 Additional Information on Signs and Labels: In addition to the contents of signs and labels prescribed in 180 NAC 21, the registrant must provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

21-007.05B Posting of notices to workers

21-007.05B1 Each registrant must post current copies of the following documents:

1. The regulations - 180 NAC 21;
2. The certificate of registration;
3. The operating procedures applicable to activities under the registration; and
4. Any notice of violation involving radiological working conditions, proposed, imposition of civil penalty, or order issued pursuant to 180 NAC 21-010 and any response from the registrant.

21-007.05B2 If posting of a document specified in 180 NAC 21-007.05B1, item 1, 2., or 3. is not practicable, the registrant may post a notice which describes the document and states where it may be examined.

21-007.05B3 Department documents posted pursuant to 180 NAC 21-007.05B1, item 4., must be posted within two working days after receipt of the documents from the Department; the registrant's response, if any, must be posted within two working days after dispatch from the registrant. The documents must remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

21-007.05B4 Documents, notices or forms posted pursuant to 180 NAC 21-007.05B must appear in a sufficient number of places to permit individuals engaged in work under the registration to observe them on the way to or from any particular work location to which the document applies, must be conspicuous, and must be replaced if defaced or altered.

21-007.05C Notice to employees: Department Form NRH-3, "Notice to Employees" must be posted by each registrant wherever individuals work in or frequent any portion of a restricted area.

21-007.05D Registrants required to have tests performed per 180 NAC 21-007.10 must select any qualified person authorized by registration through the Department.

21-007.06 Dental Radiation Machine Requirements

21-007.06A Technique Indicators

21-007.06A1 The technique factors to be used during an exposure must be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure must be indicated.

21-007.06A2 The requirement of 180 NAC 21-007.06A may be met by permanent markings on equipment having fixed technique factors.

21-007.06A3 Means must be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated.

21-007.06A4 The indicated technique factors must be accurate to within manufacturer's specification. If these specifications are not available from the manufacturer, the factors must be accurate to within ±10% of the indicated setting.

21-007.06B Warning Label: The control panel containing the main power switch will bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

21-007.06C Mechanical Support of Tube Head: The tube housing assembly support must be adjusted such that the tube housing assembly will remain stable during the exposure, unless the tube housing movement is a designed function of the x-ray system or ~~it's~~its supports. ~~and t~~The position indicating device must not be hand held.

21-007.06D Battery Charge Indicator: On battery-powered x-ray generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

21-007.06E Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source must not exceed 0.88 milligray (mGy) air kerma (100 milliroentgens (mR) exposure)) ~~25.8 uC/kg(100 milliroetgens)~~ in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means must be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

21-007.06F Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly will not exceed an air kerma of 18 microgray (2 milliroentgens exposure) ~~2 milliroentgens (0.516 uC/kg)~~ in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance will be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

21-007.06G Timer

21-007.06G1 The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer

accuracy must be ±10% of the indicated time with testing performed at 0.5 second.

21-007.06G2 Means must be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it must not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

21-007.06H Exposure Reproducibility: When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems will not exceed 0.05. This requirement applies to clinically used techniques.

21-007.06I Kilovolt Peak: If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine must meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak must be accurate to within ± 10% of the indicated setting(s). For dental radiation generating equipment with fewer than three fixed kilovolt peak settings, the radiation machine will be checked at those settings.

21-007.06J Tube Stability: The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant will assure proper and free movement of the dental radiation generating equipment.

21-007.06K Collimation: Field limitation must meet the requirements of 180 NAC 21-007.07 or 180 NAC 21-007.08.

21-007.06L kVp Limitations: Dental x-ray radiation generating equipment with a nominal fixed kVp of less than 50 kVp must not be used to make diagnostic dental radiographs of humans.

21-007.06M Beam Quality

21-007.06M1 Half-value Layer

1. The half-value layer of the useful beam for a given x-ray tube potential must not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. Positive means must be provided to ensure that at least minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter

interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE I		
Design Operating Range	Measured Potential (kVp)	Half-value Layer in mm Aluminum
Below 51	30	N/A
	40	N/A
	50	1.5
51 to 70	51	1.5 (1.2)*
	60	1.5 (1.3)*
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1
\1\ Dental intra-oral x-ray systems manufactured on or before December 1, 2006.		

2. For capacitor energy storage equipment, compliance with the requirements of 180 NAC 21-007.06F must be determined with the system fully charged.

21-007.06M2 Filtration Controls: For x-ray systems which have variable kVp and variable filtration for the useful beam, a device will link the kVp selector with the filter(s) and will prevent an exposure unless the minimum amount of filtration required by 180 NAC 21-007.06M, item 1 is in the useful beam for the given kVp which has been selected.

21-007.06M3 Any other system having removable filters will be required to have the minimum amount of filtration as required by 180 NAC 21-007.06M1, item 1 permanently located in the useful beam during each exposure.

21-007.06N Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected will be clearly indicated prior to initiation of the exposure. This indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

21-007.06O Maintaining Compliance: Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020.30 and 1020.31) must be maintained in compliance with applicable requirements of that standard.

21-007.06P X-ray Control: An x-ray control will be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less. Each x-ray control will be located in such a way as to permit the operator to remain in an area of less than 2 millirem in any one hour during the entire exposure. The exposure switch will be of the continuous pressure type.

21-007.06Q Security and Control of Dental Radiation Generating Equipment

21-007.06Q1 The registrant must secure dental radiation generating equipment from unauthorized removal.

21-007.06Q2 The registrant must use devices and/or administrative procedures to prevent unauthorized use of dental radiation generating equipment.

21-007.06R Certified Dental Radiation Generating Equipment for Dental Facilities: In addition to the requirements of 180 NAC 21, the registrant must not make, nor cause to be made, any modification of components or installations of components certified in accordance with the United States Food and Drug Administration Title 21, CFR, Part 1020.30 & 1020.31, "Performance Standards for Ionizing Radiation Emitting Products," as amended, in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in Title 21, CFR, Part 1020.30 and 1020.31, except where a variance has been granted by the Director, Center for Devices and Radiological Health, United States Food and Drug Administration. A copy of the variance must be maintained by the registrant in accordance with 180 NAC 21-009.21 for inspection by the Department.

21-007.07 Additional requirements for dental intraoral systems: In addition to the provisions of 180 NAC 21, the requirements of 180 NAC 21-007.07 apply to x-ray equipment used for dental intraoral radiography.

21-007.07A Source-to-Skin Distance (SSD): X-ray systems designed for use with an intraoral image receptor must be provided with means to limit the SSD.

~~1. 18 centimeters if operable above 50 kVp, or~~
~~2. 10 centimeters if not operable above 50 kVp~~

21-007.07B Beam Limitation:

21-007.07B1 Radiographic systems designed for use with an intraoral image receptor must be provided with means to limit the x-ray beam such that the

beam at the minimum SSD must be containable in a circle having a diameter of no more than 7 centimeters.

21-007.07B2 If the minimum source-to-skin distance is less than 18 centimeters, the x-ray field at the minimum source-to-skin distance will be restricted to a dimension of no more than 6 centimeters.

~~21-007.07B1 Radiographic systems designed for use with an intraoral image receptor must be provided with means to limit the x-ray beam such that the beam at the minimum SSD must be containable in a circle having a diameter of no more than 7 centimeters.~~

~~21-007.07B2 If the minimum source-to-skin distance is less than 18 centimeters, the x-ray field at the minimum source-to-skin distance will be restricted to a dimension of no more than 6 centimeters.~~

21-007.08 Additional Requirements for Dental Extraoral System

21-007.08A Field limitation: Dental rotational panoramic systems must be provided with means to restrict the x-ray beam to the following:

1. The imaging slit in the transverse axis;
2. No more than a total of 0.5 inches larger than the imaging slit in the vertical axis;

21-007.08B All other dental extraoral radiographic systems (e.g., cephalometric) will be provided with means to restrict the x-ray field to the image receptor. The x-ray field must not exceed the image receptor by more than:

1. 2.0% of the source-to-image receptor distance for the length or width of the image receptor for rectangular collimation; or
2. 2.0% of the source-to-image receptor distance for the diagonal of the image receptor for circular or polygon collimations.

21-007.09 Additional Operational Controls

21-007.09A When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices must be used except in individual cases in which the registrant has determined that the hold devices are contraindicated.

21-007.09B The registrant's written operating and safety procedures required by 180 NAC 21-007.03 will include the following:

1. A list of circumstances in which exceptions to using mechanical holding devices may apply;

2. A procedure used for selecting an individual to hold or support the patient or image receptor; and
3. A procedure the individual must follow when holding or supporting the patient or image receptor.

21-007.09C The operator must stand at least six feet from the useful beam or behind a protective barrier. The operator must maintain verbal, aural, and visual contact with the patient.

21-007.09D The tube housing support must be constructed and adjusted so that the tube housing will not drift from its set position during an exposure. Neither the tube housing nor support housing will be hand-held during an exposure.

21-007.09E Patient and film holding devices must be used when the techniques permit.

21-007.09F The tube housing and the PID (position indicating device) will not be hand-held during an exposure.

21-007.10 Equipment Performance Evaluation

21-007.10A For all dental radiation generating equipment, the registrant must perform, or cause to be performed, tests necessary to assure proper function of equipment with the indicated standard for each item specified in 180 NAC 21-007.06G through K and for dental intraoral systems a measurement of the in-air exposure at the technique factors used for an~~the~~ average adult patient thickness in routine intraoral (bitewing) radiography. After installation, the tests listed must be performed every five years.

21-007.10B Records of the test results, including any numerical readings must be maintained by the registrant in accordance with 180 NAC 21-009.21.

21-007.10C Any items not meeting the specifications of the tests must be corrected or repaired. Correction or repair must begin within 30 days following the check and must be performed according to a plan designated by the registrant. Correction or repair must be completed no longer than 90 days from discovery unless authorized by the Department. Records of corrections or repairs will be maintained by the registrant in accordance with 180 NAC 21-009.21.

21-007.10D Measurements of the radiation output of a x-ray system must be performed with a calibrated dosimetry system. The dosimetry system must have been calibrated within the preceding 24 months and the calibration must be traceable to a national standard. During the calendar year in which the dosimetry system is not calibrated, an intercomparison to a system calibrated within the previous 12 months must be performed.

21-007.11 Dental Research: Any research using dental radiation generating equipment on humans must be approved by an Institutional Review Boards required by Title 45, CFR,

Part 46 and Title 21, CFR, Part 56. The Institutional Review Board must include at least one dentist to direct any use of radiation in accordance with 180 NAC 21.

21-007.12 Automatic and Manual Film Processing for Dental Facilities and Mobile Dental Services

21-007.12A Films will be developed in accordance with the time-temperature relationships recommended by the film manufacturer. The specified developer temperature for automatic processing and the time-temperature chart for manual processing will be posted in the darkroom. If the registrant determines an alternate time-temperature relationship is more appropriate for a specific facility, that time-temperature relationship must be documented and posted.

21-007.12B Devices must be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

21-007.12~~B~~C Chemicals must be replaced according to the chemical manufacturer's or supplier's recommendations or at an interval not to exceed three months.

21-007.12~~C~~D The darkroom must be light tight and use a proper safelight in accordance with 21-007.12E ~~Darkroom light leak tests must be performed and any light leaks corrected at intervals not to exceed six months.~~

21-007.12~~D~~E Lighting in the film processing/loading area will be maintained with the filter, bulb wattage, and distances recommended by the film manufacturer for that film emulsion or with products that provide an equivalent level of protection against fogging.

~~21-007.12E Corrections or repairs of the light leaks or other deficiencies in 180 NAC 21-007.12B, C and D will be maintained at the site where performed and will include the date and initials of the individual completing these items. These records will be maintained in accordance with 180 NAC 21-009.21.~~

21-007.13 Alternative Processing Systems: Users of daylight processing systems, laser processors, self-processing film systems, or other alternative processing systems will follow manufacturer's recommendations for image processing. Documentation that the registrant is following manufacturer's recommendations will include the date and initials of the individual completing the document and will be made and maintained at the site where performed in accordance with 180 NAC 21-009.21 for inspection by the Department.

21-007.14 The speed of film or screen and film combinations must be the fastest speed consistent with the diagnostic objective of the examination

21-008 RECORDS AND REPORTS

21-008.01 General Provisions

21-008.01A Each registrant must use the SI units gray, sievert and coulomb per kilogram, or the special units rad, rem, and roentgen, including multiples and subdivisions, and must clearly indicate the units of all quantities on records required by 180 NAC 21.

21-008.01B The registrant must make a clear distinction among the quantities entered on the records required by 180 NAC 21, such as, total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent.

21-008.01C All records required by 180 NAC 21 must be accurate and factual.

21-008.01D Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Records, such as letters, drawings, and specifications, will include all pertinent information, such as stamps, initials, and signatures.

21-008.01E Form of Records: Each record required by 180 NAC 21 must be legible throughout the specified retention period. The record must be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The registrant must maintain adequate safeguards against tampering with and loss of records.

21-008.02 Reports

21-008.02A Reports of Stolen Lost, or Missing or Registered Sources of Radiation

21-008.02A1 Telephone Reports: Each registrant must report to the Department by telephone a stolen, lost or missing radiation machine immediately after its occurrence becomes know to the registrant.

21-008.02A2 Written Reports: Each registrant required to make a report pursuant to 180 NAC 21-008.02B1, item 1 must, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

1. A description of the registered dental radiation generating equipment involved, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
2. A description of the circumstances under which the loss or theft occurred;

3. A statement of disposition, or probable disposition, of the registered dental radiation generating equipment involved;
4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
5. Actions that have been taken, or will be taken, to recover the source of radiation; and
6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of registered sources of radiation.

21-008.02A3 Subsequent to filing the written report, the registrant must also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

21-008.02A4 The registrant must prepare any report filed with the Department pursuant to 180 NAC 21-008.02B1 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

21-008.02B Notification of Incidents

21-008.02B1 Immediate Notification: Notwithstanding other requirements for notification, each registrant must immediately report each event involving dental radiation generating equipment possessed by the registrant that may have caused or threatens to cause any of the following conditions:

1. An individual to receive:

   a. A total effective dose equivalent of 0.25 Sv (25 rem) or more; or
   b. A lens dose equivalent of 0.75 Sv (75 rem) or more; or
   c. A shallow dose equivalent to the skin or extremities of 2.5 Gy (250 rad) or more; or

21-008.02B2 Twenty-Four Hour Notification: Each registrant must, within 24 hours of discovery of the event, report to the Department each event involving loss of control of dental radiation generating equipment possessed by the registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of 24 hours:

   a. A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
   b. A lens dose equivalent exceeding 0.15 Sv (15 rem); or
   c. A shallow dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem); or

21-008.02B3 The registrant must prepare each report filed with the Department pursuant to 180 NAC 21-008.02B2 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

21-008.02B4 Registrants must make the reports required by 180 NAC 21-008.02B1 and 2 by initial contact by telephone to the Department and must confirm the initial contact by telegram, FAX, or electronic media to the Department.

21-008.02C Reports of Exposure and Radiation Levels Exceeding the Limits

21-008.02C1 Reportable Events: In addition to the notification required by 180 NAC 21-008.02B, each registrant must submit a written report within 30 days after learning of any of the following occurrences:

1. Any incident for which notification is required by 180 NAC 21-008.02B; or
2. Doses in excess of any of the following:

    a. The occupational dose limits for adults in 180 NAC 21-007.04A1.; or
    b. The occupational dose limits for a minor in 180 NAC 21-007.04A3; or
    c. The limits for an embryo/fetus of a declared pregnant woman in 180 NAC 21-007.04A2 or
    d. The limits for an individual member of the public in 180 NAC 21-007.04B; or
    e. Any applicable limit in the registration; or

3. Levels of radiation in:

    a. A restricted area in excess of applicable limits in the registration; or
    b. An unrestricted area in excess of 10 times the applicable limit set forth in 180 NAC 21.007.04B, whether or not involving exposure of any individual in excess of the limits in 180 NAC 21-007.04B.

21-008.02C2 Contents of Report

21-008.02C2a Each report required by 180 NAC 21-008.02C1 must describe the extent of exposure of individuals to radiation:

1. Estimates of each individual's dose; and
2. The levels of radiation; and
3. The cause of the elevated exposures, or dose rates; and

4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated registration conditions.

21-008.02C2b Each report filed pursuant to 180 NAC 21-008.02C1 must include for each individual exposed: the name, the individual's ~~Social Security account~~ identification number, and date of birth. With respect to the limit for the embryo fetus in 180 NAC 21-007.04A2, the identifiers should be those of the declared pregnant woman. The report must be prepared so that this information is stated in a separate and detachable portion of the report.

21-008.02C3 All registrants who make reports pursuant to 180 NAC 21-008.02C1 must submit the report in writing to the Department.

21-008.02D Notification and Reports to Individuals

21-008.02D1 If applicable, radiation exposure data for an individual must be reported to the individual as specified in 180 NAC 21-008.02D. The information reported must include data and results obtained pursuant to Title 180, orders or certificate of registration conditions, as shown in records maintained by the registrant pursuant to 180 NAC 21-008. Each notification and report must:

1. Be in writing;
2. Include appropriate identifying data such as the name of the registrant, the name of the individual, and the individual's ~~Social Security account~~ identification number.
3. Include the individual's exposure information; and
4. Contain the following statement:

"This report is furnished to you under the provisions of 180 NAC 21. You should preserve this report for further reference."

21-008.02D2 If applicable, each registrant must furnish each worker annually a written report of the worker's dose as shown in records maintained by the registrant pursuant to 180 NAC 21-008.02C.

21-008.02D3 When a registrant is required pursuant to 180 NAC 21-008.02B and C, to report to the Department any exposure of an individual to sources of radiation, the registrant must also provide the individual a written report on the exposure data included therein. The reports must be transmitted at a time not later than the transmittal to the Department.

21-009 COMPLIANCE PROCEDURES

PRESENCE OF REPRESENTATIVE OF REGISTRANT AND WORKERS DURING INSPECTION

21-009.01 Each registrant must afford to the Department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to 180 NAC 21. The registrant must make available to the Department for inspection records maintained pursuant to 180 NAC 21.

21-009.02 During an inspection, Department inspectors may consult privately with workers as specified in 180 NAC 21-009.08 through 21-009.10. The registrant may accompany Department inspectors during other phases of an inspection.

21-009.03 If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the registrant must notify the inspectors of the authorization and must give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

21-009.04 Each workers' representative must be routinely engaged in work under control of the registrant and must have received instructions as specified in 180 NAC 21-007.04C.

21-009.05 Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

21-009.06 With the approval of the registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative, must be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

21-009.07 Notwithstanding the other provisions of 180 NAC 21-009.01 through 21.009.07, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area must be an individual previously authorized by the registrant to enter that area.

CONSULTATION WITH WORKERS DURING INSPECTIONS

21-009.08 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of the regulations and certificates of registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

21-009.09 During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, 180 NAC 21, or registration condition, or any unnecessary exposure of an individual to sources of radiation under the registrant's control. Any such notice in writing must comply with the requirements of 180 NAC 21-009.11.

21-009.10 The provisions of 180 NAC 21-009.09. must not be interpreted as authorization to disregard instructions pursuant to 180 NAC 21-007.04C.

REQUESTS BY WORKER FOR INSPECTIONS

21-009.11 Any worker or representative of workers who believes that a violation of the Act, 180 NAC 21 or registration conditions exists or has occurred in work under a registration to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. Any such notice must be in writing, must set forth the specific grounds for the notice, and must be signed by the worker or representative of the workers. A copy will be provided to the registrant by the Department no later than at the time of inspection except that, upon the request of the worker giving the notice, his/her name and the name of individuals referred to therein must not appear in the copy or on any record published, released, or made available by the Department, except for good cause shown.

21-009.12 If, upon receipt of the notice, the Department determines that the complaint meets the requirements set forth in 180 NAC 21-009.11, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, s/he must cause an inspection to be made as soon as practicable, to determine if the alleged violation exists or has occurred. Inspections pursuant to 180 NAC 21-009.11, 21-009.12 and 21-009.13 need not be limited to matters referred to in the complaint.

21-009.13 A registrant, or contractor or subcontractor of a registrant must not discharge or in any manner discriminate against any worker because the worker has filed any complaint or instituted or caused to be instituted any proceeding under 180 NAC 21 or has testified or is about to testify in any such proceeding or because of the exercise by the worker on behalf of himself/herself or others of any option afforded by 180 NAC 21.

INSPECTIONS NOT WARRANTED: INFORMAL REVIEW

21-009.14 If the Department determines, with respect to a complaint under 180 NAC 21-009.11 through 21-009.13 that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department will notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position to the Director of the Division of Public Health, who will provide the registrant with a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position to the Director of the Division of Public Health, who will provide the complainant with a copy of the statement by certified mail.

21-009.15 Upon the request of the complainant, the Director of the Division of Public Health, may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Director of the Division of Public Health, will affirm, modify, or reverse

the determination of the Department and furnish the complainant and the registrant a written notification of the decision and the reason therefor.

21-009.16 If the Department determines that an inspection is not warranted because the requirements of 180 NAC 21-009.11 have not been met, the Director of the Division of Public Health will notify the complainant in writing of such determination. The determination must be without prejudice to the filing of a new complaint meeting the requirements of 180 NAC 21-009.11.

21-009.17 The routine inspection interval for dental facilities is five years. On-site inspection and interim inspections may be alternated. Registrant's having certificates of registration authorizing multiple uses will be inspected on-site at the most frequent interval specified for the uses authorized.

21-009.18 Notwithstanding the inspection interval of 180 NAC 21-009.17, the Department may inspect registrants more frequently due to:

1. The persistence or severity of violations found during an inspection;
2. Investigation of an incident or complaint concerning the facility;
3. A request for an inspection by a worker(s) in accordance with 180 NAC 21-009.11 through 21-009.13;
4. Any changes in a facility or dental radiation generating equipment that might cause a significant increase in radiation output or hazard; or

21-009.19 For interim inspection of dental radiation generating equipment, each registrant must:

1. Respond to a request from the Department for a interim inspection;
2. Complete the interim inspection forms (NRH-21) in accordance with the instructions included with the forms; and
3. Return to the Department the completed interim inspection forms with documentation of the most recent equipment performance evaluation performed in accordance with 180 NAC 21-007.10D by the deadline indicated in the notice ~~on the forms~~.

21-009.20 Each registrant must perform, upon instruction from the Department, or must permit the Department to perform such reasonable surveys as the Department deems appropriate or necessary including but not limited to, surveys of:

1. Dental radiation generating equipment;
2. Facilities where dental radiation generating equipment are used; and
3. Other equipment and devices used in connection with utilization or storage of dental radiation generating equipment.

21-009.21 Record/document requirements: Each registrant must maintain the following records/documents at each location and make available to the Department for inspection.

	Name of Records/Document	Regulation Cross-Reference	Time Interval for Keeping Record/Document
I	Inventory of all Dental Radiation Generating Equipment Possessed	180 NAC 21-006.04F	5 Years after records is made
II	Receipt, Transfer, and Disposal of Each Radiation Machine Possessed	180 NAC 21-006.04D	Until termination of registration
III	Current Operating and Safety Procedures	180 NAC 21-007.03	Until termination of registration
IV	Current 180 NAC 21	180 NAC 21-007.05B	Until termination of registration
V	Current Certificate of Registration (NRH-4)	180 NAC 21-007.05B	Until termination of registration
VI	Notice of Violation From Last Inspection	180 NAC 21-007.05B	Until next on-site inspection
VII	Documentation of Corrections of any Violations	180 NAC 21-007.05B	Until next on-site inspection
VIII	Equipment Performance Evaluation Tests	180 NAC 21-009.19	Until next on-site inspection
IX	Automatic and Manual Film Processing Records	180 NAC 21-007.12	1 Year
X	Alternative Film Processing Records	180 NAC 21-007.13	1 Year
XI	United States Food and Drug Administration Variance	180 NAC 21-007.06R	Until transfer of machine or termination of registration

21-010 HEARING AND ENFORCEMENT PROCEDURES - ENFORCEMENT OF RADIATION CONTROL ACT AND RIGHTS TO HEARING PROCEDURES FOR REGISTRANTS; PENALTIES.

21-010.01 Public Hearings: The Department will hold public hearings in any proceeding for the issuance or modification of rules or regulations relating to control of sources of radiation, the Department will provide an opportunity for public participation through written comments and a public hearing.

21-010.02 Right to a Public Hearing: When the Department:

1. Denies:
   a. An application for a license or registration,
   b. An amendment to a license or registration, or
   c. An application for an exemption from license or registration requirements;
2. Revokes, suspends, modifies, conditions, or limits a license or registration; or

3. Imposes a civil penalty or appropriate order.

The Department will provide the applicant or licensee an opportunity for a hearing in accordance with the Department's Rules of Practice and Procedures for Administrative Hearings, adopted pursuant to the Administrative Procedures Act, currently at 184 NAC 1.

21-010.03 Discipline

21-010.03A Any person who violates any provision of the Radiation Control Act, or any rule, regulation, or order issued pursuant to such Act, or any term, condition, or limitation of any registration issued pursuant to such Act or has engaged in deliberate misconduct is subject to:

1. Revocation, denial, suspension, modification, condition or limitation;
2. The imposition of a civil penalty; or
3. The terms of an appropriate order issued by the Department.

21-010.03B Compliance

21-010.03B1 In all instances other than the issuance of emergency sanctions pursuant to 180 NAC 21-010.06, the Department may afford the registrant the opportunity to:

1. Correct violations and show compliance with applicable provisions of the Act, or the rules and regulations, or registration requirements, and any orders of the Department issued thereunder, or
2. Attend an enforcement conference to discuss with the Department methods and schedules for correcting the violation(s) or to show compliance with the Act, rules and regulations and registration conditions. Notice of any enforcement conference will be sent by personal service or certified mail, return receipt requested. An enforcement conference is not a prerequisite for any action.

21-010.03B2 The Department may permit the registrant to respond in writing to the alleged violation of the Act, rule, regulation, order, or any term, conditions of limitation of registration.

21-010.03B3 Failure of a registrant to respond is cause for the Department to proceed with disciplinary action.

21-010.04 Hearings: Whenever the Department proposes to subject a registrant to the provisions of 180 NAC 21-010.03A, the Department will notify the person in writing, (a) setting forth the date, facts, and nature of each act or omission with which the person is charged, (b) specifically identifying the chapter, rule, regulation, order, registration certificate involved in the violation and (c) of the sanction or order to be imposed. If a civil penalty is imposed, the notice will include a statement that it can be collected by civil

action. The notice will be delivered to each alleged violator by personal service, by certified or registered mail to his/her last known address, or by publication. Notice by publication will only be made if personal service or service by mail cannot be effectuated. The sanction or order in the notice will become final 30 days after the mailing of the notice unless the applicant or registrant, within the 30-day period, requests, in writing, a hearing before the department. If the notice is served by personal service or publication, the sanction order will become final 30 days after completion of the service unless the applicant, or registrant, within the 30-day period, requests, in writing, a hearing before the department.

21-010.05 Sanctions

21-010.05A The Department may consider the following:

1. Criteria in determining what sanctions are appropriate:

   a. Previous history of noncompliance;
   b. Action necessary to deter future violations;
   c. Lack of reasonable efforts to correct the violation(s);
   d. Willfulness; and
   e, Any other aggravating factors.

2. The severity levels: The seriousness of violations will be categorized by one of the following severity levels:

   a. Severity Level I - Violations that are most significant and have a direct negative impact on occupational and/or public health and safety or on the environment.
   b. Severity Level II - Violations that are very significant and have an impact on occupational and/or public health and safety or on the environment.
   c. Severity Level III - Violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment.
   d. Severity Level IV - Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances affecting public health and safety.
   e. Severity Level V - Violations that are of minor public health and safety or environmental significance.

21-010.05B Civil Penalties: May impose a civil penalty in an amount not to exceed $10,000 for each violation. If any violation is a continuing one, each day a violation continues may be considered a separate violation for purposes of penalty assessment. Table II provides examples for civil penalties.

TABLE II
Examples of
Civil Penalty Base

Amounts Based on Severity Level of Violations

Severity Level	Amount
I	$5,000
II	$3,000
III	$1,500
IV	$ 500
V	$ 100

Adjustments to the amounts in Table II may be made for the presence of the criteria set out in 180 NAC 21-010.05A, item 1.

21-010.05C Suspension and Revocation of a Registration: In addition to the other factors set out in 180 NAC 21-010, used by the Department to determine appropriateness of registration revocation or suspension, the Department may act to suspend or revoke a registration if a person:

1. Knowingly causes a material misstatement or misrepresentation to be made in the application for registration if such misstatement would impair the Department's ability to evaluate the applicant's qualifications, or
2. Willfully aids another person in violating the Act or these regulations.

21-010.06 Emergency Sanctions: In the event of an emergency requiring immediate action to protect the occupational or public health and safety, or the environment, the Department may immediately, without prior notice or hearing:

1. Issue a regulation or order citing the existence of such emergency and require that certain actions be taken to meet the emergency:

   a. An emergency regulation or order takes effect immediately upon service on the person to whom the order is directed.
   b. Any person receiving such emergency regulation or order must comply immediately.

2. If the Department determines that a person possessing sources of radiation is not equipped to observe or fails to observe the provisions of the Act or these rules and regulations, then the Department may impound or order the impounding of the sources of radiation. Any person receiving an order of impoundment will comply immediately.

3. Service of any regulation order, or other notice or pleading under 180 NAC 21-010 will be made by personal service or by certified mail, return receipt requested. Affidavit of service, proof of mailing to the proper address, or the return receipt is evidence of service.

4. Hearings on Emergency Sanctions

   a. A hearing will be held on an emergency regulation or order pursuant to 180 NAC 21-010.06 item 1 or upon an impoundment or order of impoundment pursuant to 180 NAC 21-010.06 item 2 if the person to whom the regulation or order of impoundment is directed makes a written application to the Department for a hearing; said application must be filed within 15 days of receipt of the emergency regulation or order of impoundment or notice of impoundment.
   b. The hearing must be held not less that 15 days nor more than 30 days after filing the written application for hearing unless waived by the person requesting the hearing.
   c. On the basis of the evidence presented at the hearing, the Department will, within 30 days after such hearing, continue, modify or revoke the emergency regulation or order of~~or~~ impoundment or order of impoundment that was the subject of the hearing, and the Department will send the applicant a copy of its findings of fact and determination.

5. Any final department action on emergency regulations or orders of~~or~~ impoundment of sources of radiation is subject to judicial review pursuant to the Administrative Procedure Act.

21-011 DISPOSITION OF AN IMPOUNDED SOURCE OF RADIATION: Any source of radiation impounded by the Department is declared to be a common nuisance and cannot be subject to a replevin action. Disposal of an impounded source of radiation will be determined by 180 NAC 21-010.07 and Neb. Rev. Stat. §71-3516.01.

21-011.01 The Department will keep any source of radiation impounded under Neb.Rev.Stat. §71-3516~~2516~~ for as long as it is needed as evidence for any hearing.

21-011.02 Prior to the issuance of an order of disposition for an impounded source of radiation, the Department will notify in writing any person, known by the Department to claim an interest in the source of radiation that the Department intends to dispose of the source of radiation. Notice will be served by personal service, by certified or registered mail to the last-known address of the person, or by publication. Notice by publication will only be made if personal service or service by mail cannot be effectuated.

21-011.03 Within 15 days after service of the notice under 180 NAC 21-011.02, any person claiming an interest in the impounded source of radiation may request, in writing, a hearing before the Department to determine possession of the source of radiation. The hearing will be held in accordance with rules and regulations adopted and promulgated by the Department. If the Department determines that the person claiming an interest in the source of radiation has proven by a preponderance of the evidence that such person:

1. Had not used or intended to use the source of radiation in violation of the Radiation Control Act,
2. Has an interest in the source of radiation acquired in good faith as an owner, a lien holder, or otherwise, and
3. Has the authority under the Radiation Control Act to possess such source of radiation, the Department will order that possession of the source of radiation be given to such person. If possession of the impounded source of radiation is not given to the person requesting the hearing, such person may appeal the decision of the Department, and the appeal will be in accordance with the Administrative Procedure Act. If possession of the impounded source of radiation is not given to the person so appealing, the Department will order such person to pay for the costs of the hearing, storage fees, and any other reasonable and necessary expenses related to the impounded source of radiation.

21-011.04 If possession of the impounded source of radiation is not given to the person requesting the hearing under 180 NAC 21-011.03, the Department will issue an order of disposition for the source of radiation and will dispose of the source of radiation as directed in the order. Disposition methods are at the discretion of the Department and may include, but are not limited to:

1. Sale of the source of radiation to a person authorized to possess the source of radiation under the act,
2. Transfer to the manufacturer of the source of radiation, or
3. Destruction of the source of radiation.

The order of disposition will be considered a transfer of title of the source of radiation.

21-011.05 If expenses related to the impounded source of radiation are not paid under 180 NAC 21-011.03, the Department will pay such expenses from:

1. Proceeds from the sale of the source of radiation, if sold; or
2. Available funds in the Department of Health and Human Services Cash Fund.

21-012 DELIBERATE MISCONDUCT

21-012.01 Any registrant, applicant for a registration, employee of a registrant, contractor or subcontractor to a registrant, or applicant for a registration, or employee of any contractor or subcontractor to a registrant, or applicant for a registration, who knowingly provides to any registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a registrant's or applicant's activities covered by the Radiation Control Act, must not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any registration issued by the Department; or

2. Intentionally submit to the Department, a registrant, an applicant, or a registrant's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

21-012.02 Any person who violates 180 NAC 21-012, is subject to the provisions of 180 NAC 21-010.03.

Nebraska Department of Health and Human Services

Form NRH-3
Form NRH-3D
DRAFT Date

Nebraska Department of Health and Human Services
Division of Public Health - Radiological Health, P.O. Box 95026
301 Centennial Mall South
Lincoln, Nebraska 68509-5026

NOTICE TO EMPLOYEES

Standards for Protection Against Radiation; Notices,
Instructions and Reports to Workers; Inspections

In Title 180, Regulations for Control of Radiation, the Nebraska Department of Health and Human Services has established standards for your protection against radiation hazards and has established certain provisions for the options of workers engaged in work under an Department license or registration.

YOUR EMPLOYER'S RESPONSIBILITY:

Your Employer is Required to:

1. Apply these regulations to work involving sources of radiation.

2. Post or otherwise make available to you a copy of Title 180, Regulations for Control of Radiation, Chapter 21 (180 NAC 21) and the operating procedures which apply to work you are engaged in, and explain their provisions to you.

3. Post any Notice of Violation involving radiological working conditions, proposed imposition of civil penalties or orders.

YOUR RESPONSIBILITY AS A WORKER:

You should familiarize yourself with those provisions of 180 NAC 21 and operating procedures which apply to the work in which you are engaged. You should observe their provisions for your own protection and protection of your co-worker.

WHAT IS COVERED BY THESE REGULATIONS:

1. Limits on exposure to radiation in restricted and unrestricted areas;

2. Measures to be taken after accidental exposure;

3. Personnel monitoring, surveys and equipment;

4. Caution signs, labels, and safety interlock equipment;

5. Exposure records and reports; and

6. Options for workers regarding Department Inspections; and

7. Related maters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY:

1. The 180 NAC 21 require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in any license. The basic limits for exposure to employees are set forth in 180 NAC 21-007.04. These sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air.

2. If you work where personnel monitoring is required:

   (a) Upon your request, your employer must give you a written report of your radiation exposures upon termination of your employment; and
   (b) Your employer must advise you annually of your exposure to radiation.

INSPECTIONS:

All licensed or registered activities are subject to inspection by representatives of the Department of Health and Human Service, Division of Public Health, Radiological Health. In addition, any worker or representative of workers who believes that there is a violation of the Nebraska Radiation Control Act, the regulations issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026. The request must set forth the specific grounds for the notice, and must be signed by the worker as representative of the workers. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which s/he believes contributed to or caused any violation as described above.

POSTING REQUIREMENTS

Copies of this notice must be posted in a sufficient number of places in every establishment where employees are employed in activities licensed or registered, pursuant to 180 NAC 21 by the Department of Health and Human Services, to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

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Department of Health & Human Services
DHHS
NEBRASKA

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Type or print except where indicated.
Retain one copy for your records.
Refer to NRH-4 Instructions as needed.

Submit original application to:

Nebraska Dept. of Health and Human Services
Office of Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026

Department Use Only	
County	Reg. Number
State	Region
Priority	Label
Renewal Date	Fee

1.a LEGAL NAME AND STREET ADDRESS (INSTITUTION, FIRM, PERSON, ETC.)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone :		FAX:	
E-Mail:			
1.b RADIATION GENERATING EQUIPMENT LOCATION (IF DIFFERENT THAN 1.a)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone:		FAX:	
Temporary job sites throughout Nebraska? ☐ Yes ☐ No			
2. BILLING INFORMATION			
Address (if different than 1.a):			
City, State, Zip:			
Telephone:		FAX:	
Contact Person:			
3. PRACTICE TYPE (SEE NRH-4 INST)			

4. RADIATION GENERATING EQUIPMENT (use additional sheets if necessary – NRH-4a)
List each machine on a separate line.

Machine Type (See NRH-4 Inst)	Number Tubes	Control Manufacturer	Control Model No.	Control Serial No.	Manufacture Date	Install Date	Master Control Location

5. RADIATION SAFETY OFFICER (RSO) (see 180 NAC 2-004.02 or 21-007.01B)

Radiation Safety Officer (Print or Type)	Signature	Date

6. ATTESTATION AND CERTIFICATION

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

Check only ONE box below:

☐ I am a citizen of the United States

☐ I am a qualified alien under the Federal Immigration and Nationality Act.
Immigration status and alien number: _____
USCIS documentation enclosed.

☐ Application is for a separate legal entity (Ex: corporation, partnership, etc.) **Explain:** _____

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

The applicant and any official executing this document on behalf of the applicant named in Item 1.a. certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Title 180 Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of their knowledge.

Certifying Official (Print or Type)	Applicant/Facility Name (see item 1.a)

Signature	Date

Department of Health & Human Services
DHHS
NEBRASKA

For Department Use Only

NEBRASKA DEPARTMENT OF
HEATLH AND HUMAN SERVICES
RADIOLOGICIAL HEALTH
X-RAY PROGRAM

Regist. No. _____
State _____ **Co.** _____
Region

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Instructions: Type or Print except where indicated. Retain one copy for your files and submit original application to: Nebraska Dept. of Health and Human Services , Radiological Health, 301 Centennial Mall South, P O Box 95026, Lincoln, NE 68509-5026.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip: _____

Telephone #: _____

FAX #: _____

eMail Address:

1.b Street address(es) at which Radiation Generating Equipment will be used. (If different than 1.a)

(1) Permanent — Address: _____

_____

City, State Zip: _____

(2) Temporary Job Sites Throughout Nebraska? ☐ Yes ☐ No

2. Billing Information

Address(if different than 1.a):

_____

_____

Person to Contact: _____

Telephone #: _____

3. Radiation Safety Officer (RS0) (See 180 NAC 2-004.02,or 21-007.01B)

_____

Title: _____

Telephone #: _____

4. Type of Practice (see Instruction Sheet) _____

5. RADIATION GENERATING EQUIPMENT (USE ADDITIONAL SHEETS IF NECESSARY)

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Control. Model No.	Control. Serial No.	Date Installed	Date Manufactured	Control Room #

6. I do hereby accept the responsibility of radiation safety officer.

Type or print name of Radiation Safety Officer from item 3.	Signature of Radiation Safety Officer	Date

7. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____

OR

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

8. CERTIFICATION
(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services,, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge.

_____

Applicant Name from Item 1.a.

By: _____ *Date:* _____

Signature of certifying official authorized to act on behalf of applicant

_____

Print Name and Title of certifying official

Your Application will not be processed without items 6., 7., and 8. being complet

Department of Health & Human Services
DHHS
NEBRASKA

NRH – 4a - ADDITIONAL MACHINES

Type or print machine information in correct fields.

List each machine on separate line.
Provide registration number if known.

Registration #_____

Machine Type (See NRH-4 INST)	Number Tubes	Control Manufacturer	Control Model No.	Control Serial No.	Manufacture Date	Install Date	Master Control Location

FORM NRH-4a (Additional Machines) **Registration No.** _____
Effective Date February 24, 2013

5a. LIST ADDITIONAL MACHINES ON THIS SHEET

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Control Model No.	Control. Serial No.	Date Installed	Date Manufactured	Control Room #

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Form NRH -21
DRAFT Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
X-RAY PROGRAM

DENTAL INTERIM INSPECTION FORM

Registration No.:_____ **Date:**_____

Name:_____
Address:_____
_____ **City – State – Zip** _____
Phone Number_____ **Fax Number** _____
E-Mail _____

- Complete this form and return it to this Department by the date specified in the enclosed letter.
- Include all corrective actions taken for any violation.
- Submit copies of the Equipment Performance Evaluation results for each radiation machine.
  - ~~Include all corrective actions taken for any violation.~~
- Include a current inventory list of all radiation machines.

1.	Yes	No	Do you have a copy of a current Certificate of Registration?
2.	Yes	No	Are all operable dental radiation generating machines properly registered?
3.	Yes	No	Do you have a record of receipt for all radiation machines?**
4.	Yes	No	Have you transferred any radiation machines to another location or disposed of any units? (Must notify the Department within 30 days of any radiation inventory change)
5.	Yes	No	Is a copy of the current regulations 180 NAC 21 available in your facility? (Regulations available at http://www.dhhs.ne.gov/rad)
6.	Yes	No	Is a "Notice to Employees" (NRH-3) posted? (It is available at http://www.dhhs.ne.gov/rad
7.	Yes	No	Have *Equipment Performance Evaluations been performed on all radiation machines at the required five year interval?
8.	Yes	No	Do you have written Operating and Safety Procedures available for all operators of the dental radiation generating machines?
9.	Yes	No	Do operators maintain a six foot distance while continuously viewing the patient during exposures?
10.	Yes	No	(If all radiographs are obtained digitally, **STOP HERE**) Are all films developed using the time/temperature method recommended by the film manufacturer?
11.	Yes	No	Is the specified developer time/temperature for auto/manual processing posted in the film processing area?
12.	Yes	No	Have all film processing chemicals been replaced according to the chemical manufacturer/supplier recommendations or at an interval which does not exceed three months?
13.	Yes	No	Is a log maintained that includes the date the processing chemicals were replaced and initials of individual performing the change?
14.	Yes	No	If a daylight processor is used, **STOP**:**HERE** Is the lighting in the film processing/loading area maintained using the manufacturer's recommendation for the filter, bulb wattage and working distance?
15.	Yes	No	Have darkroom light leak tests been performed at an interval not exceeding six months?
~~16.~~	~~Yes~~	~~No~~	~~Is a log maintained that includes date and initials of individual performing darkroom light leak tests or dates of any corrective repairs?~~

*Equipment Performance Evaluations (machine calibrations) are performed by your service company.
**If records of receipt are not available (Question 3), document the following information:

Name of manufacturer — Model number from control panel
Serial number from control panel — Approximate date of manufacture
Name of company from which equipment was purchased

Comments:

Form Completed by: _____Date_____
Signature of Radiation Safety Officer _____Date_____

- Please retain a copy of the completed inspection form for your records

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Form NRH -21A
DRAFT Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
X-RAY PROGRAM

EQUIPMENT LIST

Registration Number _____ Name of Registrant _____ Date_____

Machine Number on NRH 4	Machine Type	Manufacturer	Date Installed	Model No. from Control Panel	Serial No. from Control Panel	Location	Date of Manufacture	Calibration Dates

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FORM NRH 21B
DRAFT Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
X-RAY PROGRAM

DENTAL EQUIPMENT PERFORMANCE EVALUATION

~~DENTAL UNIT~~

~~Registration Number _____ Date _____~~
~~Name of Registrant _____~~

~~Registration Number of Service Company _____~~
~~Service Company _____~~

~~Survey instrument used _____ Calibration date _____~~

~~Type of measuring device: External Probe (ion chamber) _____~~
~~Ion Chamber within a housing _____~~
~~X-ray unit identification (control panel):_____~~
~~Manufacturer Model No._____~~
~~Serial No. _____ Location _____~~

Evaluation Date: _____

Registrant: _____ Registration Number: _____

Service Company: _____ Registration Number: **RS** _____

Survey Instrument: _____ Calibration Date: _____

Ion Chamber: ☐ Within A Housing ☐ External Probe

Control Panel Information

Manufacturer: _____ Model Number: _____

Serial Number: _____ Location: _____

~~TIMER ACCURACY~~

~~The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer specifications are not obtainable, the timer accuracy must be within10% of the indicated time with the testing performed at 0.5 second.~~

~~Timer accuracy determined by (select which one used):~~

~~Manufacturer's timer deviation tolerance _____ **OR**~~
~~10% tolerance with testing performed at 0.5 second (.500 milliseconds)~~

~~Time used for testing _____ ____mS _____Pulses~~
~~Perform four measurements at the above time setting:~~
~~_____milliseconds/pulses~~
~~_____milliseconds/pulses~~
~~_____milliseconds/pulses~~
~~_____milliseconds/pulses~~

TIMER ☐ PASS ☐ FAIL

The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer specifications are not obtainable, the timer accuracy must be ±10% of the indicated time with the testing performed at 0.5 second.

Manufacturer's Specifications: OR ±10%

Time Used for Testing: ☐seconds ☐ milliseconds ☐ pulses

Measured				
Deviation	%	%	%	%

~~EXPOSURE REPRODUCIBILITY~~

~~When all technique factors are held constant, the coefficient of exposures for both manual and AEC systems must not exceed 0.05.~~

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}(x_1 - \bar{x})^2}{n-1}\right]^{1/2}$$

~~Technical Factors Selected: _____ma _____kVp _____time~~
~~Output Measurements:~~
~~_____mR~~ ~~s = estimated standard deviation of the population~~
~~_____mR~~ ~~X = mean value of observations in sample~~
~~_____mR~~ ~~Xi= ith observation in sample~~
~~_____mR~~ ~~n = number of observations in sample~~

EXPOSURE REPRODUCIBILITY ☐ PASS ☐ FAIL

When all technique factors are held constant, the coefficient of variation of exposures for both manual and automatic exposure control systems must not exceed 0.05. This requirement applies to clinically used techniques.

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}(x_1 - \bar{x})^2}{n-1}\right]^{1/2}$$

s = estimated standard deviation of the population
X = mean value of observations in sample
Xi= ith observation in sample
n = number of observations in sample.

Technical Factors Selected: kVp mA / mAs seconds / milliseconds / pulses

Measured	mR	mR	mR	mR

Coefficient of Variation:

Manufacturer: _____ Serial Number: _____

~~KVP TEST~~

~~The indicated kVp must be accurate to within 10% of the indicated setting at no less than three points over the usual operating range of the machine. For units with fewer than three fixed kVp settings, the units shall be checked at those settings.~~

~~Indicated kVp _____Measured kVp _____Deviation _____%~~
~~Indicated kVp _____Measured kVp _____Deviation _____%~~
~~Indicated kVp _____Measured kVp _____Deviation _____%~~
~~Indicated kVp _____Measured kVp _____Deviation _____%~~

~~((Measured kVp - Indicated kVp) ÷ Indicated kVp) H 100 = % Deviation~~

~~Measured kVp within " 10% of the indicated setting: Yes ( ) No ( )~~

Kilovolt Peak ☐ PASS ☐ FAIL

If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine must meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak must be accurate to within ±10% of the indicated setting(s). For dental radiation generating equipment with fewer than three fixed kilovolt peak settings, the radiation machine will be checked at those settings.

Manufacturer's Specifications: _____ OR ±10%

Kilovolt Peak Used for Testing: _____

Measured:				
Deviation:	%	%	%	%

~~TUBE STABILITY~~

~~The tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant must assure proper and free movement of the unit.~~

~~Tube stable in all orientations: Yes ( ) No ( ) Free movement where designed: Yes ( ) No ( )~~

~~COLLIMATION~~

~~Field limitation must meet the requirements of 180 NAC 21~~

~~**Intraoral:**~~
~~Minimum source to skin distance (SSD) _____cm.~~
~~Field size at tip of cone cm.~~
~~Field size to 7 cm.: If the minimum SSD is 18 cm or more Yes ( ) No ( ) N/A ( )~~
~~Field size to 6 cm.: If the minimum SSD is less than 18 cm Yes ( ) No ( ) N/A ( )~~

~~**Panoramic:**~~
~~X-ray field misalignment at image receptor slit: _____in. X _____in.~~
~~(transverse) (vertical)~~

~~Misalignment cannot exceed 0.0 inches in the transverse axis: In compliance Yes ( ) No ( )~~

~~Misalignment cannot exceed 0.5 inches in the vertical axis: In compliance Yes ( ) No ( )~~

~~**Cephalometric:**~~
~~Source to image distance (SID) _____in./cm.~~
~~Indicated field size in./cm. X _____in./cm.~~
~~Measured field size in./cm. X _____ in./cm.~~
~~Misalignment _____ in./cm. X _____ in./cm.~~
~~Does misalignment exceed 2% of the SID: Yes ( ) No ( )~~

Tube Stability ☐ PASS ☐ FAIL

The tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant must assure proper and free movement of the unit.

Collimation ☐ PASS ☐ FAIL

Field limitation must meet the requirements of 180 NAC 21-007.07 or 21-007.08

Intraoral:
Source-to-Skin Distance (SSD): _____ cm Greater than 18 cm: ☐ Yes ☐ No
AND
Beam limited to a diameter of 7 cm at minimum SSD: ☐ Yes ☐ No

Panoramic:
Transverse axis: x-ray beam restricted to 0.0 inches of the imaging slit: ☐ Yes ☐ No
AND
Vertical axis: x-ray beam restricted to no more than 0.5 inches larger than the imaging slit: ☐ Yes ☐ No

Cephalometric:
Rectangular collimation: x-ray field does not exceed 2.0% of the source-to-image receptor distance for the length or the width of the image receptor ☐ Yes ☐ No
OR
Circular or polygon collimation: x-ray field does not exceed 2.0% of the source-to-image distance for the diagonal of the image receptor ☐ Yes ☐ No

~~**ENTRANCE EXPOSURE (EE) (See Form NRH 21B for instructions)**~~

~~EE levels-~~
~~Technique Factors selected: kVp _____mA(s) _____time _____(for intraoral bite wing only)~~
~~Source to Skin Distance (SSD):_____ in/cm Source to Detector Distance (SDD):_____ in/cm~~
~~Is tip of cone positioned ⅛ inch or less from surface of instrument housing or probe? Yes __No__~~
~~EE _____mR Calculated Measurement _____ Direct Measurement _____~~

~~Signature of surveyor:_____ Date:_____~~

IN-AIR EXPOSURE MEASUREMENT

For dental intraoral systems, use techniques factors used for the average adult patient thickness in routine bitewing radiography.

Technique Factors: _____ kVp _____ mA / mAs _____ seconds / milliseconds / pulses

For Calculated Measurement only
Source to Skin Distance (SSD): _____ cm Source to Detector Distance (SDD): _____ cm

Measured: _____ mR ☐ Calculated Measurement ☐ Direct Measurement

Surveyor Name: _____ Surveyor Signature: _____

DETERMINING IN-AIR EXPOSURE MEASUREMENT FOR INTRAORAL DENTAL EXAMINATIONS

A. CALCULATION

Note: Ion chambers may be located within the instrument housing rather than within an external probe. In this situation, the distance from the top surface of the housing to the ion chamber below must be known. If this type of instrument is used for the measurements, the inverse square law must be utilized for accurate results.

$IAE = Measured \times (SDD \div SSD)^2$

Where: IAE = in-air exposure
Measured = indicated exposure on measuring instrument
SDD = source (target) to detector (ion chamber) distance in centimeters
SSD = source (target) to skin distance in centimeters

1. Place the tip of the cone within ½ inch from the housing of the measuring instrument.
2. Measure the distance from the source to the entrance/tube side surface of the housing. This is the SSD.
3. Determine the distance from the source to the ion chamber within the housing. This is the SDD.
4. Select the kVp, mA(s), and time normally used for an average adult patient thickness in routine bitewing radiography at that facility.
5. Make an exposure and document the radiation output in millirem.
6. Using the above formula, calculate the in-air exposure.

B. DIRECT MEASUREMENT

Note: Use this procedure only if and external probe (ion chamber) is available for the measurements.

1. Position the tube so the end of the cone is not greater the ½ inch from the probe. Do not put the probe inside the cone or allow the cone to have direct contact with the probe.
2. Select the kVp, mA(s), and time normally used for an average adult patient thickness in routine bitewing radiography at that facility.
3. Make an exposure and document the radiation output in millirem. This direct measurement is the in-air exposure.

~~DETERMINING THE ENTRANCE EXPOSURE (EE) FOR INTRAORAL DENTAL EXAMINATIONS~~

~~A. DETERMINING ENTRANCE EXPOSURE BY CALCULATION:~~

~~Note: Ion chambers may be located within the instrument housing rather than within an external probe. In this situation the distance from the top surface of the housing to the ion chamber below must be known. If this type of instrument is used for the EE measurements, the inverse square law must be utilized for accurate results.~~

~~$EE=mR(measured) \times (SDD \div SSD)^2$~~

~~Where: EE = entrance exposure~~
~~mR (measured) = indicated exposure on measuring instrument~~
~~SDD = source (target) to detector (ion chamber) distance~~

SSD = source (target) to skin distance

(a) Place the tip of the cone within ½ inch from the housing of the measuring instrument.
(b) Measure the distance form the source to the entrance/tube side surface of the housing.
(c) Determine the distance from the source to the ion chamber within the housing.
(d) Convert all measurements to the same unit. (i.e., Do not use the SDD in inches and the SSD in centimeters.)
(e) Select the kVp, mA, and time normally used for an intraoral bite wing x-ray at that facility. Document the selected technique factors.
(f) Make an exposure and document the measurement in millirem.
(g) Using the above formula, calculate the EE.

B. DETERMINING ENTRANCE EXPOSURE BY DIRECT MEASUREMENT:

Note: Use this procedure only if and external probe (ion chamber) is available for the measurements.

(a) Position the tube so the end of the cone is not greater the ½ inch from the probe. Do not put the probe inside the cone or allow the cone to have direct contact with the probe.
(b) Select the kVp, mA, and time normally used for an intraoral bite wing x-ray at the facility.
Document the selected technique factors.
(c) Measure the distance from the target (source) to the end of the cone. Document this distance.
(d) Make and exposure and document the radiation output in millirem. This direct measurement is the entrance exposure.

EXPOSURE REPRODUCIBILITY CALCULATIONS

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

EQUATION

Where:

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

In this example, the exposures are considered to be reproducible.
Example:

The four (*n*) exposures (X_i) measured 409 mR, 387 mR, 391 mR, and 410 mR.

STEP 1 Determine the mean value (X) of the four exposures taken.

(409 MR + 387 mR + 391 mR +410 mR) ÷ 4 = 399.25 mR

STEP 2 Find the difference between each exposure and the mean value (disregard sign).

409.00 mR	387.00 mR	391.00 mR	410.00 mR
-399.25 mR	-399.25 mR	-399.25 mR	-399.25 mR
9.75 mR	12.25 mR	8.25 mR	10.75 mR

STEP 3 Square each of the differences

9.75^2 = 95.06 12.25^2 = 150.06
10.75^2 = 115.56 8.23^2 = 68.06

STEP 4 Divide each number by 3 (*n*-1) and add the results

95.06 • • 3 = 31.88
150.06 • • 3 = 50.02

68.06 • • 3 = 22.69
115.56 • • 3 = 38.85
143.11

STEP 5 For s, determine the square root of the above number

$\sqrt{143.11} = 11.96$

STEP 6 Divide s by the mean value (0)

11.9629 • • 399.25 = .0299 = c = the coefficient of variation

STEP 7 If c=0.05 or less, the exposures are considered to be reproducible

EXPOSURE REPRODUCIBILITY

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

Where:

s = Estimated standard deviation of the population
$\bar{x}$ = Mean value of observations in sample
X_i = i^{th} observation in sample
n = Number of observations in sample

Example:

The four *(n)* exposures *(X_i)* measured 409 mR, 387 mR, 391 mR, and 410 mR

STEP 1 Determine the mean value *($\bar{x}$)* of the four exposures taken

(409 mR + 387 mR + 391 mR + 410 mR) ÷ 4 = 399.25 mR

STEP 2 Find the difference between each exposure and the mean value ($\bar{x}$) (disregard sign)

409.00 mR	387.00 mR	391.00 mR	410.00 mR
-399.25 mR	-399.25 mR	-399.25 mR	-399.25 mR
9.75 mR	12.25 mR	8.25 mR	10.75 mR

STEP 3 Square each of the differences

$(9.75)^2 = 95.06$ $(12.25)^2 = 150.06$

$(10.75)^2 = 115.56$ $(8.25)^2 = 68.06$

STEP 4 Divide each number by 3 *(n-1)* and add the results

95.06 ÷ 3 = 31.69
150.06 ÷ 3 = 50.02
68.06 ÷ 3 = 22.69
115.56 ÷ 3 = 38.52
142.92

STEP 5 For *s*, determine the square root of the above number

$\sqrt{142.92} = 11.95$

STEP 6 Divide *s* by the mean value ($\bar{x}$)

11.95 ÷ 399.25 = .0299 = the coefficient of variation *(C)*

STEP 7 If $C \leq 0.05$, the exposures are considered to be reproducible

~~**ATTACHMENT 21-1**~~

~~**21 CFR 56**~~

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pertaining to the financial interests of clinical investigators who conducted studies on which the application relies and who are not full or part-time employees of the applicant, as follows:

(i) Complete records showing any financial interest or arrangement as described in §54.4(a)(3)(i) paid to such clinical investigators by the sponsor of the covered study.

(2) Complete records showing significant payments of other sorts, as described in §54.4(a)(3)(ii), made by the sponsor of the covered clinical study to the clinical investigator.

(3) Complete records showing any financial interests held by clinical investigators as set forth in §54.4(a)(3)(iii) and (a)(3)(iv).

(b) *Requirements for maintenance of clinical investigators' financial records.* (1) For any application submitted for a covered product, an applicant shall retain records as described in paragraph (a) of this section for 2 years after the date of approval of the application.

(2) The person maintaining these records shall, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to and copy and verify these records.

PART 56—INSTITUTIONAL REVIEW BOARDS

Subpart A—General Provisions

Subpart B—Organization and Personnel

Subpart C—IRB Functions and Operations

Subpart D—Records and Reports

Subpart E—Administrative Actions for Noncompliance

AUTHORITY: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

SOURCE: 46 FR 8975, Jan. 27, 1981, unless otherwise noted.

Subpart A—General Provisions

§56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[46 FR 8975, Jan. 27, 1981, as amended at 64 FR 399, Jan. 5, 1999; 65 FR 20599, Apr. 24, 2001]

§56.102 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended

(secs. 201-902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321-392)).

(b) *Application for research or marketing permit* includes:

(1) A color additive petition, described in part 71.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in § 170.35.

(3) A food additive petition, described in part 171.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in part 312 of this chapter.

(7) A new drug application, described in part 314.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in part 320.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in part 330.

(10) An application for a biologics license, described in part 601 of this chapter.

(11) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in part 601 of this chapter.

(12) An Application for an Investigational Device Exemption, described in part 812.

(13) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in part 860.

(14) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in part 861.

(15) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(16) A product development protocol for a medical device for human use, described in section 515 of the act.

(17) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(18) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in § 1010.4.

(19) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5.

(20) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in subpart D of part 1003.

(21) Data and information about a clinical study of an infant formula when submitted as part of an infant formula notification under section 412(c) of the Federal Food, Drug, and Cosmetic Act.

(22) Data and information submitted in a petition for a nutrient content claim, described in § 101.69 of this chapter, and for a health claim, described in § 101.70 of this chapter.

(23) Data and information from investigations involving children submitted in a new dietary ingredient notification, described in § 190.6 of this chapter.

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms *research, clinical research, clinical study, study,* and *clinical investigation* are deemed to be synonymous for purposes of this part.

(d) *Emergency use* means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

(e) *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

(f) *Institution* means any public or private entity or agency (including Federal, State, and other agencies). The term *facility* as used in section 520(g) of the act is deemed to be synonymous with the term *institution* for purposes of this part.

(g) *Institutional Review Board (IRB)* means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase *institutional review committee* as used in section 520(g) of the act.

(h) *Investigator* means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Sponsor* means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(k) *Sponsor-investigator* means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(l) *Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354–360F of the Public Health Service Act.

(m) *IRB approval* means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the

IRB and by other institutional and Federal requirements.

[46 FR 8975, Jan. 27, 1981, as amended at 54 FR 9038, Mar. 3, 1989; 56 FR 28028, June 18, 1991; 64 FR 399, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 65 FR 52302, Aug. 28, 2000; 66 FR 20599, Apr. 24, 2001; 74 FR 2368, Jan. 15, 2009]

§ 56.103 Circumstances in which IRB review is required.

(a) Except as provided in §§ 56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in §§ 56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

[46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981]

§ 56.104 Exemptions from IRB requirement.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991]

§ 56.105 Waiver of IRB requirement.

On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities or for classes of research activities, otherwise covered by these regulations.

Subpart B—Organization and Personnel

§ 56.106 Registration.

(a) *Who must register?* Each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the act and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products must register at a site maintained by the Department of Health and Human Services (HHS). (A research permit under section 505(i) of

the act is usually known as an investigational new drug application (IND), while a research permit under section 520(g) of the act is usually known as an investigational device exemption (IDE).) An individual authorized to act on the IRB's behalf must submit the registration information. All other IRBs may register voluntarily.

(b) *What information must an IRB register?* Each IRB must provide the following information:

(1) The name, mailing address, and street address (if different from the mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;

(2) The IRB's name, mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson's name, phone number, and electronic mail address; and the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(3) The approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an "active protocol" is any protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and

(4) A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

(c) *When must an IRB register?* Each IRB must submit an initial registration. The initial registration must occur before the IRB begins to review a clinical investigation described in paragraph (a) of this section. Each IRB must renew its registration every 3 years. IRB registration becomes effective after review and acceptance by HHS.

(d) *Where can an IRB register?* Each IRB may register electronically through *http://ohrp.cit.nih.gov/efile*. If an IRB lacks the ability to register electronically, it must send its registration information, in writing, to the Good Clinical Practice Program (HF-34), Office of Science and Health Coordination, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(e) *How does an IRB revise its registration information?* If an IRB's contact or chair person information changes, the IRB must revise its registration information by submitting any changes in that information within 90 days of the change. An IRB's decision to review new types of FDA-regulated products (such as a decision to review studies pertaining to food additives whereas the IRB previously reviewed studies pertaining to drug products), or to discontinue reviewing clinical investigations regulated by FDA is a change that must be reported within 30 days of the change. An IRB's decision to disband is a change that must be reported within 30 days of permanent cessation of the IRB's review of research. All other information changes may be reported when the IRB renews its registration. The revised information must be sent to FDA either electronically or in writing in accordance with paragraph (d) of this section.

[74 FR 2368, Jan. 15, 2009]

§ 56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and

practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the instituton's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

[46 FR 8975, Jan 27, 1981, as amended at 56 FR 28028, June 18, 1991; 56 FR 29756, June 28, 1991]

Subpart C—IRB Functions and Operations

§ 56.108 IRB functions and operations.

In order to fulfill the requirements of these regulations, each IRB shall:

(a) Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review; (3) for ensuring prompt reporting to the IRB of changes in research activity; and (4) for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see § 56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991; 67 FR 9585, Mar. 4, 2002]

§ 56.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 50.25. The IRB may require that information, in addition to that specifically mentioned in § 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with § 50.27 of this chapter, except as follows:

(1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or

(2) The IRB may, for some or all subjects, find that the requirements in § 50.24 of this chapter for an exception from informed consent for emergency research are met.

(d) In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(e) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. For investigations involving an exception to informed consent under § 50.24 of this chapter, an IRB shall promptly notify in writing the investigator and the sponsor of the research when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception provided under § 50.24(a) of this chapter or because of other relevant ethical concerns. The written notification shall include a statement of the reasons for the IRB's determination.

(f) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(g) An IRB shall provide in writing to the sponsor of research involving an exception to informed consent under § 50.24 of this chapter a copy of information that has been publicly disclosed under § 50.24(a)(7)(ii) and (a)(7)(iii) of this chapter. The IRB shall provide this information to the sponsor promptly so that the sponsor is aware that such disclosure has occurred. Upon receipt, the sponsor shall provide copies of the information disclosed to FDA.

(h) When some or all of the subjects in a study are children, an IRB must determine that the research study is in compliance with part 50, subpart D of this chapter, at the time of its initial review of the research. When some or all of the subjects in a study that is ongoing on April 30, 2001 are children, an IRB must conduct a review of the research to determine compliance with part 50, subpart D of this chapter, either at the time of continuing review or, at the discretion of the IRB, at an earlier date.

[46 FR 8975, Jan. 27, 1981, as amended at 61 FR 51529, Oct. 2, 1996; 66 FR 20590, Apr. 24, 2001]

§ 56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Food and Drug Administration has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the FEDERAL REGISTER.

(b) An IRB may use the expedited review procedure to review either or both of the following: (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, (2) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the IRB chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all

of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited review procedure set forth in §56.108(c).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991]

§56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by §50.27.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(c) In order to approve research in which some or all of the subjects are children, an IRB must determine that all research is in compliance with part 50, subpart D of this chapter.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991; 66 FR 20599, Apr. 24, 2001]

§56.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§56.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any

suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

§ 56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

Subpart D—Records and Reports

§ 56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by § 56.108 (a) and (b).

(7) Statements of significant new findings provided to subjects, as required by § 50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991; 67 FR 9585, Mar. 4, 2002]

Subpart E—Administrative Actions for Noncompliance

§ 56.120 Lesser administrative actions.

(a) If apparent noncompliance with these regulations in the operation of an IRB is observed by an FDA investigator during an inspection, the inspector will present an oral or written summary of observations to an appropriate representative of the IRB. The Food and Drug Administration may subsequently send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a time period specified by FDA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest in the agency's action of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§ 56.121 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the agency under § 56.120(a), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in part 16.

(b) The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

(c) If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in § 56.123.

§ 56.122 Public disclosure of information regarding revocation.

A determination that the Food and Drug Administration has disqualified an institution and the administrative record regarding that determination are disclosable to the public under part 20.

§ 56.123 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 56.121(c).

§ 56.124 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to

or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

Subpart A—General Provisions

Subpart B—Organization and Personnel

Subpart C—Facilities

Subpart D—Equipment

Subpart E—Testing Facilities Operation

Subpart F—Test and Control Articles

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

Subparts H–I [Reserved]

Subpart J—Records and Reports

Subpart K—Disqualification of Testing Facilities

AUTHORITY: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

SOURCE: 43 FR 60013, Dec. 22, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 64 FR 399, Jan. 5, 1999]

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~~ATTACHMENT 21-2~~

~~Title 21, CFR §1020.30 & 1020.31~~

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the tube, as measured in accordance with this section.

(ii) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x-radiation, with the beam blocking device in the open position, shall not exceed (Pi) steradians.

(2) *Measurements.* (i) Compliance with the exposure rate limit defined in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

(ii) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of thirty (30) centimeters from any point on the external surface of the enclosure, provided:

(*a*) In the case of enclosures containing tubes designed primarily to demonstrate the production of x radiation, measurements shall be made with any beam blocking device in the beam blocking position, or

(*b*) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of such enclosure in the position which would maximize external exposure levels.

(3) *Test conditions.* (i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) *Instructions, labels, and warnings.* (i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and:

(*a*) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and (*b*) in the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability.* (1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977, or after June 10, 2006.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(F) Image receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006.

(G) Fluoroscopic air kerma display devices manufactured on or after June 10, 2006.

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32, which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and §1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) "Technique factors";

(iii) Section 1020.30(b) "CT," "Dose," "Scan," "Scan time," and "Tomogram";

(iv) Section 1020.30(h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33(a) and (b);

(vii) Section 1020.33(c)(1) as it affects §1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and §1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) *Definitions.* As used in this section and §§1020.31, 1020.32, and 1020.33, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Air kerma means kerma in air (see definition of *Kerma*).

Air kerma rate (AKR) means the air kerma per unit time.

Aluminum equivalent means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions, as the material in question.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Automatic exposure rate control (AERC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device which provides a means to restrict the dimensions of the x-ray field.

C-arm fluoroscope means a fluoroscopic x-ray system in which the image receptor and the x-ray tube

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in "Aluminum Standards and Data" (1969). Copies may be obtained from The Aluminum Association, New York, NY.

housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Coefficient of variation means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}}\left[\sum_{i=1}^{n}\frac{\left(X_i - \bar{X}\right)^2}{n-1}\right]^{1/2}$$

where:

s = Estimated standard deviation of the population.
$\bar{X}$ = Mean value of observations in sample.
X_i = ith observation sampled.
n = Number of observations sampled.

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device:

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

Cumulative air kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name for the unit of absorbed dose is gray (Gy).

Equipment means x-ray equipment.

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field.

Fluoroscopic air kerma display device means a device, subsystem, or component that provides the display of AKR and cumulative air kerma required by §1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

Image receptor support device means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material: thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

Last-image-hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

Leakage radiation means radiation emanating from the diagnostic source assembly except for:

(1) The useful beam; and

(2) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the

diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illuminance is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100(V_n - V_l)/V_l$$

where:

V_n = No-load line potential and
V_l = Load line potential.

Maximum line current means the root mean square current in the supply line of an x-ray machine operating at its maximum rating.

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

Non-image-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

Pulsed mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Quick change x-ray tube means an x-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of this section;

(2) The focal spot position will not cause noncompliance with the provisions of this section or §1020.31 or 1020.32;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube

housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of §§ 1020.31 and 1020.32.

Radiation therapy simulation system means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiography means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the x-ray high-voltage generator.

Rated output voltage means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a retrievable form of an image resulting from x-ray photons.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Solid state x-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

Source means the focal spot of the x-ray tube.

Source-image receptor distance (SID) means the distance from the source to the center of the input surface of the image receptor.

Source-skin distance (SSD) means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through a body.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes

high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device means a beam-limiting device which has the capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) *Mobile x-ray equipment* means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) *Portable x-ray equipment* means x-ray equipment designed to be hand-carried; and

(3) *Stationary x-ray equipment means* x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Communication, Education, and Radiation Programs of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

(d) *Assemblers' responsibility.* An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by §1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, CDRH. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements.* Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to CDRH in the report required under §1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv)(A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component
This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in §1010.3 of this chapter, manufacturers of components subject to this section and §§1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide information necessary to allow the assembler to determine the maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) *Information to be provided to users.* Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters (mm) of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts. If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-

pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided:

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(5) *Imaging system information.* For x-ray systems manufactured on or after June 10, 2006, that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

(i) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the manner in which the automatic adjustment is controlled. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

(ii) For each mode of operation, a descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

(6) *Displays of values of AKR and cumulative air kerma.* For fluoroscopic x-ray systems manufactured on or after

pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided:

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(5) *Imaging system information.* For x-ray systems manufactured on or after June 10, 2006, that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

(i) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the manner in which the automatic adjustment is controlled. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

(ii) For each mode of operation, a descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

(6) *Displays of values of AKR and cumulative air kerma.* For fluoroscopic x-ray systems manufactured on or after

June 10, 2006, the following shall be provided:

(i) A schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of allowed uncertainty specified by § 1020.32(k)(6) and, if the capability for user calibration of the display is provided, adequate instructions for such calibration;

(ii) Identification of the distances along the beam axis:

(A) From the focal spot to the isocenter, and

(B) From the focal spot to the reference location to which displayed values of AKR and cumulative air kerma refer according to § 1020.32(k)(4);

(iii) A rationale for specification of a reference irradiation location alternative to 15 cm from the isocenter toward the x-ray source along the beam axis when such alternative specification is made according to § 1020.32(k)(4)(ii).

(i) [Reserved]

(j) *Warning label.* The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

(k) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microGy (vice 2 mR exposure) in 1 hour at 5 cm from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(m) *Beam quality*—(1) *Half-value layer (HVL).* The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in table 1 in paragraph (m)(1) of this section under the heading "Specified Dental Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading "I—Other X-Ray Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading "II—Other X-Ray Systems," for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table 1 in paragraph (m)(1) of this section, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

[2] In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE 1

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems[1]	I—Other X-Ray Systems[2]	II—Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
[2] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.
[3] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

(2) *Optional filtration.* Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the HVL provisions of §1020.30(m)(1). The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

(3) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in table 2 in paragraph (n) of this section, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in table 1 in paragraph (m)(i) of this section for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. Table 2 follows:

TABLE 2

Item	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Front panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

(o) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(p) [Reserved]

(q) *Modification of certified diagnostic x-ray components and systems.* (1) Diagnostic x-ray components and systems certified in accordance with §1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with §1010.4 of this chapter or an exemption under section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of §1020.31, 1020.32, or 1020.33. The owner who causes such modification need not submit the reports required by subpart B of part 1002 of this chapter, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with §1020.31, 1020.32, or 1020.33.

[71 FR 34028, June 10, 2006, as amended at 72 FR 17401, Apr. 9, 2007]

§1020.31 Radiographic equipment.

The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the

fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Control and indication of technique factors*—(1) *Visual indication.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls.* When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliampere-seconds (mAs), whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph (a)(3)(iii) of this section, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 1020.30(h)(3).

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3):

(1) *Coefficient of variation.* For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field

emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity.* The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Equipment having independent selection of x-ray tube current (mA).* The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(2) *Equipment having selection of x-ray tube current-exposure time product (mAs).* For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10\ (X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) *Measuring compliance.* Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

(d) *Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.* Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 centimeters (cm) shall be equal to or less than 5 cm.

(2) *Visual definition.* (i) Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 mm.

(e) *Field indication and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(3) Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(4) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 cm or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm; and

(ii) If the minimum SSD is less than 18 cm, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 cm.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for mammography*—(i) Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this

section. For systems that allow changes in the SID, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(iii) Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2), (f)(3), and (h) of this section and systems covered in paragraph (f)(1) of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) of this section; or when alignment means are also provided, may be met with either;

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Positive beam limitation (PBL).* The requirements of this paragraph shall apply to radiographic systems which contain PBL.

(1) *Field size.* When a PBL system is provided, it shall prevent x-ray production when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (g)(1)(i) of this section without regard to sign exceeds 4 percent of the SID.

(iii) The beam limiting device is at an SID for which PBL is not designed for sizing.

(2) *Conditions for PBL.* When provided, the PBL system shall function as described in paragraph (g)(1) of this section whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are less than 50 cm;

(iii) The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(3) *Measuring compliance.* Compliance with the requirements of paragraph (g)(1) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (g)(2) of this section are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(4) *Operator initiated undersizing.* The PBL system shall be capable of operation such that, at the discretion of the operator, the size of the field may be made smaller than the size of the

image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm. Return to PBL function as described in paragraph (g)(1) of this section shall occur automatically upon any change of image receptor size or SID.

(5) *Override of PBL.* A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-ray Field Limitation System Failure
The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(h) *Field limitation and alignment for spot-film devices.* The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(2) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

(4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(i) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

(ii) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(i) *Source-skin distance*—(1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(i) Eighteen cm if operable above 50 kVp; or

(ii) Ten cm if not operable above 50 kVp.

(2) Mobile and portable x-ray systems other than dental shall be provided

with means to limit the source-skin distance to not less than 30 cm.

(j) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(k) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(l) *Radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube shall not exceed:

(1) An air kerma of 0.26 microGy (vice 0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimension greater than 20 cm; and

(2) An air kerma of 0.88 mGy (vice 100 mR exposure) in 1 hour at 100 cm from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(m) *Primary protective barrier for mammography x-ray systems*—(1) For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma 5 cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 microGy (vice 0.1 mR exposure) for each activation of the tube.

(2) For mammographic x-ray systems manufactured on or after September 30, 1999:

(i) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(ii) The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(2)(i) of this section.

(iii) The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma 5 cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 microGy (vice 0.1 mR exposure) for each activation of the tube.

(3) Compliance with the requirements of paragraphs (m)(1) and (m)(2)(iii) of this section for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

[70 FR 34036, June 10, 2005]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is

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learned that the United States or an employee, agent, or cost plus contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

PART 36—INDEMNIFICATION OF HHS EMPLOYEES

§ 36.1 Policy.

(a) The Department of Health and Human Services may indemnify, in whole or in part, its employees (which for the purpose of this regulation includes former employees) for any verdict, judgment or other monetary award which is rendered against any such employee, provided that the conduct giving rise to the verdict, judgment or award was taken within the scope of his or her employment with the Department and that such indemnification is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(b) The Department of Health and Human Services may settle or compromise a personal damage claim against its employee by the payment of available funds, at any time, provided the alleged conduct giving rise to the personal damage claim was taken within the scope of employment and that such settlement or compromise is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(c) Absent exceptional circumstances, as determined by the Secretary or his or her designee, the Department will not entertain a request either to agree to indemnify or to settle a personal damage claim before entry of an adverse verdict, judgment or monetary award.

(d) When an employee of the Department of Health and Human Services becomes aware that an action has been filed against the employee in his or her individual capacity as a result of conduct taken within the scope of his or her employment, the employee should immediately notify the Department that such an action is pending.

(e) The employee may, thereafter, request either (1) indemnification to satisfy a verdict, judgment or award entered against the employee or (2) payment to satisfy the requirements of a settlement proposal. The employee shall submit a written request, with documentation including copies of the verdict, judgment, award or settlement proposal, as appropriate, to the head of his employing component, who shall thereupon submit to the General Counsel, in a timely manner, a recommended disposition of the request. The General Counsel shall also seek the views of the Department of Justice. The General Counsel shall forward the request, the employing component's recommendation and the General Counsel's recommendation to the Secretary for decision.

(f) Any payment under this section either to indemnify a Department of Health and Human Services employee or to settle a personal damage claim shall be contingent upon the availability of appropriated funds of the employing component of the Department of Health and Human Services.

(Authority: 5 U.S.C. 301)

[53 FR 11280, Apr. 6, 1988]

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Sec.

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D—Additional Protections for Children Involved as Subjects in Research

Subpart E—Registration of Institutional Review Boards

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289(a).

EDITORIAL NOTE: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost—sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9306, Mar. 4, 1982.

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject

to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures. [1]

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements

[1] Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether

the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be

submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

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[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§§ 46.104–46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in §46.103(b)(4) and, to the extent required by, §46.103(b)(5).

(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be

expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the

basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorised representatives of the department or agency at reasonable times and in a reasonable manner.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo

or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the

representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.121 [Reserved]

§46.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

SOURCE: 66 FR 56770, Nov. 13, 2001, unless otherwise noted.

§ 46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at §46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of §46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in §46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Definitions.

The definitions in §46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point

may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no added risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §§46.204 or 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

(1) That the research in fact satisfies the conditions of §46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

SOURCE: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8396, Jan. 26, 1981]

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research

SOURCE: 48 FR 9816, Mar. 8, 1983, unless otherwise noted.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

[48 FR 9818, Mar. 8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991]

§46.402 Definitions.

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) That the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent

may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Subpart E—Registration of Institutional Review Boards

SOURCE: 74 FR 2605, Jan. 15, 2009, unless otherwise noted.

§46.501 What IRBs must be registered?

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§46.502 What information must be provided when registering an IRB?

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and

the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§ 46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under § 46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

Each IRB must be registered electronically through *http://ohrp.cit.nih.gov/efile* unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§ 46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with § 46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

PART 50—U.S. EXCHANGE VISITOR PROGRAM—REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

Sec.

AUTHORITY: 75 Stat. 527 (22 U.S.C. 2651 et seq.); 94 Stat. 116 (8 U.S.C. 1182(e)).

SOURCE: 49 FR 9930, Mar. 16, 1984, unless otherwise noted.

§ 50.1 Authority.

Under the authority of Mutual Educational and Cultural Exchange Act of 1961 (75 Stat. 527) and the Immigration and Nationality Act as amended (84 Stat. 116), the Department of Health and Human Services is an "interested United States Government agency" with the authority to request the Department of State to recommend to the Attorney General waiver of the two-year foreign residence requirement for Exchange Visitors under the Mutual

TITLE 180 CONTROL OF RADIATION

CHAPTER 24 PHYSICAL PROTECTION OF RADIOACTIVE MATERIAL

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at: http://www.gpoaccess.gov/cfr/index.html

TITLE 180 CONTROL OF RADIATION

CHAPTER 24 PHYSICAL PROTECTION OF RADIOACTIVE MATERIAL

24-001 SCOPE AND AUTHORITY:

24-001.01 180 NAC 24 has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix 24-A of 180 NAC 24. These requirements provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of 180 NAC 24 authorizes possession of licensed material.

24-001.02 180 NAC 24-004 through 24-019 apply to any person who, under 180 NAC 24, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

24-001.03 180 NAC 24-020 through 24-025 applies to any person who:

24-001.03A Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or

24-001.03B Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

24-002 DEFINITIONS: For purposes of 180 NAC 24:

Access control means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

Aggregated means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

Approved individual means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with 180 NAC 24-004 through 24-010 and who has completed the training required by 180 NAC 24-012.03.

Background investigation means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

Category 1 quantity of radioactive material means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix 24-A in 180 NAC 24. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Category 2 quantity of radioactive material means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix 24-A in 180 NAC 24. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Diversion means the unauthorized movement of radioactive material subject to 180 NAC 24 to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

Escorted access means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

FBI Federal Bureau of Investigation

Fingerprint orders means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by the Department or Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

License issuing authority means the licensing agency that issued the license, i.e. the Department, the U.S. Nuclear Regulatory Commission or the appropriate agency of an Agreement State.

Local law enforcement agency (LLEA) means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

Mobile device means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

Movement control center means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

No-later-than arrival time means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than 6 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

Reviewing official means the individual who must make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

Sabotage means deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

Safe haven means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

Security zone means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

State means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Telemetric position monitoring system means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

Trustworthiness and reliability are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

Unescorted access means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

United States when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

24-003 SPECIFIC EXEMPTIONS

24-003.01 A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements 180 NAC 24 24-004 through 25-025. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 4,409 pounds (2,000 kg) is not exempt from the requirements 180 NAC 24. The licensee must implement the following requirements to secure the radioactive waste:

24-003.01A Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

24-003.01B Use a locked door or gate with monitored alarm at the access control point;

24-003.01C Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

24-003.01D Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

BACKGROUND INVESTIGATIONS AND ACCESS CONTROL PROGRAM

24-004 PERSONNEL ACCESS AUTHORIZATION REQUIREMENTS FOR CATEGORY 1 OR CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

24-004.01 General

24-004.01A Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold must establish, implement, and maintain its access authorization program in accordance with the requirements of 180 NAC 24-004 through 24-010.

24-004.01B An applicant for a new license and each licensee that would become newly subject to the requirements of 180 NAC 24-004 through 24-010 upon application for modification of its license must implement the requirements of 180 NAC 24-004 through 24.010, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

24-004.01C Any licensee that has not previously implemented the Security Orders or been subject to the provisions of 180 NAC 24-004 through 24-010 must implement

the provisions of 180 NAC 24-004 through 24-010 before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

24-004.02 General Performance Objective: The licensee's access authorization program must ensure that the individuals specified in 180 NAC 24-004.03A are trustworthy and reliable.

24-004.03 Applicability

24-004.03A Licensees must subject the following individuals to an access authorization program:

24-004.03A1 Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

24-004.03A2 Reviewing officials.

24-004.03B Licensees need not subject the categories of individuals listed in 180 NAC 24-008.01, items 1 through 13 to the investigation elements of the access authorization program.

24-004.03C Licensees must approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

24-004.03D Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR 73 in the access authorization program under 180 NAC 24-004 through 24-010.

24-005 ACCESS AUTHOIZATION PROGRAM REQUIREMENTS

24-005.01 Granting Unescorted Access Authorization

24-005.01A Licensees must implement the requirements of 180 NAC 24-004 through 24-010 for granting initial or reinstated unescorted access authorization.

24-005.01B Individuals who have been determined to be trustworthy and reliable must also complete the security training required by 180 NAC 24-012C before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

24-005.02 Reviewing Officials

24-005.02A Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

24-005.02B Each licensee must name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee must provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee must recertify that the reviewing official is deemed trustworthy and reliable every ten years in accordance with 180 NAC 24-006.02.

24-005.02C Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

24-005.02D Reviewing officials cannot approve other individuals to act as reviewing officials.

24-005.02E A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

1. The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

2. The individual is subject to a category listed in 180 NAC 24-008.01.

24-005.03 Informed Consent

24-005.03A Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee must provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of 180 NAC 24-006.02. A signed consent must be obtained prior to any reinvestigation.

24-005.03B The subject individual may withdraw his or her consent at any time. Licensees must inform the individual that:

1. If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his/her consent; and
2. The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

24-005.04 Personal History Disclosure
Any individual who is applying for unescorted access authorization must disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information, required by 180 NAC 24.004 through 24-10 is sufficient cause for denial or termination of unescorted access

24-005.05 Determination Basis

24-005.05A The reviewing official must determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of 180 NAC 24-004 through 24-010.

24-005.05B The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of 180 NAC 24-004 through 24-010 and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

24-005.05C The licensee must document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

24-005.05D The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

24-005.05E Licensees must maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee must remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

24-005.06 Procedures Licensees must develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

24-005.07 Right to Correct and Complete Information

24-005.07A Prior to any final adverse determination, licensees must provide each individual subject to 180 NAC 24-004 through 24-010 with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one year from the date of the notification.

24-005.07B If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least tendays for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his/her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

24-005.08 Records

24-005.08A The licensee must retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

24-005.08B The licensee must retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee must retain the superseded material for three years after the record is superseded.

24-005.08C The licensee must retain the list of persons approved for unescorted access authorization for three years after the list is superseded or replaced.

24-006 BACKGROUND INVESTIGATION

24-006.01 Initial Investigation: Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees must complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

24-006.01A Fingerprinting and an FBI identification and criminal history records check in accordance with 180 NAC 24-007;

24-006.01B Verification of true identity. Licensees must verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who s/he claims to be. A licensee must review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees must document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with 180 NAC 24-009. Licensees must certify in writing that the identification was properly reviewed, and must maintain the certification and all related documents for review upon inspection;

24-006.01C Employment history verification. Licensees must complete an employment history verification, including military history. Licensees must verify the individual's employment with each previous employer for the most recent seven years before the date of application;

24-006.01D Verification of education. Licensees must verify that the individual participated in the education process during the claimed period;

24-006.01E Character and reputation determination. Licensees must complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under 180 NAC 24-004 through 24-010 must be limited to whether the individual has been and continues to be trustworthy and reliable;

24-006.01F The licensee must also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

24-006.01G If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after ten business days of the request or if the licensee is unable to reach the entity, the licensee must document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

24-006.02 Grandfathering

24-006.02A Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals must be subject to the reinvestigation requirement.

24-006.02B Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee must document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR 73 or a security order. Security order, in this context, refers to any order that was issued by the U.S. Nuclear Regulatory Commission that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals must be subject to the reinvestigation requirement.

24-006.03 Reinvestigations Licensees must conduct a reinvestigation every ten years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation must consist of fingerprinting and an FBI identification and criminal history records check in accordance with 180 NAC 24-007. The reinvestigations must be completed within ten years of the date on which these elements were last completed.

24-007 REQUIREMENTS FOR CRIMINAL HISTORY RECORDS CHECKS OF INDIVIDUAL GRANTED UNESCORTED ACCESS TO CATEGORY 1 OR CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIALS

24-007.01 General Performance Objective and Requirements

24-007.01A Except for those individuals listed in 180 NAC 24-008 and those individuals grandfathered under 180 NAC 24-006.02, each licensee subject to the provisions of this 180 NAC 24-004 through 24-010 must fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees must transmit all collected fingerprints to the U.S. Nuclear Regulatory Commission for transmission to the FBI. The licensee must use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

24-007.01B The licensee must notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and must inform him/her of the procedures for revising the record or adding explanations to the record.

24-007.01C Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

24-007.01C1 The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his/her unescorted access authorization; and

24-007.01C2 The previous access was terminated under favorable conditions.

24-007.01D Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under 180 NAC 24-004 through 24-010, the Fingerprint Orders, or 10 CFR 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of 180 NAC 24-009.03.

24-007.01E Licensees must use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

24-007.02 Prohibitions

24-007.02A Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

24-007.02A1 An arrest more than one year old for which there is no information of the disposition of the case; or

24-007.02A2 An arrest that resulted in dismissal of the charge or an acquittal.

24-007.02B Licensees may not use information received from a criminal history records check obtained under 180 NAC 24-004 through 24-010 in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor must licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

24-007.03 Procedures for Processing of Fingerprint Checks

24-007.03A For the purpose of complying with 180 NAC 24-004 through 24-010, licensees must use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545

Rockville Pike, ATTN: Criminal History Program/Mail T-03B46M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-(301)415-7513, or by e-mail to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at http://www.nrc.gov/site-help/e-submittals.html.

24-007.03B Fees for the processing of fingerprint checks are due upon application. Licensees must submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-415-7513.) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)

24-007.03C The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

24-008 RELIEF FROM FINGERPRINTING IDENTIFICATION, AND CRIMINAL HISTORY RECORDS CHECK AND OTHER ELEMENTS OF BACGROUND INVESTIGATIONS FOR DESIGNATED CATEGOREIS OF INDIVIDUALS PERMITTED UNESCORTED ACCESS TO CERTAIN RADIOACTIVE MATERIAL

24-008.01 Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

1. An employee of the U.S. Nuclear Regulatory Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;
2. A Member of Congress;
3. An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;
4, The Governor of a State or his or her designated State employee representative;
5. Federal, State, or local law enforcement personnel;
6. State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

7. Agreement State employees conducting security inspections on behalf of the U.S. Nuclear Regulatory Commission under an agreement executed under section 274.i. of the Atomic Energy Act;
8. Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the U.S. Nuclear Regulatory Commission;
9. Emergency response personnel who are responding to an emergency;
10. Commercial vehicle drivers for road shipments of category 2 quantities of radioactive material;
11. Package handlers at transportation facilities such as freight terminals and railroad yards;
12. Any individual who has an active Federal security clearance, provided that s\he makes available the appropriate documentation. Written confirmation from the agency/employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee must retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and
13. Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee must retain the documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

24-008.02 Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that s\he makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee must retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

1. National Agency Check;
2. Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;
3. Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;
4. Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;
5. Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license under 49 CFR part 1572; and
6. Customs and Border Protection's Free and Secure Trade (FAST) Program.

24-009 PROTECTION OF INFORMATION

24-009.01 Each licensee who obtains background information on an individual under 180 NAC 24-004 through 24-010 must establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

24-009.02 The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his/her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

24-009.03 The personal information obtained on an individual from a background investigation may be provided to another licensee:

24-009.03A Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

24-009.03B The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

24-009.04 The licensee must make background investigation records obtained under 180 NAC 24-004 through 24-010 available for examination by an authorized representative of the Department to determine compliance with the regulations and laws.

24-009.05 The licensee must retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

24-010 ACCESS AUTHORIZATION PROGRAM REVIEW

24-010.01 Each licensee must be responsible for the continuing effectiveness of the access authorization program. Each licensee must ensure that access authorization programs are reviewed to confirm compliance with the requirements of 180 NAC 24-004 through 24-010 and that comprehensive actions are taken to correct any noncompliance that is identified. The review program must evaluate all program performance objectives and requirements. Each licensee must periodically (at least annually) review the access program content and implementation.

24-010.02 The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee

must review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

24-010.02 Review records must be maintained for three years.

PHYSICAL PROTECTION REQUIREMENTS DURING USE

24-011 SECURITY PROGRAM

24-011.01 Applicability

24-011.01A Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material must establish, implement, and maintain a security program in accordance with the requirements of this 180 NAC 24-011 through 24-019.

24-011.01B An applicant for a new license and each licensee that would become newly subject to the requirements of 180 NAC 24-011 through 24-019 upon application for modification of its license must implement the requirements of 180 NAC 24-011 through 24-019, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

24-011.01C Any licensee that has not previously implemented the Security Orders or been subject to the provisions of 180 NAC 24-011 through 24-019 must provide written notification to the Department in accordance with 180 NAC 1-012 at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

24-011.02 General Performance Objective: Each licensee must establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

24-011.03 Program Features: Each licensee's security program must include the program features, as appropriate, described in 180 NAC 24-012 through 24-018.

24-012 GENERAL SECURITY PROGRAM REQUIREMENTS

24-012.01 Security Plan

24-012.01A Each licensee identified in 180 NAC 24-011 must develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by 180 NAC 24-011 through 24-019. The security plan must, at a minimum:

24-012.01A1 Describe the measures and strategies used to implement the requirements of 180 NAC 24-011 through 24-019; and

24-012.01A2 Identify the security resources, equipment, and technology used to satisfy the requirements of 180 NAC 24-011 through 24-019.

24-012.01B The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

24-012.01C A licensee must revise its security plan as necessary to ensure the effective implementation of Department requirements. The licensee must ensure that:

24-012.01C1 The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

24-012.01C2 The affected individuals are instructed on the revised plan before the changes are implemented.

24-012.01D The licensee must retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee must retain the superseded material for three years after the record is superseded.

24-012.02 Implementing Procedures

24-012.02A The licensee must develop and maintain written procedures that document how the requirements of 180 NAC 24-011 through 24-019 and the security plan will be met.

24-012.02B The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

24-012.02C The licensee must retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure must be retained for three years after the record is superseded.

24-012.03 Training

24-012.03A Each licensee must conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

24-012.03A1 The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

24-012.03A2 The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Department requirements;

24-012.03A3 The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

24-012.03A4 The appropriate response to security alarms.

24-012.03B In determining those individuals who must be trained on the security program, the licensee must consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

24-012.03C Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

24-012.03C1 Review of the training requirements of 180 NAC 24-012.03 and any changes made to the security program since the last training;

24-012.03C2 Reports on any relevant security issues, problems, and lessons learned;

24-012.03C3 Relevant results of Department inspections; and

24-012.03C Relevant results of the licensee's program review and testing and maintenance.

24-012.03D The licensee must maintain records of the initial and refresher training for three years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

24-012.04 Protection of Information

24-012.04A Licensees authorized to possess category 1 or category 2 quantities of radioactive material must limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

24-012.04B Efforts to limit access must include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures.

24-012.04C Before granting an individual access to the security plan or implementing procedures, licensees must:

24-012.04C1 Evaluate an individual's need to know the security plan or implementing procedures; and

24-012.04C2 If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination must be conducted by the reviewing official and must include the background investigation elements contained in 180 NAC 24-006.01B through 24-006.01G.

24-012.04D Licensees need not subject the following individuals to the background investigation elements for protection of information:

24-012.04D1 The categories of individuals listed in 180 NAC 24-008.01, items 1 through 13; or

24-012.04D2 Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in 180 NAC 24-006.01B through 24-006.01G, has been provided by the security service provider.

24-012.04E The licensee must document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

24-012.04F Licensees must maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access authorization requirements for access to the information, the licensee must remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

24-012.04G When not in use, the licensee must store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

24-012.04H The licensee must retain as a record for three years after the document is no longer needed:

24-012.03H1 A copy of the information protection procedures; and

24-012.03H2 The list of individuals approved for access to the security plan or implementing procedures.

24-013 LLEA COORDINATION

24-013.01 A licensee subject to this 180 NAC 24-011 through 24-019 must coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

24-013.01A A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with 180 NAC 24-011 through 24-019; and

24-013.01B A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

24-013.02 The licensee must notify the Department within three business days if:

24-013.02A The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

24-013.02B The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

24-013.03 The licensee must document its efforts to coordinate with the LLEA. The documentation must be kept for three years.

24-013.04 The licensee must coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

24-014 SECURITY ZONES

24-014.01 Licensees must ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

24-014.02 Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

24-014.03 Security zones must, at a minimum, allow unescorted access only to approved individuals through:

24-014.03A Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

24-014.03B Direct control of the security zone by approved individuals at all times; or

24-014.03C A combination of continuous physical barriers and direct control.

24-014.04 For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee must, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

24-014.05 Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

24-015 MONITORING DETECTION, AND ASSESSMENT

24-015.01 Monitoring and Detection

24-015.01A Licensees must establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees must provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

24-015.01B Monitoring and detection must be performed by:

24-015.01B1 A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

24-015.01B2 Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

24-015.01B3 A monitored video surveillance system; or

24-015.01B4 Direct visual surveillance by approved individuals located within the security zone; or

24-015.01B5 Direct visual surveillance by a licensee designated individual located outside the security zone.

24-015.01C A licensee subject to 180 NAC 24.011 through 24-019 must also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

24-015.01C1 For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

1. Electronic sensors linked to an alarm; or
2. Continuous monitored video surveillance; or
3. Direct visual surveillance.

24-015.01C2 For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

24-015.02 Assessment: Licensees must immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

24-015.03 Personnel Communications and Data Transmission: For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees must:

24-015.03A Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

24-015.03B Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

24-015.04 Response: Licensees must immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response must include requesting, without delay, an armed response from the LLEA.

24-016 MAINTENANCE AND TESTING

24-016.01 Each licensee subject to 180 NAC 24-011 through 24-019 must implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of 180 NAC 24 must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

24-016.02 The licensee must maintain records on the maintenance and testing activities for three years.

24-017 REQUIREMENTS FOR MOBILE DEVICES: Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

24-017.01 Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

24-017.02 For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee must utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees must not rely on the removal of an ignition key to meet this requirement.

24-018 SECURITY PROGRAM REVIEW

24-018.01 Each licensee must be responsible for the continuing effectiveness of the security program. Each licensee must ensure that the security program is reviewed to confirm compliance with the requirements of 180 NAC 24-011 through 24-019 and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee must periodically (at least annually) review the security program content and implementation.

24-018.02 The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee must review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

24-018.03 The licensee must maintain the review documentation for three years.

24-019 REPORTING OF EVENTS;

24-019.01 The licensee must immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee must notify the Office of Radiological Health at (402) 471-2168 during business hours or (402) 471-4545 after business hours. In no case must the notification to the Department be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

24-019.02 The licensee must assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee must notify the notify the Office of Radiological Health at (402) 471-2168 during business hours or (402) 471-4545 after business hours.

24-019.03 The initial telephonic notification required by 180 NAC 24-019.01 must be followed within a period of 30 days by a written report submitted to the Department in accordance with 180 NAC 1-012. The report must include sufficient information for Department analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

PHYSICAL PROTECTION IN TRANSIT

24-020 ADDITIONAL REQUIREMENTS FOR TRANSFER OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL: A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the, U.S. Nuclear Regulatory Commission or an Agreement State must meet the license verification provisions listed below instead of those listed in 180 NAC 3-025.04:

24-020.01 Any licensee transferring category 1 quantities of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission or an Agreement State, prior to conducting such transfer, must verify with the U.S. Nuclear Regulatory's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor must document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

24-020.02 Any licensee transferring category 2 quantities of radioactive material to a licensee of the Department, U.S. Regulatory Commission or an Agreement State, prior to conducting such transfer, must verify with the U.S. Nuclear Regulatory's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor must document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

24-020.03 In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee must keep a copy of the certification. The certification must be confirmed by use of the U.S. Nuclear Regulatory's license verification system or by contacting the license issuing authority by the end of the next business day.

24-020,04 The transferor must keep a copy of the verification documentation as a record for three years.

24-021 APPLICABILITY OF PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL DURING TRANSIT

24-021.01 For shipments of category 1 quantities of radioactive material, each shipping licensee must comply with the requirements for physical protection contained in 180 NAC 24-022.01 and 24-022.05; 180 NAC 24-023; 24-024.01A, 24-024.02A, 24-024.03, and 24-025.01, 24-025.03, 24-025.05, 24-025.07 and 24-025.08.

24-021.02 For shipments of category 2 quantities of radioactive material, each shipping licensee must comply with the requirements for physical protection contained in 180 NAC 24-022.02 through 24-022.05; 24-024.01B, 24-024.01C, 24-024.02B, and 24-024.03; and 24-025.02, 24-025.04, 24-025.06, 24-025.07 and 24-025.08. For those shipments of category 2 quantities of radioactive material that meet the criteria of 180 NAC 13-020.02, the shipping licensee must also comply with the advance notification provisions of 180 NAC 13-020.

24-021.03 The shipping licensee must be responsible for meeting the requirements of this 180 NAC 24-020 through 24-025 unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under 180 NAC 24-020 through 24-025.

24-021.04 Each licensee that imports or exports category 1 quantities of radioactive material must comply with the requirements for physical protection during transit contained in 24-022.01B and 24-022.05; 24-023, and 24-024.01A, 24-024.02A, and 24-024.03; and 24-025.01, 24-025.03, 24-025.05, 24-025.07 and 24-025.08 for the domestic portion of the shipment.

24-021.05 Each licensee that imports or exports category 2 quantities of radioactive material must comply with the requirements for physical protection during transit contained in 180 NAC 24-024.01B. 24-024.01C and 24-024.02B, and 180 NAC 24-025.02, 24-025.04, 24-025.06, 24-025.07 and 24-025.08 for the domestic portion of the shipment.

24-022 PREPLANNING AND COORDINATION OF SHIPMENT OF CATEGORY 1 OR CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL;

24-022.01 Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage must:

24-022.01A Preplan and coordinate shipment arrival and departure times with the receiving licensee;

24-022.01B Preplan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

24-022.01B1 Discuss the State's intention to provide law enforcement escorts; and

24-022.01B2 Identify safe havens; and

24-022.01C Document the preplanning and coordination activities.

24-022.02 Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage must coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee must document the coordination activities.

24-022.03 Each licensee who receives a shipment of a category 2 quantity of radioactive material must confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee must notify the originator.

24-022.04 Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to 180 NAC 24-022.02, must promptly notify the receiving licensee of the new no-later-than arrival time.

24-022.05 The licensee must retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for three years

24-023 ADVANCE NOTIFICATION OF SHIPMENT OF CATEGORY 1 OR CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL: As specified in 180 NAC 24-023.01 and 24-023.02, each licensee must provide advance notification to the U.S. Nuclear Regulatory Commission and the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

24-023.01 Procedures for submitting advance notification

24-023.01A The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission's Web site at http://nrc-stp.ornl.gov/special/designee.pdf.

24-023.01B A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

24-023.01C A notification delivered by any means other than mail must reach the Department or at least 4 days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the State.

24-023.02 Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

24-023.02A The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

24-023.02B The license numbers of the shipper and receiver;

24-023.02C A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

24-023.02D The point of origin of the shipment and the estimated time and date that shipment will commence;

24-023.02E The estimated time and date that the shipment is expected to enter each State along the route;

24-023.02F The estimated time and date of arrival of the shipment at the destination; and

24-023.02G A point of contact, with a telephone number, for current shipment information.

24-023.03 Revision Notice:

24-023.03A The licensee must provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the Department, the governor of the State or the governor's designee.

24-023.03B A licensee must promptly notify the Department, the governor of the State or the governor's designee of any changes to the information provided in accordance with 180 NAC 24-023.02 and 24-023.03A.

24-023.04 Cancellation notice: Each licensee who cancels a shipment for which advance notification has been sent must send a cancellation notice to the Department, the governor of each State or to the governor's designee previously notified. The licensee must send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee must state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

24-023.05 Records: The licensee must retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

24-024 REQUREMENTS FOR PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL DURING SHIPMENT:

24-024.01 Shipment by Road:

24-024.01A Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material must:

24-024.01A1 Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, seven days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

24-024.01A2 Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

24-024.01A3 Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

24-024.01A4 Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24 hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

24-024.01A5 Develop written normal and contingency procedures to address:

24-024.01A5a Notifications to the communication center and law enforcement agencies;

24-024.01A5b Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

24-024.01A5c Loss of communications; and

24-024.01A5d Responses to an actual or attempted theft or diversion of a shipment.

24-024.01A6 Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material must ensure that drivers,

accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

24-024.01B Each licensee that transports category 2 quantities of radioactive material must maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

24-024.01C Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material must:

24-024.01C1 Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

24-024.01C2 Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

24-024.01C3 Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

24-024.02 Shipment by Rail

24-024.02A Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material must:

24-024.02A1 Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center must provide positive confirmation of the location of the shipment and its status. The communications center must implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

24-024.02A2 Ensure that periodic reports to the communications center are made at preset intervals.

24-024.02B Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material must:

24-024.02B1 Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package

tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

24-024.02B2 Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

24-024.02B3 Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

24-024.03 Investigations: Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material must immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material must immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

24-025 REPORTING OF EVENTS:

24-025.01 The shipping licensee must notify the appropriate LLEA and the licensee must notify the Office of Radiological Health at (402) 471-2168 during business hours or (402) 471-4545 after business hours within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by 180 NAC 24-024.03, the shipping licensee will provide agreed upon updates to the Department on the status of the investigation.

24-025.02 The shipping licensee must notify the Office of Radiological Health at (402) 471-2168 during business hours or (402) 471-4545 after business hours within four hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee must immediately notify the Department.

24-025.03 The shipping licensee must notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee must notify the Department upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

24-025.04 The shipping licensee must notify the Office of Radiological Health at (402) 471-2168 during business hours or (402) 471-4545 after business hours as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

24-025.05 The shipping licensee must notify the Office of Radiological Health at (402) 471-2168 during business hours or (402) 471-4545 after business hours and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

24-025.06 The shipping licensee must notify the Office of Radiological Health at (402) 471-2168 during business hours or (402) 471-4545 after business hours as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

24-025.07 The initial telephonic notification required by 180 NAC 24-025.01 through 24-026.04 must be followed within a period of 30 days by a written report submitted to the Department in accordance with 180 NAC 1-012. A written report is not required for notifications on suspicious activities required by 180 NAC 24-025.03 and 24-025.04. In addition, the licensee must provide one copy of the written report addressed to the Department. The report must set forth the following information:

24-025.07A A description of the licensed material involved, including kind, quantity, and chemical and physical form;

24-025.07B A description of the circumstances under which the loss or theft occurred;

24-025.07C A statement of disposition, or probable disposition, of the licensed material involved;

24-025.07D Actions that have been taken, or will be taken, to recover the material; and

24-025.07E Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

24-025.08 Subsequent to filing the written report, the licensee must also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

RECORDS

24-026 FORM OF RECORDS: Each record required by 180 NAC 24 must be legible throughout the retention period specified by Department regulation. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

24-027 RECORD RETENTION: Licensees must maintain the records that are required by the regulations in 180 NAC 24 for the period specified by the appropriate regulation. If a retention

period is not otherwise specified, these records must be retained until the Department terminates the facility's license. All records related to 180 NAC 24 may be destroyed upon Department termination of the facility license.

APPENDIX 24 -A

Table 1 – Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The ”sum of fractions” methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this part.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this part apply.

II. First determine the total activity for each radionuclide from Table 1 of Appendix 24-A. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 of Appendix 24-A in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1
R_2 = total activity for radionuclide 2
R_n = total activity for radionuclide n
AR_1 = activity threshold for radionuclide 1
AR_2 = activity threshold for radionuclide 2
AR_n = activity threshold for radionuclide n

$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right]\geq 1.0$$