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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION ADMINISTRATION
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PART A

GENERAL PROVISIONS

Sec. A.1 Scope. Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.[1] This part also gives notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of registration holder's activities subject to these regulations, that they may be individually subject to Maryland Department of the Environment enforcement actions for violation of A.16.

Sec. A.2 Definitions. As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

"A1" means the maximum activity of special form radioactive material permitted in a Type A package.

"A2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix A of Part T of these regulations, Table I, or may be derived in accordance with the procedure prescribed in Appendix A of Part T of these regulations.

"Absorbed dose" [See "Dose"]

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

"Act" means the Annotated Code of Maryland, Environment Article, Title 8 "Radiation."

"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 Maryland Department of Environment, Radiological Health Program.

"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.

"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 material exists in concentrations:

(1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of Part D of these regulations, or

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

"Annually" means at intervals not to exceed one year (12 consecutive months).

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[1] Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

"As low as 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.

"Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in Sections G.55(a) and G.59; or

(2) Is identified as an authorized nuclear pharmacist on:

(i) A specific license issued by the Agreement State or NRC that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) An authorization issued by an Agreement State or NRC broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with Sec. C.28(j)(2)(iv).

"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 or radiation producing machines regulated by the Agency.

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

"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 these regulations, "radio bioassay" is an equivalent term.

"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 using special nuclear material;

(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 solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ‘‘byproduct material’’ within this definition;

(3) (i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(a) Has been made radioactive by use of a particle accelerator; and

(b) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The NRC, in consultation with the Administrator of the Environmental Protection Agency, the 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

(ii) Before, on, or after August 8, 2005, 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 shall begin in January and subsequent calendar quarters shall 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 the method observed by him of determining calendar quarters for purposes of these regulations except at the beginning of a calendar 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.

"CFR" means Code of Federal Regulations.

"Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

"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.

"COMAR" means Code of Maryland Regulations

"Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility or licensee subject to these regulations that has a connection to radiological health and safety.

"Committed dose equivalent" [See "Dose"]

"Committed effective dose equivalent" [See "Dose"]

“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.

"Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to these regulations that are related to radiological health and safety. The term “construction” does not include:

(i) Changes for temporary use of the land for public recreational purposes;
(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
(iii) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to these regulations;
(v) Excavation;
(vi) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
(vii) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
(viii) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
(ix) Taking any other action that has no connection to radiological health and safety.

“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 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^{7} tps. One microcurie (μCi) = 0.000001 curie = 3.7×10^{4} tps (see A.12 for SI equivalent becquerel).

"Decommission” means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:
(1) Release of the property for unrestricted use and termination of the license; or
(2) Release of the property under restricted conditions and termination of the license.

"Deep dose equivalent" [see "Dose"]

“Department” [see “Agency”]

"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.

“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.

“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.

"Dose" is a generic term that means absorbed dose, committed dose equivalent, committed effective dose equivalent, deep dose equivalent, dose equivalent, effective dose equivalent, external dose, eye dose equivalent, shallow dose equivalent, total effective dose equivalent, or total organ dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) "Committed dose equivalent" ($H_{T,50}$) 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.

(3) "Committed effective dose equivalent" ($H_{E,50}$) 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 ($H_{E,50} = \Sigma\, w_T H_{T,50}$).

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

(5) "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.

(6) "Effective dose equivalent (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 ($H_E = \Sigma\, w_T H_T$).

(7) “External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

(8) "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).

(9) "Shallow dose equivalent" (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 centimeter (7 mg/cm^2).

(10) "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).

(11) "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 D.1107(a)(vi) of this regulation.

"Dose equivalent" [see "Dose"]

"Dose Limits" means the permissible upper bounds of radiation doses established in accordance with this regulation. For purposes of this regulation, "limits" is an equivalent term.

"Effective dose equivalent" [See "Dose"]

"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.

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

"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 special unit of exposure is the roentgen (R). See A.13 "Units of Exposure and Dose" for SI equivalent.[2]

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" [See "Dose"]

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

"Eye dose equivalent" [See "Dose"]

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

“Film badge” [See “Individual monitoring devices”]

"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.

[2] When not underlined as above, the term 'Exposure' has a more general meaning in this regulation.

"General 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. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means a system of rules or methods of performing particular actions including the systematic application of knowledge or skill in effecting a desired result acquired by experience, study, or observation relating to the science of medical diagnosis, treatment, or surgery.

"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.

"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 definition of DAC-hours in Part D.]

"Individual monitoring devices" (individual monitoring equipment) means devices accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) designed to be worn by a single individual for the assessment of dose equivalent, such as film badges, thermoluminescent dosimeters (TLDs), and personal dosimeters capable of recording personnel dose.

"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 Agency.

"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.

"License" means a license to possess or use radioactive material, including a license amendment, issued by the Agency.

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

"Licensed practitioner of the healing arts" means a person duly licensed to practice medicine and surgery, osteopathic medicine and surgery, chiropractic, dentistry, podiatry, or veterinary medicine and surgery approved by a health regulatory board of Maryland for the ascertainment, cure, relief, palliation, adjustment, or correction of any human/animal disease, ailment, deformity, or injury.

"Licensee" means any person who is licensed by the Agency in accordance with these regulations.

"Licensing State" means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Limits" [See "Dose Limits"]

"Lost or missing licensed material" means licensed material 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.

"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 Section T.4 of this regulation.

“Medical use” means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects in the practice of the healing arts.

"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.

"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 purposes of these regulations, "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.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

“Normal form radioactive material” means radioactive material that has not been demonstrated to qualify as “special form radioactive material.”

"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 involved exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. This includes exposure to radiation from registered and unregistered radiation machines or exposure to radioactive material from licensed and unlicensed sources of radiation. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Sec. G.75, 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" 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 MeV.

"Person" means an individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind and any partnership, firm, association, corporation, or other entity. "Person" includes any public or municipal corporation and any agency, bureau, department, or instrumentality of State or local government and, to the extent authorized by federal law, federal government.

“Personal dosimeter” [See “Individual monitoring devices”]

"Personnel monitoring equipment" [See "Individual monitoring devices"]

“Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

"Physician" means an individual who is authorized under the Maryland Medical Practice Act to practice medicine in this State.

“Positron emission tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

“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.

"Public dose" means the dose received by a member of the public from exposure to radiation and/or to radioactive material released by a licensee or registrant, or to any other source of radiation under the control of the 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 Sec. G.75, or dose 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 1 and 2 of A.13, 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/gram or 0.01 joule/kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any 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 machine" means any assemblage of components capable of producing radiation except those devices with radioactive material as the only source of radiation. This assemblage may include, as determined by the Agency:

(1) Not more than one control panel;

(2) The necessary supporting structures; and

(3) Any additional components or auxiliary equipment that function with the assemblage to produce the result desired by using the machine.

"Radiation safety officer" means an individual who:

(1) Meets the requirements in Secs. G.50(a) or (c)(1) and G.59; or

(2) Is identified as a Radiation Safety Officer on:

(i) A specific medical use license issued by an Agreement State or the NRC; or

(ii) A medical use permit issued by a NRC master material licensee; or

(3) Has been determined by a registrant as an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

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

"Registrant" means any person who is registered with the Agency or is legally obligated to register with the Agency pursuant to these regulations and Act.

"Registration" means registration with the Agency in accordance with the regulations adopted by the Agency.

"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 sievert).

"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 Part D.

"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. A 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 2.58×10^{-4} coulombs/kilogram of air (see "Exposure").

"Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

"Shallow dose equivalent" [See "Dose"]

"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).

"Site Boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

"Source material" means:

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

(2) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) 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 activity that results in the production of byproduct material as defined by definition (2) of byproduct material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"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 mm (0.2 in); and

(3) It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015 in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

"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 of the foregoing 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 shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

"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.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Temporary jobsite" means any location where a portable source of radiation is used or stored, other than a location listed in a specific license or registration, for a period of no longer than 365 continuous days.

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

"These regulations" means all parts of COMAR 26.12 "Radiation Management."

"Total effective dose equivalent" [See "Dose"]

"Total organ dose equivalent" [See "Dose"]

"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 sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 to 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 to 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. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

"Unrestricted area" means any area, access to which is not limited by the licensee or registrant.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.[3]

"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, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

[3] 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.

"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.

"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 dose.

[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 specified guidance is issued.

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 Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

"Working level" means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of $1.3x10^5$ 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.

“Written directive” means:

(1) For radioactive material, an authorized user’s written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Sec. G.40.

(2) For registrants, for teletherapy, an order in writing for a specific patient or human research subject, dated and signed by a physician containing the total dose, dose per fraction, treatment site and overall treatment period.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these regulations. 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.

Exemptions from the Regulatory Requirements

Sec. A.3 Exemptions.

(a) General Provision. The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) 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:

(i) that the exemption of the prime contractor or subcontractor is authorized by law; and

(ii) 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.

General Regulatory Requirements

Sec. A.4 Records.

(a) Each person who is a licensee for the use of radioactive materials shall maintain records required by these regulations at the licensee's office in Maryland. If a licensee maintains more than one office in Maryland, he shall inform the Agency of the location of the office where required records will be maintained.

(b) Each person responsible for a radiation machine facility shall maintain such records as required by these regulations at the facility where the radiation machine is located or stored.

(c) Each licensee or registrant shall maintain records showing the receipt, inventory, transfer, and disposal of all sources of radiation.

(d) Additional record requirements are specified elsewhere in these regulations.

Sec. A.5 Inspections.

(a) Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation, the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available, upon inspection by the Agency, records maintained pursuant to these regulations.

Sec. A.6 Tests. Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) sources of radiation;

(b) facilities wherein sources of radiation are used or stored;

(c) radiation detection and monitoring instruments; and

(d) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

Additional Regulatory Requirements

Sec. A.7 Additional Requirements. The Agency may, by rule, regulation, order, license amendment or registrant condition, impose such requirements upon any licensee/registrant above and beyond those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

Enforcement Requirements

Sec. A.8 Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

Sec. A.9 Impounding. Sources of radiation shall be subject to impounding pursuant to the Act.

Sec. A.10 Prohibited Uses.

(a) A hand-held fluoroscopic screen using X-ray equipment shall not be used 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.

(b) A shoe-fitting fluoroscopic device shall not be used.

(c) No person shall possess or store a radiation machine which does not meet the requirements of these regulations or COMAR 26.12.02 unless such radiation machine has been internally rendered inoperable, in a manner approved by the Department, by a service provider registered under COMAR 26.12.01.01B.6.

Interpretations

Sec. A.11 Interpretations. Except as specifically authorized by the Agency in writing, no interpretation of these regulations by an officer or employee of the Agency will be recognized to be binding upon the Agency.

Communications

Sec. A.12 Communications. All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Maryland Department of the Environment, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230.

Sec. A.13 Units of Exposure and Dose.

(a) As used in these regulations, the unit of Exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per Kilogram of air.

(b) As used in these regulations, the units of dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

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).

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).

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).

(c) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in Table 1.

TABLE 1
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-speed 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 rad equal to 1 rem or the absorbed dose in gray equal to 1 Sv.

(d) If it is more convenient to measure the neutron fluency rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in A.13c., 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 2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE 2
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy	Quality Factor[a]	Fluence per unit Dose Equivalent[b]	Fluence per unit Dose Equivalent[b]
	(MeV)	(Q)	(neutrons $cm^{-2}rem^{-1}$)	(neutrons $cm^{-2}Sv^{-1}$)
(thermal)	$2.5x10^{-8}$	2	$980x10^{6}$	$980x10^{8}$
	$1x10^{-7}$	2	$980x10^{6}$	$980x10^{8}$
	$1x10^{-6}$	2	$810x10^{6}$	$810x10^{8}$
	$1x10^{-5}$	2	$810x10^{6}$	$810x10^{8}$
	$1x10^{-4}$	2	$840x10^{6}$	$840x10^{8}$
	$1x10^{-3}$	2	$980x10^{6}$	$980x10^{8}$
	$1x10^{-2}$	2.5	$1010x10^{6}$	$1010x10^{8}$
	$1x10^{-1}$	7.5	$170x10^{6}$	$170x10^{8}$
	$5x10^{-1}$	11	$39x10^{6}$	$39x10^{8}$
	1	11	$27x10^{6}$	$27x10^{8}$
	2.5	9	$29x10^{6}$	$29x10^{8}$
	5	8	$23x10^{6}$	$23x10^{8}$
	7	7	$24x10^{6}$	$24x10^{8}$
	10	6.5	$24x10^{6}$	$24x10^{8}$
	14	7.5	$17x10^{6}$	$17x10^{8}$
	20	8	$16x10^{6}$	$16x10^{8}$
	40	7	$14x10^{6}$	$14x10^{8}$
	60	5.5	$16x10^{6}$	$16x10^{8}$
	$1x10^{2}$	4	$20x10^{6}$	$20x10^{8}$
	$2x10^{2}$	3.5	$19x10^{6}$	$19x10^{8}$
	$3x10^{2}$	3.5	$16x10^{6}$	$16x10^{8}$
	$4x10^{2}$	3.5	$14x10^{6}$	$14x10^{8}$

[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.

Sec. A.14 Units of Radioactivity. For 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.

(a) One becquerel (Bq) = 1 disintegration or transformation per second (s^{-1}) (dps or tps).

(b) One curie (Ci) = $3.7x10^{10}$ disintegrations or transformations per second = $3.7x10^{10}$ becquerel (Bq) = $2.22x10^{12}$ disintegrations or transformations per minute.

Sec. A.15 False Statements, Representations and Certifications.

No person shall:

(a) make a false statement, representation, or certification in any application, record, report, plan or other document regarding radiation levels, tests performed, radiation safety conditions, practices or notices, or

(b) falsify, tamper with or render inaccurate any monitoring device or method for data collection if the data collected by that device or method is required by these regulations, or by any license or registration condition.

Sec. A.16 Deliberate Misconduct.

(a) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, shall not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or

(2) Deliberately submit to the Department, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder'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.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with Maryland Environmental Article, Sections 1-301, 8-101, 8-509(b) and 8-510(b).

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

Sec. A.17 Public Posting of Notices of Violation.

(a) A notice of violation issued by the Agency to a registered or licensed facility shall be conspicuously posted at the facility for public review within two (2) working days after receipt.

(b) A notice of violation shall remain posted for a minimum of 30 working days or until action correcting the violation has been completed and this correction has been verified by the Agency.

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PART B

REGISTRATION OF RADIATION MACHINES FACILITIES AND SERVICE PROVIDERS

Sec. B.1 Purpose and Scope.

(a) This Part provides for the registration of radiation machine facilities and of persons installing or servicing radiation machines or radiation machine facilities.

(b) In addition to the requirements of this part, all registrants are subject to the applicable provisions of other parts of these regulations.

Sec. B.2 Definitions.

"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.

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable by a person registered under Sec. B.6 of this Part.

Sec. B.3 Exemptions.

(a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Part, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5 μSv (0.5 millirem) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(b) Radiation machines while in transit or storage, pending relocation or transfer to an authorized recipient, are exempt from the requirements of this Part for a period not to exceed 20 days.

(c) Domestic television receivers are exempt from the requirements of this Part.

Sec. B.4 Shielding Plan Review.

(a) For x-ray systems of less than 150 KeV, the following requirements shall apply:

(1) At least 30 days prior to the installation or relocation of a radiation machine intended for use for diagnostic purposes, any person owning or operating a radiation machine facility shall submit floor plans, shielding specifications and equipment arrangement of this installation to the Agency for review and approval on forms provided by the Agency. Appendix A is provided as a guide for the proper design of an operator's booth.

(2) After January 19, 1987, structural shielding designs shall be performed by a person currently registered as a Service Provider with the Agency under this Part.

(3) The approval of such plans shall 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 Part D of these regulations.

(4) After installation of a radiation machine, the registrant shall maintain for inspection by the Agency:

(i) The maximum rated technique factors of each x-ray system control panel;

(ii) A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by individuals in such areas. In addition, the drawing shall include:

(a) The results of a survey for radiation present at the operator's position and at pertinent points outside the room at specified test conditions, or

(b) The type and thickness of materials, or lead equivalency, of each protective barrier.

(5) For computed tomography x-ray systems including CT simulators regulated under Section F.11, additional requirements in Section F.11(c) apply.

(b) For x-ray systems 150 KeV or greater, the following requirements shall apply:

(1) No less than 45 days prior to installation, all high energy facilities with therapeutic, non-human use or industrial radiation machines that produce photons and/or electrons with a maximum energy in excess of 150 KeV shall submit to the Agency for approval shielding plans which contain, as a minimum, the following information:

(i) 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 shall be specified;

(ii) 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, and the anticipated number of patients to be treated per day or week;

(iii) A facility blueprint/drawing, including both floor plan and elevation views, indicating:

(a) Relative orientation of the high energy radiation machine;

(b) A scale (0.25 inch = 1 foot is typical);

(c) Direction of North;

(d) Thickness and minimum density of shielding material(s);

(e) Normal location of the high energy radiation machine's radiation port(s);

(f) The port's travel and traverse limits;

(g) General direction(s) of the useful beam;

(h) Locations and sizes of all windows, doors and penetrations;

(i) Location of the high energy radiation machine control panel; and

(j) Details of the door(s) and maze.

(iv) The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floors, and ceilings of the room(s)concerned;

(v) 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;

(vi) Description of all assumptions included 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], workload, 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, such as walls, floor, and ceiling, and allowed radiation exposure in both restricted and unrestricted areas; and

(vii) At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition; for example, primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s), and shielding material in the facility:

(a) If commercial software is used to generate shielding requirements, identify the software and version/revision date; and

(b) If the software used to generate shielding requirements is discussed in open literature, submit quality control sample calculations to verify the result obtained with the software.

(2) Neutron Shielding. In addition to the requirements in Section B.4(b)(1), any person owning or operating a facility that utilizes therapeutic, non-human use, or industrial radiation machines that produce photons and/or electrons with a maximum energy in excess of 10 MeV shall submit shielding plans which contain, as a minimum, the following additional information:

(i) The structural composition, thickness, minimum density and location of all neutron shielding material;

(ii) 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;

(iii) 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:

(a) If commercial software is used to generate shielding requirements, identify the software and version/revision date; and

(b) If the software used to generate shielding requirements is discussed in open literature, submit quality control sample calculations to verify the result obtained with the software.

(iv) The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed.

(3) All high energy facilities shall maintain for inspection by the Agency copies of the submittals required in Section B.4(b), as well as all Agency approvals.

Sec. B.5 Registration of Radiation Machine Facilities.

Each person owning or operating a radiation machine facility shall:

(a) Apply for registration of such facility with the Agency prior to the following, whichever is earliest:

(1) The completion of the installation or the use of a radiation machine in the facility;

(2) The receipt of a radiation machine by a facility, if installation is not required by a service provider as described in Section B.6;

(3) The relocation of a radiation machine to a new facility location; or

(4) The purchase of the facility or radiation machine in the facility.

(b) Complete application forms for registration furnished by the Agency that contain all the information required by the forms and accompanying instructions;

(c) Designate on the application form the individual to be responsible for radiation protection.

(d) Include full payment of all fees in the application for registration, as specified in COMAR 26.12.03 for the type(s) of radiation machine(s).

(e) Prohibit any person from furnishing radiation machine servicing or services as described in B.6(d) to a radiation machine facility until such person provides evidence to the registrant that they are currently registered with the Agency as a service provider in accordance with B.6.

(f) Apply for certification of the radiation machine(s) to be located in such facility if the radiation machines will be classified in Groups 1, 2, 3, 4, or 5, as described in COMAR 26.12.02.02B. Application for certification of radiation machines shall be made in accordance with COMAR 26.12.02.02D(2).

(g) Apply for renewal of facility registration at least 14 days prior to the date specified on the radiation machine facility's certificate of registration in accordance with B.9.

Sec. B.5A Cancellation of Facility Registration.

(a) When a registrant plans to cease operation of all radiation machines at a radiation machine facility, the registrant shall submit a written request to the Agency to cancel the radiation machine facility's registration at least 14 days prior to the planned date of cessation of operation of the radiation machine facility. The registrant shall provide the Agency with acceptable documentation of removal or disablement of all radiation machines located in the radiation machine facility as described in B.5A(b).

(b) A registrant who possesses an expired certificate of registration shall remain subject to the regulations of this Subtitle until the Agency has received from the registrant (1) a request for cancellation of the radiation machine facility's registration, and (2) a Form MDE RX-24 signed and dated by a State-registered service provider, or a fully executed and dated Bill of Sale, for every radiation machine in the radiation machine facility documenting the removal or disablement of each such radiation machine.

Sec. B.6 Application for Registration of Servicing and Services.

(a) Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration of such services with the Agency prior to furnishing or offering to furnish any such services.

(b) Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.

(c) Each person applying for registration under this part shall specify:

(1) A knowledge and understanding of the requirements of these regulations;

(2) A list of services to be provided under the registration;

(3) The training and experience provided to all repair staff as required in Sections B.6(j)(2) and (3);

(4) The type of measurement instrument(s) to be used, frequency of calibration, and source of calibration; and

(5) The type of personnel dosimeters used, frequency of reading, and replacement or exchange schedule for the exposure monitoring required in B.6(g).

(d) For the purposes of B.6, services may include but shall not be limited to:

(1) Installation and/or servicing of radiation machines and associated radiation machine components,

(2) Calibration of radiation machines or radiation measurement instruments or devices,

(3) Performance of radiation machine preventive maintenance tests and measurements,

(4) Radiation protection or health physics consultations or surveys, and

(5) Personnel dosimetry services.

(e) In performance of radiation machine preventive maintenance services, each registered service provider shall provide the radiation machine facility with a complete preventive maintenance report for each radiation machine for which preventive maintenance has been provided.

(1) Each Preventive Maintenance Report shall be completed on the specific preventive maintenance form made available by the Agency applicable to the type of machine tested. One form is required for each machine for which preventive maintenance has been performed. Each form shall be signed and dated by both the registrant and the service provider.

(2) If the Agency has not published a specific Preventive Maintenance Report form for the type of radiation machine tested, a registered service provider shall use its own preventive maintenance report format containing at minimum the following information:

(i) Signature and date of signature of both registered service provider and authorized facility representative;

(ii) Registered service provider's name and registration number;

(iii) Facility name and facility registration number;

(iv) Tested machine's MDE Machine Number if available and tube serial number;

(v) Room number or room name in which tested machine is located;

(vi) Date of preventive maintenance service;

(vii) Written values of every test taken and measurement made including average value as required, and results of all tests and measurements performed. If calibrations or adjustments are made, the report must include the values measured before and after any calibration or adjustment. Tests performed must comprise at minimum every maintenance service or calibration recommended by the machine's manufacturer; and

(viii) Written documentation that machine passes or fails preventive maintenance tests;

(f) The documentation listed in subsection (e) above shall be provided to the facility within one week after completion of the preventive maintenance service. If preventive maintenance includes installation, assembly, disablement, or disposal of a radiation machine, the 15 day Agency notification requirement in Section B.12(a) shall apply.

(g) Personnel Monitoring. Each person registered by the Agency to provide services to radiation machine facilities including installation, assembly, calibration, repair, maintenance, disablement, or removal of radiation machines shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D of this regulation. Such monitoring of exposures must be performed during all work with or involving radiation machines by means of each service provider and the provider's employees wearing individual monitoring devices to include at minimum film badges.

(1) Film badge reports shall be reviewed by each registered service provider to assure compliance with the occupational dose limits. Such reports shall be required from the film badge supplier on either a monthly or quarterly basis.

(2) Application for registration or renewal of registration to provide services, as listed in this section, to radiation machine facilities must also specify the dosimetry information required in B.6(c)(5).

(h) No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the Agency.

(i) Duration of Registration. A service provider registration shall remain in effect for 3 years from date of issuance. Application for renewal of registration shall be made to the Department at least 30 days prior to the expiration date of the registration.

(j) Additional Requirements for Service Provider Registration. For a service provider registration to be approved, an applicant for service provider registration:

(1) Shall demonstrate compliance with the State Workers' Compensation Laws as required by Environment Article §1-202, Annotated Code of Maryland;

(2) Shall ensure that all repair staff have been trained in radiation safety and in protective measures to reduce potentially hazardous conditions; and

(3) Shall ensure that all repair staff have a level of training and applied radiation machine experience equal to or greater than one of the following sets of criteria:

(a) Completion of applicable radiation equipment manufacturer's service school; or

(b) One year of applied radiation machine experience acceptable to the Department; or

(c) Advanced tradesman training in the service and repair of radiation emitting equipment including radiation safety and complex systems skill sets.

(k) Cancellation of Service Provider Registration.

(1) A registered service provider may request cancellation of its registration by submitting a request for cancellation to the Agency.

(2) The Agency may cancel a service provider registration if the service provider is found by the Agency to have:

(a) falsified data on a report;

(b) performed work or services outside the provider's scope of practice as identified to the Agency in the provider's application; or

(c) permitted employees who do not have the required level of training and applied radiation machine experience as identified in Sections B.6(j)(2) and (3) to perform service or repair work at a Maryland radiation machine facility.

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Agency Issues

Sec B.7 Issuance and Posting of Certificate of Registration.

(a) Upon a determination that an applicant meets the requirements of the regulations, the Agency shall issue a certificate of registration. Each certificate of registration shall be publicly posted by the radiation machine facility.

(b) The Agency may incorporate in the certificate of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, transfer, or servicing of radiation machines as it deems appropriate or necessary.

Sec. B.8 Expiration of Certificate of Registration.

Except as provided by B.9(b), each certificate of registration shall expire at the end of the specified day in the month and year stated therein. A registrant with an expired certificate of registration will remain subject to the regulations in this Subtitle until the provisions of B.5A(b) have been fulfilled.

Sec. B.9 Renewal of Certificate of Registration.

(a) Each application for renewal of a certificate of registration of a radiation machine facility must be received by the Agency at least 14 days prior to the date specified on the facility's certificate of registration. Such application shall be made in accordance with the provisions of Section B.5. The Agency will approve an application for renewal of a certificate of registration upon payment in full of all fees required by the Agency including all past due fees and submission of all documentation required by the Agency.

(b) If a registrant has filed a complete application, not less than 14 days prior to the expiration of the existing certificate of registration, including payment of all fees and submission of reports of inspections of all radiation machines identified in COMAR 26.12.02.02B. as required by COMAR 26.12.02.02D.(2)(b) with all violations corrected, the existing certificate of registration shall not expire until the application status has been determined by the Agency.

(c) Failure to timely renew a radiation machine facility registration may result in issuance by the Agency of a Notice of Violation and further enforcement action.

Sec. B.10 Report of Changes.

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the certificate of registration no longer accurate. This includes, but is not limited to, requests for registration cancellation, or changes of location and ownership.

Sec. B.10A Compliance with Regulations.

All owners, operators, or possessors of a radiation machine(s) shall comply with all applicable requirements of COMAR 26.12.01, .02, and .03. Any Agency Form RX-2 or RX-2a citing a regulation violation(s) which is presented to a radiation machine facility during or following an inspection by an Agency or State-licensed private inspector constitutes a notice to the facility that a violation(s) has been observed by the inspector. An as-found violation(s):

(1) Must be corrected and written evidence of correction submitted to the Agency within the time frame set by the Agency (if a certified facility, the correction(s) must be verified by the State-licensed private inspector);and

(2) Is (are) subject to the penalty provisions of Subtitle 5, "Enforcement" of Title 8, "Radiation" of the Environment Article, Annotated Code of Maryland, which include the facility's liability for a monetary penalty for each day that each violation occurs or continues, subject to the penalty amount and imposition limits set forth in the Statute.

Disclaimer

Sec. B.11 Approval Not Implied. No person, in any advertisement, shall refer to the fact that he/she or his/her facility is registered with the Agency pursuant to the provisions of B.5 or B.6, and no person shall state or imply that any activity under such registration has been approved by the Agency.

Assembler and Transferor Obligations

Sec. B.12 Assembler and/or Transfer or Service Obligation.

(a) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this State shall notify the Agency within 15 days on forms provided by the Agency of the following:

(1) The present and previous machine location; and

(2) The manufacturer, model, date of manufacture and other general information required by the form.

(b) No person shall make, sell, lease, transfer, lend, assemble, install, or service radiation machines or the supplies used in connection with such machines unless such machines and supplies, when properly placed in operation and used, meet the requirements of these regulations.

(c) A person who sells, leases, transfers, lends, assembles or installs radiation machines in Maryland shall comply with the use of certified components as required by 21 CFR 1020.30 through 21 CFR 1020.33.

(d) A person who sells, leases, transfers, lends, assembles, or installs radiation machines in Maryland shall provide to registrants manuals or instruction sheets including the following technical and safety information:

(1) Instructions adequate to safely and effectively operate radiation emitting equipment for its intended purpose utilizing appropriate radiological safety procedures and precautions necessary;

(2) A schedule of maintenance necessary to keep the equipment in compliance with Sections E, F, H, or I of these regulations; and

(3) For imaging 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; and

(ii) A schedule of maintenance for any system instrumentation associated with display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of manufacturer specified uncertainty, and if the capability for user calibration of the display is provided, adequate instructions for such calibration.

(e) A person who sells, leases, transfers, lends, assembles, services, or installs radiation machines in Maryland shall notify the Agency if a facility is possessing, using, or storing a radiation machine for more than 20 days which:

(1) Does not meet the requirements of COMAR 26.12 "Radiation Management";

(2) Is located in a radiation machine facility that is not registered as required by Section B.5;

(3) Has been installed or serviced by any person who is not registered with the Agency as a Service Provider in accordance with Section B.6;

(4) Has been modified as described in Section B.14(a); or

(5) Has not been maintained in a manner consistent with the minimal recommendations in the Requirements of the Original Equipment Manufacturer.

Sec. B.13 [Reserved].

Sec. B.14 Possession, Storage or Modification of Radiation Machines.

(a) No person shall modify a radiation machine, or any other auxiliary equipment that functions with the radiation machine, to produce the result desired by use of the machine, in such a manner that the machine or auxiliary equipment fails to operate properly or otherwise does not meet one or more provision(s) of these regulations.

(b) Each person owning or operating a radiation machine facility shall direct the operation of a radiation machine through administrative controls to ensure that the requirements of these regulations are met.

(c) Except as provided under B.6, no person shall possess, use, or store a radiation machine which:

(1) Does not meet the requirements of COMAR 26.12 "Radiation Management",

(2) Is located in a radiation machine facility that is not registered as required by B.5,

(3) Has been installed or serviced by any person who is not registered with the Agency as a service provider in accordance with B.6, or

(4) Has been modified as described in B.14(a) above.

(d) A radiation machine that does not meet the requirements of B.14(a), B.14(b), or B.14(c) must, within 20 days, be

(1) Rendered internally inoperable, in a manner approved by the Department, by a service provider registered under B.6; or

(2) Removed from the facility by a service provider registered under B.6.

Temporary Radiation Machine Use

Sec. B.15 Short Term Use of Radiation Machines on Human Subjects.

(a) All radiation machines designed for use on patients in the State solely for trial or demonstration purposes shall be registered prior to such use in accordance with Sec. B.5. Registration by the Agency includes payment of the annual registration fee in accordance with the fee schedule described in COMAR 26.12.03.03, based on the proposed use of the machine as described in COMAR 26.12.02.02(B) or COMAR 26.12.03.03(B). The registrant shall comply with the requirements of COMAR 26.12.01.01B.5A when use in Maryland of radiation machines being used for trial or demonstration will cease.

(b) In addition to the requirements in B.15(a), radiation machines designed for use in hospitals or medical facilities, where use of the machine is solely for trial or demonstration purposes, shall meet all applicable requirements of COMAR 26.12.01.01, including but not limited to the following requirements:

(1) Each trial or demonstration machine shall be used in a room with a shielding plan approved by the Agency in accordance with B.4.

(2) Each trial or demonstration machine shall be inspected by a State-licensed private inspector prior to use in accordance with COMAR 26.12.02.02 and the inspection report shall be submitted to the Agency in accordance with COMAR 26.12.02.05. Any violations noted on the inspection report must be corrected prior to use of the radiation machine for trial or demonstration.

PART B

APPENDIX A

DESIGN GUIDELINES FOR AN OPERATOR'S BOOTH

1. Space Requirements:

   (a) The operator should be allotted not less than 0.7 m^2 (7.5 square feet) of unobstructed floor space in the booth.

   (b) The operator's booth may be any geometric configuration with no dimension of less than 0.6 m (2 feet).

   (c) The space should be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

   (d) The booth should be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette holder will not reach the operator's position in the booth.

2. Structural Requirements:

   (a) The booth walls should be permanently fixed barriers of at least 2.1 m (7 feet) high.

   (b) When a door or movable panel is used as an integral part of the booth structure, it should have an interlock which will prevent an exposure when the door or panel is not closed.

   (c) Shielding should be provided to meet the requirements of Part D of these regulations.

3. X-Ray Exposure Control Placement: The x-ray exposure control for the system should be fixed within the booth and:

   (a) Should be at least 0.08 m (30 inches) from any point subject to direct scatter, leakage or primary beam radiation.

   (b) Should allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

   (a) Each booth should have at least one viewing device which will:

      (i) Be so placed that the operator can view the patient during any exposure, and

(ii) be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there should be an "x-ray on" warning sign that will be lighted anytime the rotor of the x-ray tube is activated. Alternatively, an interlock should be present such that exposures are prevented unless the door is closed.

(b) When the viewing system is a window, the following requirements also apply:

(i) The window should have a viewing area of at least 0.093 m^2 (1 square foot).

(ii) Regardless of size or shape, at least 0.093 m^2 (1 square foot) of the window area should be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5 feet) from the floor.

(iii) The window should have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) should be so located as to accomplish the general requirements of Appendix A 4(a).

(d) When the viewing system is by electronic means:

(i) The camera should be so located as to accomplish the general requirements of Appendix A 4(a), and

(ii) There should be an alternate viewing system available as a backup for the primary system.

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PART C

LICENSING OF RADIOACTIVE MATERIAL

Sec. C.1 Purpose and Scope.

(a) This part, and Parts G and T, of these regulations, provide for the licensing of radioactive material. No person shall receive, manufacture, prepare, produce, possess, use, transfer, own, or acquire byproduct material except as authorized pursuant to this part or Parts G or T of these regulations, or as otherwise provided in these parts.

(b) In addition to the requirements of this part, all licensees are subject to the requirements of Parts A, D, J, and T of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part E of these regulations. Licensees using radionuclides in the healing arts are subject to the requirements of Part G of these regulations, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part W of these regulations.

Sec. C.2 Definitions.

"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 this part. 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 threshold. 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.

"Offshore waters" means that area of land and water, beyond Agreement States' Submerged Lands Act jurisdiction, on or above the U.S. Outer Continental Shelf.

"Principal activities" as used in this part, 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 licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Waste collector" means an entity, operating under a 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 land disposal facility.

"Waste processor" means an entity, operating under a 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 land disposal facility.

Exemptions from the Regulatory Requirements

Sec. C.3 Source Material.

(a) Any person is exempt from this part to the extent that such 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 percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person is exempt from this part 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, such person shall not refine or process such ore.

(c) Any person is exempt from the requirements for a license set forth in this Part and from the regulations in Parts D and J to the extent that such person receives, possesses, uses, or transfers:

(1) any quantities of thorium contained in

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

(iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

(v) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,

(vi) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

(vii) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

(2) source material contained in the following products:

(i) glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material,

(ii) glassware containing not more than 2 percent 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,

(iii) glass enamel or glass enamel frit containing not more than 10 percent 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, or

(iv) piezoelectric ceramic containing not more than 2 percent 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 percent by weight and that this exemption shall not be deemed to 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

(i) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM," 1/

(ii) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED," 1/ and

(iii) the exemption contained in this paragraph shall not be deemed to 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:

(i) the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM", and

(ii) the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm);

(7) thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium, and that the exemption contained in this paragraph does not authorize either:

(i) 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

(ii) 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) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that

(i) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide),and

(ii) the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

(d) The exemptions in C.3(c) do not authorize the manufacture of any of the products described.

(e) No person may initially transfer for sale or distribution a product containing source material to persons exempt under C.3(c), or equivalent regulations of an Agreement State or NRC, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution. Persons authorized to manufacture, process, or produce these materials or products containing source material by the Agency or an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR § 40.52 for distribution only and are exempt from the requirements of Parts D and J of this regulation and subsections C.25(a)(1) and (2).

1/ The requirements specified in C.3(c)(5)(i) and (ii) need not be met by counterweights manufactured prior to December 31, 1969; provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by 10 CFR § 40.13(c)(5)(ii) in effect on June 30, 1969.

Sec. C.4 Radioactive Material Other Than Source Material.

(a) Exempt Concentrations.

(1) Except as provided in C.4(a)(2) and (3), any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in Appendix A of this part.

(2) A manufacturer, processor, or producer of a product or material is exempt from this part to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those listed in Appendix A of this part and introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct 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.

(3) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of the NRC, any Agreement State or Licensing State, except in accordance with a specific license issued pursuant to C.28(a).

(b) Exempt Quantities.

(1) Except as provided in C.4(b)(3) through (5), any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of this part.

(2) Any person who possesses byproduct material received or acquired before September 25, 1971 under the general license formerly provided in C.22(b) is exempt from the requirements for a license set forth in this part to the extent that such person possesses, uses, transfers or owns such byproduct material.

(3) This section does not authorize the production, packaging, repackaging, or transfer of byproduct material for purposes of commercial distribution, or the incorporation of byproduct material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in Appendix B of this part, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under C.4(b) or equivalent regulations of the NRC, any Agreement State or Licensing State, except in accordance with a specific license issued by the NRC pursuant to Section 32.18 of 10 CFR Part 32 which license states that the byproduct material may be transferred by the licensee to persons exempt under C.4(b) or the equivalent regulations of the NRC, an Agreement State, or Licensing State. 2/

2/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.20555.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B of this part, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

(c) Exempt Items.

(1) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products: 2/

(i) 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:

(a) 25 millicuries (925 MBq) of tritium per timepiece.

(b) 5 millicuries (185 MBq) of tritium per hand.

(c) 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).

(d) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

(e) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.

(f) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(g) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(1) For wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface.

(2) For pocket watches, 0.1 millirad (1 μGy) per hour at 1centimeter from any surface.

(3) For any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface.

(h) One microcurie (0.037 MBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(ii) Static Elimination Devices and Ion Generating Tubes.

(a) Static elimination devices which contain, as a sealed source or sources, byproduct 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, byproduct 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 authorized before October 23, 2012 for use under the general license then provided in Section C.22 and equivalent regulations of Agreement States and the NRC and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Agency.

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

(iv) [Reserved]

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

(vi) [Reserved]

(vii) Ionization chamber smoke detectors containing not more than 1 microcurie (0.037 MBq) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

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

(a) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.

(b) 1 microcurie (37 kBq) of cobalt-60.

(c) 5 microcuries (185 kBq) of nickel-63.

(d) 30 microcuries (1.11 MBq) of krypton-85.

(e) 5 microcuries (185 kBq) of cesium-137.

(f) 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing byproduct material will not exceed 1 millirad (10 μGy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. 3/

3/ For purposes of C.4(c)(1)(viii), "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

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

(a) Each source contains no more than one exempt quantity set forth in Appendix B of this part, and

(b) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one 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 Appendix B of this part, provided that the sum of such fractions shall not exceed unity.

(c) For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under Appendix B.

(x) [Reserved]

(2) Self-Luminous Products Containing Radioactive Material.

(i) Tritium, Krypton-85, or Promethium-147.

(a) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations 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, or produced under an Agency specific license issued under Section C.28 and imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Section 32.22 that authorizes the transfer of the product to persons who are exempt from regulatory requirements.

(b) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147 for use under Section C.4(c)(2)(i)(a) should apply for a license under Section C.28. Any person who desires to initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under Section C.4(c)(2)(i)(a) should apply to the NRC for a license under 10 CFR Section 32.22 and for a certificate of registration in accordance with 10 CFR Section 32.210.

(c) The exemption in C.4(c)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to December 6, 1982.

(3) Gas and Aerosol Detectors Containing Byproduct Material.

(i) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in Parts A, C through E, G, J, W, and X of this regulation to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, or produced under an Agency specific license issued under Section C.28 or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Section 32.26 that authorizes the initial transfer of the product to persons who are exempt from regulatory requirements. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by the Agency under Section C.28 or under comparable NRC or Agreement State regulations authorizing distribution to persons exempt from regulatory requirements.

(ii) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material under C.4(c)(3) should apply to the Agency for a license under Section C.28. Any person who desires to initially transfer such products for use under Section C.4(c)(3) should apply to the NRC for a license under 10 CFR Section 32.26 and for a certificate of registration in accordance with 10 CFR Section 32.210.

(4) Radioactive Drug: Capsules Containing Carbon-14 Urea for "In vivo" Diagnostic Use for Humans.

(i) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license and from these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(ii) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Section C.

(iii) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 10 CFR §32.21.

(iv) Nothing in this section relieves persons from complying with applicable FDA, Federal, and State requirements governing receipt, administration, and use of drugs.

(5) Certain Industrial Devices.

(i) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct 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 set forth in Part C and from the regulations in all parts of COMAR 26.12.01.01 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, or produced in accordance with a specific license under Section C.28(d), or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Section 32.30 that authorizes the initial transfer of the device to persons who are exempt from regulatory requirements. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(ii) Any person who desires to manufacture, process, or produce industrial devices containing byproduct material for use under Section C.5(i) should apply to the Agency for a specific license under Section C.28(d). Any person who desires to initially transfer for sale or distribution industrial devices containing byproduct material for use under Section C.5(i) should apply to the NRC for a license in accordance with 10 CFR Section 32.30 and for a certificate of registration in accordance with 10 CFR Section 32.210.

(d) Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this Part and Parts E, G, V, W, and X of this regulation, to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

Sec. C.5 - C.19 Reserved.

Licenses

Sec. C.20 Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

(a) A general license is provided by regulation; grants authority to a person for certain activities involving byproduct material; and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license.

(b) Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document.

General Licenses

Sec. C.21 General Licenses - Source Material.

(a) 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, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) No more than 1.5 kg (3.3 lb) 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 this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium 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 70 kg (154 lb) 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 this paragraph unless it is accounted for under the limits of paragraph (a)(1) of this section; or

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

(4) No more than 7 kg (15.4 lb) 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 70 kg (154 lb) of source material in any one calendar year.

(b) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph (a) of this section:

(1) Is prohibited from administering source material, or the radiation therefrom, either externally of internally, to human beings except as may be authorized by the Agency in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) 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 this paragraph is exempt from the requirements to obtain a license under this Part 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 Part C of this regulation; or

(ii) In accordance with subsections D.1001, D.1002, D.1003, D.1005, D.1006, and D.1009 of this regulation.

(3) Is subject to the provisions of Part C of this regulation.

(4) Shall not export such source material except in accordance with 10 CFR Part 110.

(c) Any person who receives, possesses, uses, or transfers source material in accordance with this Part shall 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 shall notify the Agency in writing within 30 days of cessation.

(d) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in C.21(a) of this section is exempt from the provisions of Parts D and J of this regulation to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with D.1001 and D.1402 of this regulation to the extent necessary to meet the provisions of C.21(b)(2) and C.21(c). However, this exemption does not apply to any person who also holds a specific license issued under Part C.

(e) No person may initially transfer or distribute source material to persons generally licensed under C.21(a)(1) or (2) of this section, unless authorized by a specific license issued by NRC in accordance with 10 CFR § 40.54 or by the Agency in accordance with C.28(b). This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

(f) 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 C.21(e)(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.

(2) The general license in C.21(e)(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 C.28(m) 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) (i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by C.21(e)(1) shall notify the Agency. The notification shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish the following information and such other information as may be required by the Agency:

(a) name and address of the general licensee;

(b) a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in C.21(e)(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

(c) name and 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 C.21(e)(3)(i)(b).

(ii) The general licensee possessing or using depleted uranium under the general license established by C.21(e)(1) shall report in writing to the Agency any changes in information furnished under C.21(e)(3)(i). The report shall 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 C.21(e)(1):

(i) shall 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;

(ii) shall not abandon such depleted uranium;

(iii) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of C.40. In the case where the transferee receives the depleted uranium pursuant to the general license established by C.21(e)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of the information required by C.21(e)(3). In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.21(e)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of the information required by C.21(e)(3) 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 this regulation;

(iv) within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(v) shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.21(e)(1) is exempt from the requirements of Parts D and J of these regulations with respect to the depleted uranium covered by that general license.

Sec. C.22 General Licenses* - Radioactive Material Other Than Source Material.

(a) [Reserved]

(b) General License to Install Devices Generally Licensed in Sec. C.22

Any person who holds a specific license issued by an Agreement State or the U.S. Nuclear Regulatory Commission authorizing the holder to manufacture, install, or service a device described in C.22 within such Agreement State is hereby granted a general license to install and service such device in the State of Maryland as defined in C.90 provided that:

(1) [Reserved]

(2) 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 Agreement State.

(3) Such person assures that any labels required to be affixed to the device under regulations of the U.S. Nuclear Regulatory Commission or Agreement State that licensed manufacture of the device bear a statement that removal of the label is prohibited.

(c) Reserved.

*Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

(d) Certain Measuring, Gauging or Controlling Devices.

(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 C.22(d)(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 C.22(d)(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.28(d) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and the device has been manufactured and installed so that:

(i) The dose rate in the radiation beam of the device at 18 inches (0.46 meters) from the radiation source with the device shutter in the open position does not exceed 125 millirem (1.25 mSv) per hour; and

(ii) There is not an accessible airgap of 18 inches (0.46 meters) or greater between the radiation source and detector which would allow insertion of a 12 inch (0.30 meters) diameter sphere into the radiation beam [5/].

(3) The devices must have been received from one of the specific licensees described in C.22(d)(2) or through a transfer made under C.22(d)(4)(vii).

(4) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.22(d)(1):

(i) shall 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 shall comply with all instructions and precautions provided by such labels;

(ii) shall 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 6-month intervals or at such other intervals as are specified in the label, however,

(a) devices containing only krypton need not be tested for leakage of radioactive material, and

[5/] Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(b) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37 MBq) 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;

(iii) shall assure that the tests required by C.22(d)(4)(ii) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(a) in accordance with the instructions provided by the labels, or

(b) by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

(iv) shall maintain records showing compliance with the requirements of C.22(d)(4)(ii) and (iii). The records shall show the results of tests. The records also shall 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. Records of tests for leakage of radioactive material required by C.22(d)(4)(ii) shall be maintained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by C.22(d)(4)(ii) shall be maintained for 3 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. Records which are required by C.22(d)(4)(iii) shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed of;

(v) shall 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 under Section C or by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing 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 byproduct material in the device or as otherwise approved by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 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 Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days. Under these circumstances, the criteria set out in Section D.1402, “Radiological Criteria for Unrestricted Use”, may be applicable, as determined by the Agency on a case-by-case basis;

(vi) shall not abandon the device containing radioactive material;

(vii) shall transfer or dispose of the device containing radioactive material by transfer to another general licensee as authorized in C.22(d)(4)(x), or to a person authorized to receive the device by a specific license issued under Section C that authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or as otherwise approved under C.22(d)(4)(ix);

(viii) shall within 30 days after the transfer of a device to a specific licensee or export, furnish a report to: Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230. The report shall 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;

(ix) shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in C.22(d)(4)(vii); 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 (d)(4)(i) of this section) so that the device is labeled in compliance with D.904(a); however, the label must retain the manufacturer, model number, and serial number;

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

(d) reports the transfer under (d)(4)(viii) of this section.

(x) shall transfer the device to another general licensee only if:

(a) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of Sections C.20(a), C.22(d), C.38, D.1201, and D.1202 and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230:

(1) the manufacturer's (or initial transferor's) name,

(2) the model number and the serial number of the device transferred,

(3) the transferee's name and mailing address for the location of use, and

(4) the name, title, and phone number of the responsible individual identified by the transferee in accordance with C.22(d)(4)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(b) 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;

(xi) shall comply with the provisions of Sections D.1201 and D.1202 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts D and J;

(xii) shall 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, shall 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;

(xiii) shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Manager, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230 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;

(xiv) may not hold devices that are not in use 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 C.22(d)(4)(iii) 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;

(xv) shall not export the device containing byproduct material except in accordance with 10 CFR Part 110; and

(xvi) shall respond to written requests from the Agency 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 shall, within that same time period, request a longer period to supply the information by providing the Agency a written justification for the request.

(5) The general license in C.22(d)(1) does not authorize the manufacture of devices containing radioactive material.

(6) The general license provided in C.22(d)(1) is subject to the provisions of A.4 through A.9, C.31, C.40, C.50, and Part T of theseregulations.

(e) 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:

(i) each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(ii) each device has been manufactured, assembled or imported 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 Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in C.22(e)(1) are exempt from the requirements of Parts D and J of these regulations except that they shall comply with the provisions of D.1001, D.1201, D.1202 and D.1207.

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

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

(5) This general license is subject to the provisions of A.4 through A.9, C.31, C.40, C.50, and Part T of these regulations.

(f) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(g) 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 C.22(g)(4) and (5), americium-241 in the form of calibration or reference sources:

(i) any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material; and

(ii) any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him 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 C.22(g)(4) and (5) to any person who holds a specific license issued by the Agency which authorizes him 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 C.22(g)(4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(4) The general licenses in C.22(g)(1), (2) and (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 Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in C.22(g)(1), (2), and (3) are subject to the provisions of A.4 through A.9, C.31, C.40, C.50 and Parts D, J, and T of these regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

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

(ii) shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(a) 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 (AMERICIUM-241) (PLUTONIUM). [6/] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

[6/] Showing only the name of the appropriate material.

(b) The receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

(iii) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

(iv) shall 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

(v) shall 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.

(h) Reserved.

(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[7/]

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of C.22(i)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.

7/ The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(ii) Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.

(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.

(iv) Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.

(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(vi) Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.

(vii) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.

(viii) Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.22(i)(1) until he has filed Agency Form MDE-211, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form MDE 211 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form MDE 211 the following information and such other information as may be required by that form:

(i) Name and address of the physician, veterinarian, clinical laboratory or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, 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 C.22(i)(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 C.22(i)(1) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in C.22(i)(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by C.22(i)(1).

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

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.22(i)(1)(v) as required by D.1001 of these regulations.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.22(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.28(h) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing 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 C.22(i) or its equivalent, and

(ii) unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for <u>in vitro</u> 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

(b) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, 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 a Licensing State.

_____
Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of C.22(i)(1) shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Agency Form MDE-211. The report shall be furnished within 30 days after the effective date of such change.

(6)Any person using radioactive material pursuant to the general license of C.22(i)(1) is exempt from the requirements of Parts D and J of these regulations with respect to radioactive material covered by that general license, except that such persons shall comply with the provisions of D.1201, D.1202, and D.1207 of these regulations.

(j) 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 50 microcuries (1.85 MBq) 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 Agency or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in C.22(j)(1),

(i) shall, 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 shall dispose of the device pursuant to the provisions of D.1001 of these regulations;

(ii) shall 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

(iii) are exempt from the requirements of Parts D and J of these regulations except that such persons shall comply with the provisions of D.1001, D.1201, D.1202, and D.1207.

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

(4) This general license is subject to the provisions of A.4 through A.9, C.31, C.40, C.50, and Part T of these regulations.

(k) Registration of Generally Licensed Devices.

(1) All persons, within 30 days of initial receipt of a generally licensed device, as defined in C.22(d) and (e) (excluding tritium signs), shall register that device with the Agency in accordance with C.22(k)(5). Registration shall be done by submitting new information, verifying previously submitted registration information, correcting, and/or adding to the information from a previous registration. All registration information shall be updated with the Agency on an annual basis.

(2) All persons who possess generally licensed devices as defined in C.22(d) and (e) (excluding tritium signs) prior to the effective date of this regulation shall register such devices within ninety days of the effective date of this regulation in accordance with C.22(k)(5). All registration information submitted for these devices shall be updated with the Agency on an annual basis.

(3) For the purposes of registration of devices received or possessed under C.22(d) and (e), each address that represents a location of use is a separate general licensee and requires a separate registration.

(4) Persons generally licensed by the U.S. Nuclear Regulatory Commission or another Agreement State with respect to devices meeting the criteria in C.22(d) and (e) are required to register those devices with the Agency, if used in Maryland for a period of greater than 180 days in any calendar year.

(5) Registration of generally licensed devices shall include submission of the following information to the Agency:

(i) Name and mailing address of the general licensee.

(ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee.

(iv) Address or location at which the device(s) is (are) used and/or stored and for portable devices, the address of the primary place of storage.

(l) General License for Certain Items and Self-Luminous Products Containing Radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with Section C.22(l)(2)-(4), radium-226 contained in the following products manufactured prior to November 30, 2007.

(i) 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.

(ii) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(iii) Luminous items installed in air, marine, or land vehicles.

(iv) All other luminous products provided that no more than 100 items are used or stored at the same location at any one time.

(v) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of the 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 NRC.

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in Section C.22(l)(1) are exempt from the provisions of Parts D and J, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under Part C.

(6) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in Section C.22(l)(1):

(i) Shall notify the Agency 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 Radiological Health Program, Maryland Department of the Environment, 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days.

(ii) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 10 CFR 20.2008 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 Agency, another Agreement State, or the NRC.

(iii) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(iv) Shall 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 Part C, equivalent regulations of an Agreement State, the NRC, or as otherwise approved by the Agency.

(v) Shall respond to written requests from the Agency 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 shall, within that same time period, request a longer period to supply the information, including the length of the extension requested and a written justification for the request, to the Radiological Health Program, Maryland Department of the Environment, 1800 Washington Boulevard, Baltimore, Maryland 21230.

(7) The general license in Section C.22(l)(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

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EMERGENCY PLAN

Sec. C.23 Emergency Plan for Responding to a Release.

(a) Each application or renewal to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix C must contain either:

(1) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(2) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted pursuant to C.23(a)(1):

(1) The radioactive material is physically separated so that only a portion could be involved in an accident;

(2) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(3) The release fraction in the respirable size range would be lower than the release fraction shown in Appendix C due to the chemical or physical form of the material;

(4) The solubility of the radioactive material would reduce the dose received;

(5) Facility design or engineering safety features in the facility would cause the release fraction to be lower than shown in Appendix C;

(6) Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix C; or

(7) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted pursuant to C.23(a)(2) must include the following information:

(1) Facility Description

A brief description of the licensee's facility and area near the site.

(2) Types of Accidents

An identification of each type of radioactive materials accident for which protective actions may be needed.

(3) Classification of Accidents

A classification system for classifying accidents as alerts or site area emergencies.

(4) Detection of Accidents

Identification of the means of detecting each type of accident in a timely manner.

(5) 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.

(6) Assessment of Release

A brief description of the methods and equipment to assess releases of radioactive materials.

(7) 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 Agency; also, responsibilities for developing, maintaining, and updating the plan.

(8) 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 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 shall also commit to notify the Agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(9) 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 organizations and to the Agency.

(10) 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 shall familiarize personnel with site-specific emergency procedures. Also, the training shall 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.

(11) Safe Shutdown

A brief description of restoring the facility to a safe condition after an accident.

(12) 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 shall invite offsite response organizations to participate in 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 shall not be known to most exercise participants. The licensee shall 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.

(d) The licensee shall 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 Agency. The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

Specific Licenses

Sec. C.24 Filing Application for Specific Licenses.

(a) Applications for specific licenses shall be filed on a form prescribed by the Agency.

(b) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may not incorporate by reference information contained in previous applications, statements, or reports filed with the Agency, but must resubmit the above information after the review, and updating as necessary, as part of the current application.

(f) Applications and other documents are subject to public inspection and copying as provided at State Government Article, §10-611 et seq., Annotated Code of Maryland.

(g) Application for a Specific License to use Byproduct Material in the Form of a Sealed Source or in a Device that Contains the Sealed Source,

(1) Except as provided in Sections C.24(g)(2),(3), and (4), an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either:

(i) Identify the source or device by manufacturer and model number as registered with the Agency under Section C.37 or comparable regulations of an Agreement State or the NRC, or for a source or a device containing radium-226 or accelerator-produced radioactive material with an Agreement State or the NRC under provisions comparable to Section C.37; or

(ii) Contain the information identified in Section C.37(b).

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the Agency under Section C.37 or with the NRC or an Agreement State in accordance with provisions comparable to Section C.37, and for which the applicant is unable to provide all categories of information specified in Section C.37(b), the application must include:

(i) All available information identified in Section C.37(b) concerning the source, and, if applicable, the device; and

(ii) 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 in accordance with Section C.37(f), 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.

Sec. C.25 General Requirements for the Issuance of Specific Licenses.

(a) A license application will be approved if the Agency 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 these regulations 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 public health and safety or property;

(3) the issuance of the license will not be inimical to the health and safety of the public;

(4) the applicant satisfies any applicable special requirements in C.26, C.27, C.28, Part E, Part G, or Part W of these regulations;

(5) the applicant maintains an office in Maryland

(i) which is open for business during normal business hours,

(ii) where records are immediately available for inspection,

(iii) and where the radioactive material equipment or device will be available for inspection

(a) at either the office location, or

(b) at a temporary job site convenient to the inspector;

(6) the applicant has met the requirements for financial assurance and recordkeeping for decommission specified in C.29;

(7) the environmental report, if required by the Agency under C.25(b), is acceptable;

(8) the radioactive material being licensed is not an isotope of Cesium for the use or storage in a liquid or water environment; and

(9) the applicant has adequately described in the application how facility design and procedures for operation will, in accordance with Section D.1406, minimize, to the extent practicable, the introduction of residual radioactivity into the site, including the subsurface, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) In the case of an application for a license or amendment to an existing license to receive and possess radioactive material for the conduct of any activity which the Agency determines will significantly affect the quality of the environment, the applicant shall prepare an environmental report. The report shall address the environmental, economic, technical and other benefits against environmental costs considering available alternatives, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be 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 environmental values.

(c) Each specific license application shall contain a provision for an emergency plan as specified in C.23.

(d) A specific licensee may not possess devices containing sealed sources, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, that have not been used for a period longer than 3 years. When devices containing a shutter are not being used, the shutter must be locked in the closed position. The reporting requirements in Sec. D.1211(f) shall apply.

(e) A specific licensee which possesses devices containing sealed sources shall:

(1) For devices equipped with an "on-off" mechanism and indicator, assure that each device is tested for proper operation of the "on-off" mechanism and indicator at no longer than 6-month intervals; and

(2) Maintain records of the tests required by C.25(e)(1) for a period of 3 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.

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Sec. C.26 Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.

(a) - (b) Reserved.

(c) Specific License for Certain Measurement and Control Devices.

Effective October 1, 2013, a specific license shall be obtained from the Agency in accordance with Sections C.24 and C.25 for the possession and use of sealed source devices containing radioactive material which contain 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 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element (i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label).

(d) Specific License for Well Logging. An application for a specific license for the use of licensed material in well logging will be approved if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in Sec. C.25 for radioactive material, as appropriate, and any special requirements contained in this part.

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Agency a description of this program which specifies the:

(i) Initial training;

(ii) On-the-job training;

(iii) Annual safety reviews provided by the licensee;

(iv) Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Agency’s regulations and licensing requirements and the applicant's operating and emergency procedures; and

(v) 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 shall submit to the Agency written operating and emergency procedures as described in Sec.W.202 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the Agency its program for annual inspections of the job performance of each logging supervisor to ensure that the Agency’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 shall 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 shall 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 shall establish procedures to be followed and submit a description of these procedures to the Agency. The description must include the:

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

(iii) Pertinent experience of the person who will analyze the wipe samples.

(7) 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:

(i) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;

(ii) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

(iii) The radiation monitoring required in Sec.W.202(n) will be performed;

(iv) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

(v) 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:

(i) The word "CAUTION";

(ii) The radiation symbol (the color requirement in Sec. D.901(a) need not be met);

(iii) The date the source was abandoned;

(iv) The name of the well owner or well operator, as appropriate;

(v) The well name and well identification number(s) or other designation;

(vi) An identification of the sealed source(s) by radionuclide and quantity;

(vii) The depth of the source and depth to the top of the plug; and

(viii) An appropriate warning, such as, "DO NOT RE-ENTER THIS WELL."

(8) The licensee shall retain a copy of the written agreement for 3 years after the completion of the well logging operation.

(9) A licensee may apply, pursuant to Sec. A.(3), for Agency approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in paragraph (a)(5) of this section.

(10) 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 shall still otherwise meet the requirements in paragraphs (a)(1) through (a)(5) of this section.

(e) Specific License for Industrial Radiography. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in Sec. C.25 of this chapter for byproduct material, as appropriate, and any special requirements contained in this part.

(2) The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of Sec. E.43.

(i) After May 28, 1999, a license applicant need not describe its initial training and examination program for radiographers in the subjects outlined in Sec. E.43(g).

(ii) From the effective date of this regulation to May 28, 1999 a license applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in Sec. E.43(g).

(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 Sec. E.45.

(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 3 months as described in Sec. E.43(e).

(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 identifies and lists the qualifications of the individual(s) designated as the RSO (Sec. E.42) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(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 and the qualifications of the person(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

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

(iii) Pertinent experience of the person who will analyze the wipe samples.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant 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 Sec. E.25.

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by this part and other parts of this chapter will be maintained.

(f) Specific Licenses for Irradiators.

(1) The applicant shall satisfy the general requirements specified in Section C.25 and the requirements contained in this part.

(2) The application must describe the training provided to irradiator operators including:

(i) Classroom training;

(ii) On-the-job or simulator training;

(iii) Safety reviews;

(iv) Means employed by the applicant to test each operator's understanding of these regulations and licensing requirements and the irradiator operating and emergency procedures; and

(v) Minimum training and experience of personnel who may provide training.

(3) The application must include an outline of the written operating and emergency procedures listed in Section X.53 that describes the radiation safety aspects of the procedures.

(4) 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.

(5) The application must include a description of the access control systems required by Section X.23, the radiation monitors required by Section X.29, the method of detecting leaking sources required by Section X.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(6) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Agency. The description must include the:

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

(iii) Pertinent experience of the individual who analyzes the samples.

(7) If licensee personnel are to load or unload sources, the applicant shall 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 at its facility, the loading or unloading must be done by an organization specifically authorized by the Agency, an Agreement State or the NRC to load or unload irradiator sources.

(8) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by Section X.61.

(g) Specific License for a PET License. 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 Part C, equivalent Agreement State requirements, or 10 CFR Part 35 shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part C, another Agreement State, or an NRC license with 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 Section C.28(j)(1)(ii).

(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 Section C.28(j)(2)(ii).

(4) Information identified in Section C.28(j)(1)(iii) on the PET drugs to be noncommercially transferred to members of its consortium.

Sec. C.27 Special Requirements for Specific Licenses of Broad Scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.8/

(a) The different types of broad scope 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.

(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 Appendix D of this part, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, 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 Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

8/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(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 Appendix D of this part, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, 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 Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(b) An application for a Type A specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in C.25;

(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:

(i) 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;

(ii) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) the establishment of appropriate administrative procedures to assure:

(a) control of procurement and use of radioactive material;

(b) 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

(c) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with C.27(b)(3)(iii)(b) prior to use of the radioactive material.

(c) An application for a Type B specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in C.25; 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:

(i) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(ii) the establishment of appropriate administrative procedures to assure,

(a) control of procurement and use of radioactive material,

(b) 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

(c) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with C.27(c)(2)(ii)(b) prior to use of the radioactive material.

(d) An application for a Type C specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in C.25;

(2) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(i) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

(ii) at least 40 hours of training and 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.

(e) Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to C.27 shall not:

(i) conduct tracer studies in the environment involving direct release of radioactive material;

(ii) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the Agency under C.26, C.28 or Part G of these regulations is required; or

(iv) 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 part shall be 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 this part shall be 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 part shall be 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 C.27(d).

Sec. C.28 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.

(a) Prohibition of Introduction. No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.4(a)(1) or equivalent regulations of the NRC, an Agreement State, or a Licensing State, except in accordance with a license issued by the NRC under § 32.11. 8/

(b) Requirements for License to Transfer Small Quantities of Source Material.

(1) License to Initially Transfer Source Material for Use Under "Small Quantities of Source Material" General License. An application for a specific license to initially transfer source material for use under C.21 will be approved if:

(i) The applicant satisfies the general requirements in C.25; and

(ii) The applicant submits adequate information on, and the Agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(2) Conditions of Licenses to Initially Transfer Source Material for Use Under the "Small Quantities of Source Material" General License: Quality Control, Labeling, Safety Instructions, and Records and Reports.

(i) Each person licensed under C.28(b)(1) shall 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."

(ii) Each person licensed under C.28(b)(1) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(iii) Each person licensed under C.28(b)(1) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under C.21. 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:

8/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) A copy of C.21 and C.40 of these regulations.

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

(iv) Each person licensed under C.28(b) shall report transfers as follows:

(a) File a report with the Agency. The report shall include the following information:

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

(2) For each general licensee under C.21 to whom greater than 50 grams (0.11 lb) 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 Agreement State agency or the NRC that identifies all persons, operating under the provisions of C.21, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State or NRC 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 NRC.

(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 C.21 during the current period, a report shall be submitted to the Agency, the NRC, or responsible Agreement State Agency indicating so.

(i) Each person licensed under C.28(b) shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Agency.

(c) [Reserved]

(d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under C.22(d).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.22(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

(i) the applicant satisfies the general requirements of C.25;

(ii) 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:

(a) the device can be safely operated by persons not having training in radiological protection,

(b) 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 any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in the table in D.201(a) of these regulations, and

(c) 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 ..... 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter ..... 200 rems (2 Sv)

Other organs..... 50 rems (500 mSv); and

(d) the device has been manufactured so that:

(1) The dose rate in the radiation beam of the device at 18 inches (0.46 meters) from the radiation source with the device shutter in the open position does not exceed 125 millirem (1.25 mSv) per hour; and

(2) There is not an accessible air gap of 18 inches (0.46 meters) or greater between the radiation source and detector which would allow insertion of a

12 inch (0.30 meter) diameter sphere into the radiation beam.

(iii) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

(a) 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,

(b) 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

(c) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(1) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[9/], 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 shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

(2) The receipt, possession, use, and transfer of this device, Model _____, Serial No._____[9/], are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

(iv) The device has been registered in the Sealed Source and Device Registry.

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

(2) In the event the applicant desires that the device be required to be tested at intervals longer than 6 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 shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics 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 Agency will consider information which includes, but is not limited to:

(i) primary containment or source capsule;

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

(x) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under C.22(d), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing 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 shall include in the 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 shall 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 calendar quarter dose in excess of 10 percent of the limits specified in the table in D.201(a) of these regulations.

(4) 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 isotope and quantity, the words, “Caution – Radioactive Material”, the radiation symbol described in D.901 and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of C.26(c) 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 D.901.

(6) If a device containing byproduct material is to be transferred for use under the general license contained in C.22, each person that is licensed under C.28(d) shall 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:

(i) A copy of the general license contained in C.22; if requirements in C.22(d)(3)(ii-iv) or C.26(c) do not apply to the particular device, those requirements may be omitted;

(ii) A copy of Sections C.20(a), C.22(d), C.38, D.1201 and D.1202;

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

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

(v) An indication that the U.S. Nuclear Regulatory Commission’s policy is to issue high civil penalties for improper disposal.

(7) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under C.28(d) shall 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:

(i) A copy of the Agreement State's or U.S. Nuclear Regulatory Commission regulations equivalent to Sections C.20(a), C.22, C.38, D.1201 and D.1202, or a copy of C.20(a), C.22, C.38, D.1201 and D.1202. If a copy of Maryland regulations or the U.S. Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's or U.S. Nuclear Regulatory Commission regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State or U.S. Nuclear Regulatory Commission; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

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

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

(iv) The name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

(8) An alternative approach to informing customers may be proposed by the licensee for approval by the Agency.

(9) Each device that is transferred after February 19, 2002 must meet the labeling requirements in C.28(d)(6)(iii) through (v).

(10) If a notification of bankruptcy has been made under C.31(e) or the license is to be terminated, each person licensed under C.28(d) shall provide, upon request, to the Agency and to any appropriate Agreement State, records of final disposition required under C.28(d)(11)(iii).

(11) Each person licensed under this section to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

(i) The person shall report to the Agency all transfers of such devices to persons for use under the general license under C.22(d) and all receipts of devices from persons licensed under C.22(d). The report must be submitted on a quarterly basis to the Agency.

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

(1) 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 shall be submitted along with information on the actual location of use;

(2) 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;

(3) The date of transfer;

(4) The type, model number, and serial number of the device transferred; and

(5) The quantity and type of byproduct material contained in the device.

(b) 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).

(c) For devices received from a C.22(d) 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.

(d) If the licensee makes changes to a device possessed by a C.22(d) 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.

(e) 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.

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

(g) If no transfers have been made to or from persons generally licensed under C.22(d) during the reporting period, the report must so indicate.

(ii) The person shall report all transfers of devices to persons for use under a general license in other Agreement State's regulations or U.S. Nuclear Regulatory Commission regulations that are equivalent to C.22(d) and all receipts of devices from general licensees in U.S. Nuclear Regulatory Commission and other Agreement State's jurisdictions to the U.S. Nuclear Regulatory Commission or responsible Agreement State agency. The report must be submitted to that jurisdiction in a clear and legible report.

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

(1) 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 shall be submitted along with information on the actual location of use;

(2) 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;

(3) The date of transfer;

(4) The type, model number, and serial number of the device transferred; and

(5) The quantity and type of byproduct material contained in the device.

(b) 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).

(c) 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.

(d) 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.

(e) 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.

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

(g) If no transfers have been made to or from the U.S. Nuclear Regulatory Commission or other Agreement States during the reporting period, this information shall be reported to the responsible U.S. Nuclear Regulatory Commission or Agreement State agency upon request of that agency.

(iii) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

(e) 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 C.22(e) will be approved if:

(1) the applicant satisfies the general requirements specified in C.25; and

(2) the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56 of 10 CFR Part 32, or their equivalent.

(f) Calibration or Reference Sources Containing Americium-241 or Radium-226: Requirements for License to Manufacture or Initially Transfer. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under Section C.22(g), will be approved if:

(1) The applicant satisfies the general requirements of Section C.25;

(2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(i) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(ii) Details of construction and design;

(iii) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(iv) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(v) Details of quality control procedures to be followed in manufacture of the source;

(vi) Description of labeling to be affixed to the source or the storage container for the source;

(vii) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the source.

(3) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(4) The Agency determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(i) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(ii) The source has been subjected to and has satisfactorily passed appropriate tests required by C.28(f)(5).

(5) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(i) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(ii) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(iii) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subparagraph (iv) of this section.

(iv) Source designs are rejected for which the following has been detected for any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

(g) Calibration or Reference Sources Containing Americium-241 or Radium-226: Labeling of Devices in Section C.28(f).

Each person licensed under Section C.28(f) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

> The receipt, possession, use, and transfer of this source, Model_____, Serial No. _____, are subject to a general license and the regulations of the United States 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 AMERICIUM-241 (or RADIUM-226)
> DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE
>
> _____
> (Name of Manufacturer or Initial Transferor)

(h) 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 C.22(i) will be approved if:

(1) the applicant satisfies the general requirements specified in C.25.

(2) the radioactive material is to be prepared for distribution in prepackaged units of:

(i) carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

(ii) cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

(iii) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(iv) iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

(v) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(vi) iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

(vii) iron-59 in units not exceeding 20 microcuries (740 kBq) each.

(viii) selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

(3) each prepackaged unit bears a durable, clearly visible label:

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

(ii) displaying the radiation caution symbol described in D.901(a)(1) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for <u>in vitro</u> 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

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, 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 a Licensing State.

Name of manufacturer

(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 the 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 D.1001 of these regulations.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under C.22(j) will be approved if:

(1) the applicant satisfies the general requirements of C.25; and

(2) the criteria of Sections 32.61 and 32.62 of 10 CFR Part 32 are met.

(j) Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Part G.

(1) An application for a specific license to manufacture, prepare or transfer for commercial distribution radioactive drugs containing radioactive material for persons authorized pursuant to Part G of this regulation will be approved if:

(i) The applicant satisfies the general requirements specified in C.25;

(ii) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered or licensed 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);

(b) Registered or licensed with a state agency as a drug manufacturer;

(c) Licensed as a pharmacy by a State Board of Pharmacy;

(d) Operating as a nuclear pharmacy within a Federal medical institution; or

(e) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

(iii) 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

(iv) The applicant commits to the following labeling requirements:

(a) 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.

(b) 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 in C.28(j)(1)(ii)(c) or (d):

(i) May prepare radioactive drugs for medical use, as defined in Sec. A.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in C.28(j)(2)(ii) and (iv), or an individual under the supervision of an authorized nuclear pharmacist as specified in Sec. G.27.

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an authorized nuclear pharmacist as defined in Sec. A.2;

(b) This individual meets the requirements specified in Secs. G.55(b) and G.59 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with C.28(j)(2)(iv).

(iii) The actions authorized in C.28(j)(2)(i) and (ii) are permitted in spite of more restrictive language in license conditions.

(iv) May designate a pharmacist (as defined in Sec. A.2) as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) 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 Agency.

(v) Shall provide to the Agency:

(a) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, NRC, or an Agreement State as specified in G.55(a); or

(b) The Agreement State or NRC license; or

(c) The NRC master materials licensee permit; or

(d) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(e) 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 Agency; and

(f) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under Sections C.28(j)(2)(ii)(a) and C.28(j)(2)(ii)(c), the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall 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 shall:

(i) 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

(ii) Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) A licensee shall satisfy the labeling requirements in C.28.(j)(4).

(5) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.[10/] An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this part for the uses listed in G.200 of these regulations will be approved if:

(1) the applicant satisfies the general requirements specified in C.25;

(2) the applicant submits evidence that:

(i) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to G.200 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by C.28(k) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

[10/] Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to G.200 of these regulations may submit the pertinent information specified in C.28(k).

(l) 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 Part G for use as a calibration, transmission, or reference source, or for diagnostic, brachytherapy or teletherapy sources for the uses listed in G.400, G.500, G.600, and G.1000 of these regulations, will be approved if:

(1) the applicant satisfies the general requirements in C.25 of this part;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form, and amount,

(ii) details of design and construction of the source or device,

(iii) 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,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) 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 source or device is licensed by the Agency for distribution to persons licensed pursuant to G.400, G.500, G.600, and G.1000 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(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 6 months, he shall include in his 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; and

(6) in determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

(i) primary containment or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

(x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(m) 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 C.21(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) the applicant satisfies the general requirements specified in C.25;

(ii) 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 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in D.201 of these regulations; and

(iii) 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 Agency will approve an application for a specific license under C.28(m) 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 Agency may deny any application for a specific license under C.28(m) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.28(m)(1) shall:

(i) 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;

(ii) 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 an Agreement State;

(iii) 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";

(iv) (a) furnish a copy of the general license contained in C.21(e) to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in C.21(e), or

(b) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.21(e) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.21(e) to each person to whom he 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 C.21(e);

(v) report to the Agency all transfers of industrial products or devices to persons for use under the general license in C.21(e). Such report shall identify 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 device transferred, and the quantity of depleted uranium contained in the product or device. The report shall 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 C.21(e) during the reporting period, the report shall so indicate;

(vi)(a) report 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 Section 40.25 of 10 CFR Part 40,

(b) report to the responsible State agency all transfers of devices manufactured and distributed pursuant to C.28(m) for use under a general license in that State's regulations equivalent to C.21(e),

(c) such report shall identify 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 shall 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,

(d) if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and

(e) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

(vii) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.21(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(n) Requirement for Sealed Source and Device Sheets. Any applicant or specific licensee who wishes to manufacture and distribute a sealed source or a device containing a sealed source shall provide sufficient information to complete a sealed source and device registration.

(o) Calibration or Reference Sources Containing Americium-241 or Radium-226: Leak Testing of Each Source Under Section C.28(f). Each person licensed under Section C.28(f) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under Section C.22(g) or under equivalent regulations of NRC or an Agreement State. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured by using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source shall be rejected and shall not be transferred to a general licensee under Section C.22(g) or equivalent NRC or Agreement State regulations.

Sec. C.29 Financial Assurance and Recordkeeping for Decommissioning:

(a) (1) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material in quantities exceeding the amounts specified in Table 1 or as required by (c)(5) of this section shall submit to the Agency for review and approval a decommissioning funding plan as described in paragraph (d) of this section. 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 E.

TABLE 1

TYPE	EXCEEDING
SPECIAL NUCLEAR MATERIAL	10^5 times Appendix E. (Also, when R divided by 10^5 is greater than 1.)*
SOURCE MATERIAL	100 mCi in readily dispersible form.
BYPRODUCT MATERIAL	Half-life greater than 120 days and 10^5 times Appendix E. (Also, when R divided by 10^5 is greater than 1.)*

* For a combination of radionuclides, R is the sum of the fractions of the radionuclide divided by the Appendix E value for that radionuclide.

(2) Each 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 Appendix E (or when a combination of isotopes is involved if R, as defined in paragraph (a)(1) of this section, divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in paragraph (d) of this section. The decommissioning funding plan must be submitted to the Agency no later than two years after the effective date of this regulation.

(b) 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 Table 2 of this section shall either:

* Submit a decommissioning funding plan as described in paragraph (d) of this section; or

* Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Table 2 of this section using one of the methods described in paragraph (e) of this section. 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 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 paragraph (e) of this section must be submitted to the Agency before receipt of the licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.

(c) (1) Each holder of a specific license issued on or after October 15, 1998 which is of a type described in paragraph (a) or (b) of this section, shall provide a decommissioning funding plan in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before October 15, 1998 and of a type described in paragraph (a) of this section shall submit, on or before October 15, 1998, a decommissioning funding plan as described in paragraph (d) of this section 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 this section. If the licensee submits the certification of financial assurance instead of a decommissioning funding plan, the licensee shall provide a decommissioning funding plan on or before October 15, 2000.

(3) Each holder of a specific license issued before October 15, 1998, and of a type described in paragraph (b) of this section shall submit, on or before October 15, 1998, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before October 15, 1998, for renewal of license in accordance with C.33 shall provide financial assurance for decommissioning in accordance with paragraph (a) and (b) of this section. This assurance must be submitted on or before October 15, 2000.

(5) Waste collectors and waste processors, as defined in Section C.2 of this part, must provide financial assurance in an amount based on a decommissioning funding plan as described in paragraph (d) of this section. 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 Part D of this regulation. The decommissioning funding plan must be submitted no later than two years after the effective date of this regulation.

TABLE 2

TYPE OF RADIOACTIVE MATERIAL	EXCEEDING	ASSURANCE AMOUNT
SPECIAL NUCLEAR MATERIAL	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix E. (For a combination of radionuclides, if R 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 Appendix E. (For a combination of radionuclides, if R divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)*	$225,000
SOURCE MATERIAL	Greater than 10 mCi but less than or equal to 100 mCi in readily dispersible form.	$225,000
BYPRODUCT MATERIAL	Half-Life greater than 120 days and in quantities:	
	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix E in unsealed form. (For a combination of radionuclides, if R 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 Appendix E in unsealed form. (For a combination of radionuclides, if R 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 Appendix E in sealed sources or plated foils. (For a combination of radionuclides, if R divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1.)*	$113,000

*For a combination of radionuclides, R is the sum of the fractions of the radionuclide divided by the Appendix E value for the radionuclide.

(6) If, in surveys made under Section D.501(a) of these regulations, residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the D.1402 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of survey completion.

(d) Licensees having possession limits exceeding the upper bounds of Table 2 or as required by (c)(5) or (6) of this section must base financial assurance on a decommissioning funding plan.

(1) Each decommissioning funding plan must be submitted for review and approval and must contain:

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(a) The cost of an independent contractor to perform all decommissioning activities;

(b) The cost of meeting the Section D.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of Section D.1403 Criteria for License Termination Under Restricted Conditions, the cost estimate may be based on meeting the Section D.1403 criteria;

(c) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(d) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the Decommissioning Cost Estimate;

(iii) A description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 36 months, 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 can not 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:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(e) 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:

* *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 be made into a trust account, and the trustee and the trust must be acceptable to the Agency.

* *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. 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 Appendix F of this part. For commercial corporations 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 Appendix G of this part. 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 Appendix J of this part. 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 Appendix K of this part. 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. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) 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 Agency, 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 Agency within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning cost. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State and 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.

(iii) The surety method or insurance must remain in effect until the Agency has terminated the license.

* *An external sinking fund* in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, 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 must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (e)(2) of this section.

* 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 Table 2 of this section, and indicating that funds for decommissioning will be obtained when necessary.

(f) Each person licensed under Part C shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with C31(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for certifying that all the received records are complete and accurate and will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

* Records of spills or other occurrences involving the spread of radioactive material in and around the facility, equipment, or site. These records may be limited to instances when radioactive material remains after any cleanup procedures or when there is reasonable likelihood that radioactive material 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;

* As built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of location 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 shall substitute appropriate records of available information concerning these areas and locations; and

* Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct 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:

(i) All areas designated and formerly designated restricted areas as defined in Part A, Section 2;

(ii) All areas outside of restricted areas that require documentation under D.1202;

(iii) All areas outside of restricted areas where current and previous wastes have been buried; and

(iv) 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 meet the criteria for decommissioning in §§D.1401-1406 or apply for approval for disposal under D.1002.

* Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning, and records of funding method used for assuring funds if either a funding plan or certification is used.

(g) Approval of decommissioning funding plans and certifications.

* Upon a determination that an application under this section meets the requirements of this section, the Agency shall approve such decommissioning funding plan or certification.

* No person shall receive, possess, use, transfer, own or acquire radioactive material of a type described in paragraph (a) or (b) of this section for more than 180 days following the dates prescribed in this section for submittal of a decommissioning funding plan or certification, if that decommissioning funding plan or certification has not been approved by the Agency.

(h) Financial assurance for decommissioning pursuant to termination under restricted conditions as described in Section D.1403 of Part D shall not be considered a potential financial mechanism until such time as the licensee has submitted its intent to decommission in accordance with C.32 and has submitted a License Termination Plan (LTP) in accordance with Section D.1403(d).

(i) In providing financial assurance under this section, 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 Agency, as follows:

* 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.

* 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.

* Within 30 days of taking the actions required by paragraph (i)(1) or (2) of this section, the licensee must provide a written report of such actions to the Program Manager, Radiological Health Program, Air and Radiation Administration, and state the new balance of the fund.

Sec. C.30 Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency 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 subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

Sec. C.31 Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) (1) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall 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 Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by Section C.29.

(c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(e) Each specific licensee shall notify the Agency 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)) 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)) of the licensee.

(f) The notification specified in C.31(e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum- 99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Section G.204. The licensee shall report the results of any test that exceeds the permissible concentration listed in G.204 (a) at the time of generator elution, in accordance with D.1209. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h) Production of PET Radioactive Drugs.

(1) Authorization under Section C.26(g) 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 Section C.2667(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Section C.28(j)(1)(iv) 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.

(ii) 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 Section C.28(j)(3).

(3) A licensee that is a pharmacy authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Section C.28(j)(2), or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Section G.27.

(4) A pharmacy, authorized under Section C.26(g) to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirement of Section C.28(j)(2)(v).

Sec. C.32 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas. (See also D.1301 "Vacating Premises.")

(a) Except as provided in Md. Code Ann., State Gov't Sec. 10-226 (1996), and provided that the licensee is applying for the same activities as allowed in the current license, each specific license expires at the end of the day, in the month and year stated in the license.

(b) No less than 30 days before expiration of a license, the licensee shall notify the Agency promptly, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license.

(c) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing, as specified in subsections (d) and (f)(1)(i)-(iv) or by license conditions, 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 Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (f)(1) of this section, and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to subsection (a) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, 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 Agency requirements; or

(3) No principal activities under the license have been conducted for a period of 24 months;

(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 Agency requirements; or

(5) The licensee's right to operate has been terminated either by court action or by action of law or regulation.

(d) Coincident with the notification required by paragraph (c) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to C.29 in conjunction with a license issuance or renewal or as required by this section. 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 paragraph (f)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before the effective date of this regulation.

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(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 Agency.

(e) The Agency may grant a request to extend the time periods established in paragraph (c) of this section if the Agency 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 paragraph (c) of this section. The schedule for decommissioning set forth in paragraph (c) of this section may not commence until the Agency has made a determination on the request.

(f) (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out the decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (c) of this section if the Agency 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 paragraph (f)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor site sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to protect workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey;

(v) 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.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in paragraph (i) of this section.

(5) The proposed decommissioning plan will be approved by the Agency 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.

(g) (1) Except as provided in paragraph (h) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (h) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(h) The Agency 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 Agency 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 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 radioactive nuclides to decay; and

(5) Other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other regulatory 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.

(i) As the final step in decommissioning, the licensee shall—

(1) Certify to the Agency in writing the disposition of all licensed material, including accumulated wastes; 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 in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406. The licensee shall, as appropriate—

(i) Report levels of gamma radiation in units of millisieverts (microroentgens) 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, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instruments(s) used and certify that each instrument is properly calibrated and tested.

(3) Forward all records required by Sec. C.38 to the Agency.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

(1) Radioactive material has been properly disposed of;

(2) Reasonable effort (as determined by the Agency) has been made to eliminate residual radioactive contamination if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406.

Sec. C.33 Application for Renewal of Licenses.

(a) Subject to C.32(a), an application for renewal of a specific license must be filed on a form prescribed by the Agency, in accordance with C.24.

(b) All applications for the renewal of a specific license shall be submitted to the Agency for review and approval seven (7) months prior to the expiration date of the license.

Sec. C.34 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.24 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Sec. C.35 Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in C.25, C.26, C.27, and C.28 and in Parts E, G, or W of these regulations, as applicable.

Sec. C. 36 Person Possessing a License for Medical Use of Radioactive Material on Effective Date of These Regulations. Any person or institution possessing a specific license for the medical use of radioactive material issued prior to October 9, 1995 when the licensee was authorized according to Groups I through VI of Schedule C, Part C, shall be deemed to possess a license issued under the revised regulations, according to Part G. The existing license will be valid until its stated expiration date and the renewal will be issued in accordance with the regulations dated October 9, 1995.

Sec. C.37 Registration of Sources or Devices Containing Radioactive Materials.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency in a form acceptable to the Agency for evaluation of radiation safety information about its product and for its registration.

(b) 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.

(c) The Agency normally evaluates a sealed source or device using radiation safety criteria in accordance with accepted industry standards. If these standards and criteria do not readily apply to a particular case, the agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall 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. Section C.4 includes specific criteria that apply to certain exempt products and Section C.22 includes specific criteria applicable to certain generally licensed devices. Section C.28 includes specific provisions that apply to certain specifically licensed items.

(d) After completion of the evaluation, the Agency may issue 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.

(e) The person submitting the request for evaluation and registration of safety information about the product shall 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.

(f) 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:

(i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

(ii) 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

(i) The intended recipients are licensed under Part C of this regulation or comparable provisions of NRC or an Agreement State; or

(ii) The recipients are authorized for research and development; or

(iii) 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.

(g) After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in Section C.37. The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

(h) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Agency under Section C.37, with the NRC 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 Section C.37, the applicant shall provide:

(1) All available information identified in Section C.37 concerning the source, and, if applicable, the device; and

(2) 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 shall 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.

(i) Inactivation of Certificates.

(1) 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 Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency by an appropriate method approved by the Agency 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 shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

(2) If a distribution license is to be terminated in accordance with Part C of this regulation, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency 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) 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.

Sec. C.38 Records.

(a) Each person who receives radioactive material through a license issued pursuant to the regulations in this part shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

(1) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer of source or byproduct material until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Department terminates each license that authorizes disposal of the material.

(b) The licensee shall retain each record that is required by the regulations in this Part and Part D or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) (1) Records which must be maintained pursuant to this Part and Part D may be the original or a reproduced copy or 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 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 shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Department's regulations in this Part and Part D, 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 the regulations in this Part and Part D for such records shall apply unless the Department, pursuant to Sec. A(3)(a), has granted a specific exemption from the record retention requirements specified in the regulations in this Part or Part D.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

(1) Records of disposal of licensed material made under Secs. D.1002 (including burials authorized before September 21, 1986), D.1003, D.1005, D.1006; and

(2) Records required by Sec. D.1103(b)(iv).

(e) If licensed activities are transferred or assigned in accordance with Sec. C.31(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall 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 D.1002 (including burials authorized before January 28, 1981), D.1103, D.1105, D.1106; and

(2) Records required by D.1103(b)(iv).

(f) Prior to license termination, each licensee shall forward the records required by C.29(f) to the Agency.

Transfer of Material

Sec. C.40 Transfer of Material.

(a) No licensee shall transfer radioactive material except as authorized pursuant to C.40.

(b) Except as otherwise provided in his license and subject to the provisions of C.40(c) and (d), any licensee may transfer radioactive material:

(1) to the Agency;[11]

(2) to the U.S. Department of Energy;

(3) to any person exempt from these 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 Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, an Agreement State, or a Licensing State; or

_____ (5) as otherwise authorized by the Agency inwriting.

[11] A licensee may transfer material to the Agency only after receiving prior written approval from the Agency.

(c) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) Any of the following methods for the verification required by C.40(c) is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee 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 the transferee 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 10 days.

(4) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in C.40(d)(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 Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Shipment and transport of radioactive material shall be in accordance with the provisions of Part T of these regulations.

National Source Tracking System

C.41 Nationally Tracked Source Thresholds.

Nationally tracked source thresholds are specified in Appendix H of this Part.

C.42 Serialization of Nationally Tracked Sources.

Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alphanumeric characters.

C.43 Reports of Transactions Involving Nationally Tracked Sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall 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.

(b) Each licensee that transfers a nationally tracked source to another person shall 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 identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall 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 information with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall 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; and

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall 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.

(f) The reports discussed in C.43(a) through (e) 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 one of the following methods:

(1) Using 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 follow-up by facsimile or mail.

(g) Each licensee shall 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 shall 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 by C.43(a) through (e). 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.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 1, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 1, 2009. The information may be submitted by using any of the methods identified by C.43(f)(1) through (f)(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.

Secs.C.44–C.49 Reserved.

Modification and Revocation of Licenses

Sec. C.50 Modification and Revocation of Licenses.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Agency.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency order.

Sec. C.51 - C.89 Reserved.

RECIPROCITY

Sec. C.90 Reciprocal Recognition of Licenses.

(a) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State, and issued by the agency 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 within this state, excluding offshore waters and areas of exclusive Federal jurisdiction, for a period not in excess of 180 days in any calendar year to possess radioactive material and/or to conduct the activities authorized in such licensing document provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency 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 C.90(a)(1);

(iii) the out-of-state licensee complies with all applicable regulations of the Agency 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 Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90(a)(1) except by transfer to a person:

(a) specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material, or

(b) exempt from the requirements for a license for such material under C.4(a).

(2) Notwithstanding the provisions of C.90(a)(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 C.22(d)(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:

(i) such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) 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;

(iii) such person shall 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

(iv) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.22(d) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(b) Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.

(1) Subject to these regulations, any person who holds a specific license from a Licensing State, and issued by the agency 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 within this State for a period not in excess of 180 days in any calendar year to possess radioactive material and/or to conduct the activities authorized in such licensing document provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency 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 C.90(b)(1);

(iii) the out-of-state licensee complies with all applicable regulations of the Agency 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 Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90(b)(1) except by transfer to a person:

(a) specifically licensed by the Agency or by another Licensing State to receive such material, or

(b) exempt from the requirements for a license for such material under C.4.

(2) Notwithstanding the provisions of C.90(b)(1), any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in C.22(d)(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:

(i) Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;

(iii) Such person shall 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 the "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.22(d) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(a) Reciprocity of Maryland Licensees.

(1) Prior to a State of Maryland company conducting licensed activities in offshore waters or areas of exclusive Federal jurisdiction that company shall meet all pertinent requirements of 10 CFR 150.20.

(2) Any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in 10 CFR 150.20, shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in 10 CFR 150.20, except by transfer to a person who is specifically licensed by the NRC to receive this material.

(3) Any person who holds a specific license issued by the Agency authorizing the holder to manufacture, install, or service a device described in Section C.22(d) of this regulation within Maryland is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in 10 CFR 150.3(f), provided that:

(i) [Reserved]

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agency.

(iii) Such person assures that any labels required to be affixed to the device under Maryland regulations which licensed manufacture of the device bear a statement that removal of the label is prohibited.

Part C

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1X10^{-3}$
Argon (18)	Ar-37	$1X10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1X10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1X10^{-3}$
	Co-60		$5X10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/g for solids.

Part C

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165		$4X10^{-3}$
	Dy-166		$4X10^{-4}$
Erbium (68)	Er-169		$9X10^{-4}$
	Er-171		$1X10^{-3}$
Europium (63)	Eu-152(9.2 h)		$6X10^{-4}$
	Eu-155		$2X10^{-3}$
Fluorine (9)	F-18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd-153		$2X10^{-3}$
	Gd-159		$8X10^{-4}$
Gallium (31)	Ga-72		$4X10^{-4}$
Germanium (32)	Ge-71		$2X10^{-2}$
Gold (79)	Au-196		$2X10^{-3}$
	Au-198		$5X10^{-4}$
	Au-199		$2X10^{-3}$
Hafnium (72)	Hf-181		$7X10^{-4}$
Hydrogen (1)	H-3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In-113m		$1X10^{-2}$
	In-114m		$2X10^{-4}$
Iodine (53)	I-126	$3X10^{-9}$	$2X10^{-5}$
	I-131	$3X10^{-9}$	$2X10^{-5}$
	I-132	$8X10^{-8}$	$6X10^{-4}$
	I-133	$1X10^{-8}$	$7X10^{-5}$
	I-134	$2X10^{-7}$	$1X10^{-3}$
Iridium (77)	Ir-190		$2X10^{-3}$
	Ir-192		$4X10^{-4}$
	Ir-194		$3X10^{-4}$
Iron (26)	Fe-55		$8X10^{-3}$
	Fe-59		$6X10^{-4}$
Krypton (36)	Kr-85m	$1X10^{-6}$	
	Kr-85	$3X10^{-6}$	
Lanthanum (57)	La-140		$2X10^{-4}$
Lead (82)	Pb-203		$4X10^{-3}$
Lutetium (71)	Lu-177		$1X10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/g for solids.

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Manganese (25)	Mn-52		$3X10^{-4}$
	Mn-54		$1X10^{-3}$
	Mn-56		$1X10^{-3}$
Mercury (80)	Hg-197m		$2X10^{-3}$
	Hg-197		$3X10^{-3}$
	Hg-203		$2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147		$6X10^{-4}$
	Nd-149		$3X10^{-3}$
Nickel (28)	Ni-65		$1X10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1X10^{-3}$
	Nb-97		$9X10^{-3}$
Osmium (76)	Os-185		$7X10^{-4}$
	Os-191m		$3X10^{-2}$
	Os-191		$2X10^{-3}$
	Os-193		$6X10^{-4}$
Palladium (46)	Pd-103		$3X10^{-3}$
	Pd-109		$9X10^{-4}$
Phosphorus (15)	P-32		$2X10^{-4}$
Platinum (78)	Pt-191		$1X10^{-3}$
	Pt-193m		$1X10^{-2}$
	Pt-197m		$1X10^{-2}$
	Pt-197		$1X10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142		$3X10^{-4}$
	Pr-143		$5X10^{-4}$
Promethium (61)	Pm-147		$2X10^{-3}$
	Pm-149		$4X10^{-4}$
Rhenium (75)	Re-183		$6X10^{-3}$
	Re-186		$9X10^{-4}$
	Re-188		$6X10^{-4}$
Rhodium (45)	Rh-103m		$1X10^{-1}$
	Rh-105		$1X10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/g for solids.

Part C

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Rubidium (37)	Rb-86		$7X10^{-4}$
Ruthenium (44)	Ru-97		$4X10^{-3}$
	Ru-103		$8X10^{-4}$
	Ru-105		$1X10^{-3}$
	Ru-106		$1X10^{-4}$
Samarium (62)	Sm-153		$8X10^{-4}$
Scandium (21)	Sc-46		$4X10^{-4}$
	Sc-47		$9X10^{-4}$
	Sc-48		$3X10^{-4}$
Selenium (34)	Se-75		$3X10^{-3}$
Silicon (14)	Si-31		$9X10^{-3}$
Silver (47)	Ag-105		$1X10^{-3}$
	Ag-110m		$3X10^{-4}$
	Ag-111		$4X10^{-4}$
Sodium (11)	Na-24		$2X10^{-3}$
Strontium (38)	Sr-85		$1X10^{-4}$
	Sr-89		$1X10^{-4}$
	Sr-91		$7X10^{-4}$
	Sr-92		$7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$
Technetium (43)	Tc-96m		$1X10^{-1}$
	Tc-96		$1X10^{-3}$
Tellurium (52)	Te-125m		$2X10^{-3}$
	Te-127m		$6X10^{-4}$
	Te-127		$3X10^{-3}$
	Te-129m		$3X10^{-4}$
	Te-131m		$6X10^{-4}$
	Te-132		$3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$
Thallium (81)	Tl-200		$4X10^{-3}$
	Tl-201		$3X10^{-3}$
	Tl-202		$1X10^{-3}$
	Tl-204		$1X10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ μCi/g for solids.

Part C

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Thulium (69)	Tm-170		$5X10^{-4}$
	Tm-171		$5X10^{-3}$
Tin (50)	Sn-113		$9X10^{-4}$
	Sn-125		$2X10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4X10^{-3}$
	W-187		$7X10^{-4}$
Vanadium (23)	V-48		$3X10^{-4}$
Xenon (54)	Xe-131m	$4X10^{-6}$	
	Xe-133	$3X10^{-6}$	
	Xe-135	$1X10^{-6}$	
Ytterbium (70)	Yb-175		$1X10^{-3}$
Yttrium (39)	Y-90		$2X10^{-4}$
	Y-91m		$3X10^{-2}$
	Y-91		$3X10^{-4}$
	Y-92		$6X10^{-4}$
	Y-93		$3X10^{-4}$
Zinc (30)	Zn-65		$1X10^{-3}$
	Zn-69m		$7X10^{-4}$
	Zn-69		$2X10^{-2}$
Zirconium (40)	Zr-95		$6X10^{-4}$
	Zr-97		$2X10^{-4}$
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		$1X10^{-10}$	$1X10^{-6}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ μCi/g for solids.

Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

Note 2: For purposes of Section C.4 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1."

Example: $\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} +$

$$\frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} \leq 1$$

Note 3: To convert µCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40) Zr-97 (2×10^{-4} µCi/ml multiplied by 37 is equivalent to 74×10^{-4} MBq/l)

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Micro-curies
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
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

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Micro-curies
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
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

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Micro-curies
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
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

Part C

APPENDIX B

EXEMPT QUANTITIES

Radioactive Material	Micro-curies
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
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 1: For purposes of C.4 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

$$\frac{\text{Amt. of Radionuclide A possessed}}{\text{1000 x Appendix B quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{\text{1000 x Appendix B quantity for Radionuclide B}} \leq 1$$

Note 2: 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).

Part C

Appendix C

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	.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9(20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	2,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holminum-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000

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)
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorous-32	.5	100
Phosphorous-33	.5	1,000
Polonuim-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000

Appendix C (continued)

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)
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[1]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[2]	.0001	20
Combinations of radioactive 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 Appendix C exceeds one.

2. Waste packaged in Type B containers does not require an emergency plan.

Part C

APPENDIX D

LIMITS FOR BROAD LICENSES (C.27)

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 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01

APPENDIX D
LIMITS FOR BROAD LICENSES (C.27)

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

PART C

APPENDIX D
LIMITS FOR BROAD LICENSES (C.27)

Radioactive Material	Col. I curies	Col. II curies
Niobium-95	1	0.01
Niobium-97	100	1.0
Osmium-185	1	0.01
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

PART C

APPENDIX D
LIMITS FOR BROAD LICENSES (C.27)

Radioactive Material	Col. I curies	Col. II curies
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
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

PART C

APPENDIX D

LIMITS FOR BROAD LICENSES (C.27)

Radioactive Material	Col. I curies	Col. II curies
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 radio-active material not listed above.	0.1	0.001

Note 1: 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)

Part C

APPENDIX E

QUANTITIES OF LICENSED MATERIAL TO BE USED FOR DECOMMISSIONING ACTIVITIES

Material	Microcuries
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
Eropium-152 9.2 h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10

Part C

APPENDIX E

QUANTITIES OF LICENSED MATERIAL TO BE USED FOR DECOMMISSIONING ACTIVITIES

Material	Microcuries
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
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

APPENDIX E
QUANTITIES OF LICENSED MATERIAL TO BE USED FOR DECOMMISSIONING ACTIVITIES

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
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-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technitium-97	100
Technetium-99m	100
Technetium-99	10

APPENDIX E

QUANTITIES OF LICENSED MATERIAL TO BE USED FOR DECOMMISSIONING ACTIVITIES

Material	Microcuries
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
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—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	0.01
Any radionuclide other than alpha emitting radionuclides not listed above or mixtures of beta emitters of unknown composition	0.1

[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 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 amount of decommissioning funds being assured by a parent company guarantee 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 $21 million; and

(iv) Assets located in the United States amounting to at least 90 percent 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

(ii) Total net worth at least six times the amount of decommissioning funds being assured by a parent company guarantee 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 $21 million; and

(iv) Assets located in the United States amounting to at least 90 percent 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 compare the data used by the parent 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 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 the auditing procedure, the licensee must inform the Agency 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 Agency 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 Agency of intent to establish alternate financial assurance as specified in this appendix or Appendix G of this part. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end 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 Agency. 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 Agency, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and the Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide alternative financial assurance that meets the provisions of the Agency's regulations in the name of the licensee.

C. The parent company guarantee and the financial test provisions must remain in effect until the Agency has terminated the license, accepted in writing the parent company's alternate financial assurances, or accepted in writing the licensee's financial assurances.

D. 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 the trust must be acceptable to the Agency. 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 Agency 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 Agency 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 Agency 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 Agency, 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

(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.

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Part C

APPENDIX G

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF 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 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 II of this appendix. The terms of the self guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self guarantee.

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 G 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:

(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).

(2) Assets located in the United States amounting to at least 90 percent 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).

(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.

B. To pass the financial test, a company must meet all of the following additional requirements:

(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 compare 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 procedure, the licensee must inform the Agency 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.

(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 Agency within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in this appendix within 120 days of such notice.

III. 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 Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in this appendix within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities 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 Agency in 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.

F. The applicant or licensee must provide to the Agency 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 Agency, the licensee will fund the standby trust as described in paragraph G of this appendix in the amount guaranteed by the self-guarantee agreement.

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 Agency. 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 Agency 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 Agency may:

(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 Agency, 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.

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Appendix H

Nationally Tracked Source Thresholds

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	1600	0.6	16
Americium-241/Be	60	1600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1400	0.5	14
Cesium-137	100	2700	1	27
Gadolinium-153	1000	27000	10	270
Iridium-192	80	2200	0.8	22
Plutonium-238	60	1600	0.6	16
Plutonium-239/Be	60	1600	0.6	16
Polonium-210	60	1600	0.6	16
Promethium-147	40000	1100000	400	11000
Radium-226	40	1100	0.4	11
Selenium-75	200	5400	2	54
Strontium-90	1000	27000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20000	540000	200	5400
Ytterbium-169	300	8100	3	81

Part C

Appendix I [Reserved]

Part C

APPENDIX J

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS

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 II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

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 J 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:

(1) Tangible net worth of at least $21 million, and total net worth of 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).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by total net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company's independent certified public accountant must compare 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. In connection with the auditing procedure, the licensee must inform the Agency 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.

(2) 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 Agency within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the Agency of intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency 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 Agency, the licensee will fund the standby trust as described in paragraph E of this appendix in the amount of the current cost estimates for decommissioning.

E. 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. The trustee and trust must be acceptable to the Agency. 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 Agency will have the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

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 Agency may:

(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 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. The guarantor must notify the Agency, in writing, immediately following the occurrence of any event listed in paragraph F 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.

Part C

Appendix K

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY NONPROFIT COLLEGES, UNIVERSITIES, AND HOSPITALS

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 applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities, to pass the financial test a college or university must meet either the criteria in Paragraph II.A.(1) or the criteria in Paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of or) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test a hospital must meet either the criteria in Paragraph II.B.(1) or the criteria in Paragraph II.B.(2) of this appendix:

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of or) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

(1) The licensee's independent certified public accountant must compare the data used by the licensee 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 licensee's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the licensee'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 of this appendix. In connection with the auditing procedure, the licensee must inform the Agency 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 licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test and provide documentation of its continued eligibility to use the self-guarantee to the Agency within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee 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. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that--

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will fund the standby trust as described in paragraph F. of this section in the amount of the current cost estimates for decommissioning.

E. (1) 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 Poor's or Moody's, the licensee shall notify the Agency in 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 " and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. (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 Agency. 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 Agency has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

G. 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 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 Agency may:

(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.

H. The guarantor must notify the Agency, in writing, immediately following the occurrence of any event listed in paragraph G 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.

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PART D

STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

Sec. D.1 Purpose. The requirements of Part D 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 Part D. However, nothing in Part D shall be construed as limiting actions that may be necessary to protect health and safety.

Sec. D.2 Scope. Part D applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part D 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 G.25, or to voluntary participation in medical research programs.

Sec. D.3 Definitions. As used in Part D:

“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 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 or 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.

“Demand respirator” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix 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 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).

"Dosimetry processor" means a person 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.

“Loose-fitting facepiece” means a respiratory inlet covering that is designed to form a partial seal with the face.

“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, "deterministic effect" is an equivalent term.

“Permanent implant brachytherapy” means the use of very small implants called seeds or pellets inserted directly into a tumor and left in place until all the radiation has been used.

"Planned special exposure" means an infrequent exposure to radiation in an exceptional situation when alternatives that might avoid the higher exposures are unavailable or impractical. A planned special exposure shall be 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 faceplate 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, 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.

"Self-Shielded Irradiator" means a source of radiation that is used to irradiate materials where the source of radiation is both stored and operated within the same radiation shielding barrier and, in the designed configuration of the irradiator, does not allow exposure of any part of an individual to an exposure rate of 5 Gy (500 rads) per hour or greater.

"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. For purposes of these regulations, "probabilistic effect" is an equivalent term.

“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.

Sec. D.4 Implementation.

a. Any existing license or registration condition that is more restrictive than Part D remains in force until there is an amendment or renewal of the license or registration.

b. If a license or registration condition exempts a licensee or registrant from a provision of Part D in effect on or before October 9, 1995, it also exempts the licensee or registrant from the corresponding provision of Part D.

c. If a license or registration condition cites provisions of Part D in effect prior to October 9, 1995, which do not correspond to any provisions of Part D, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

Sec. D.101 Radiation Protection Programs.

a. In addition to complying with all other provisions of these regulations, a licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to the members of the general public that are as low as is reasonably achievable(ALARA).

b. Each person licensed to receive, use, transfer, own, or acquire radioactive material under Part C of these regulations shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of these regulations.

c. The licensee shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

d. To implement the ALARA requirements of D.101(a), and notwithstanding the requirements in D.301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall 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 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in D.1203 and promptly take appropriate corrective action to ensure against recurrence.

e. A registrant may incorporate the determination for effective dose equivalent for interventional/therapeutic fluoroscopy into its ALARA program as described in D.209. Fluoroscopic modalities may include but are not limited to interventional radiology, cardiac catheterization, vascular surgery, electrophysiology, and pain management.

OCCUPATIONAL DOSE LIMITS

Sec. D.201 Occupational Dose Limits for Adults.

a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to D.206, to the following dose limits:

   i. An annual limit, which is the more limiting of:

(1) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(2) 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).

ii. 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:

(1) A lens dose equivalent of 0.15 Sv (15 rem), and

(2) A shallow-dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall 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 D.206(f)(i) and (ii).

c. 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 Agency. 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.

d. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See D.1107.

e. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

f. The licensee or registrant shall 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. See D.205e.

Sec. D.202 Compliance with Requirements for Summation of External and Internal Doses.

a. If the licensee or registrant is required to monitor pursuant to both D.502a. and b., the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to D.502a. or only pursuant to D.502b., then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to D.202b., c. and d. 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.

b. 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:

   i. The sum of the fractions of the inhalation ALI for each radionuclide, or

   ii. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2000, or

   iii. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using 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 percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

c. Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

d. Intake through Wounds or Absorption through Skin. The licensee shall 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 D.202d.

Sec. D.203 Determination of External Dose from Airborne Radioactive Material.

a. Licensees shall, 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 B, footnotes 1 and 2.

b. Airborne radioactivity measurements and DAC values shall 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 shall be based upon measurements using instruments or individual monitoring devices.

Sec. D.204 Determination of Internal Exposure.

a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to D.502, take suitable and timely measurements of:

   i. Concentrations of radioactive materials in air in work areas; or

   ii. Quantities of radionuclides in the body; or

   iii. Quantities of radionuclides excreted from the body; or

   iv. Combinations of these measurements.

b. Unless respiratory protective equipment is used, as provided in D.703, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

c. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

   i. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

   ii. Upon prior approval of the Agency, 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

   iii. 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 B.

d. If the licensee chooses to assess intakes of Class Y material using the measurements given in D.204a.ii. or iii., the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by D.1202 or D.1203. This delay permits the licensee to make additional measurements basic to the assessments.

e. 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 shall be either:

   i. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

   ii. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the

mixture.

f. 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.

g. When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

   i. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in D.201 and in complying with the monitoring requirements in D.502b., and

   ii. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

   iii. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

h. When determining the committed effective dose equivalent, the following information may be considered:

   i. 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.

   ii. 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), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix 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 shall also demonstrate that the limit in D.201a.i.(2) is met.

Sec. D.205 Determination of Prior Occupational Dose.

a. For each individual who may receive, in a year, an occupational dose requiring monitoring pursuant to D.502, the licensee or registrants hall:

   i. Determine the occupational radiation dose received during the current year; and

   ii. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

b. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

i. The internal and external doses from all previous planned special exposures;

ii. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

iii. The cumulative occupational radiation dose of the individual.

c. In complying with the requirements of D.205a., a licensee or registrant may:

i. 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; and

ii. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form RX-37 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

iii. 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, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

d. i. The licensee or registrant shall record the exposure history, as required by D.205a., on Agency Form RX-37, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Agency Form RX-37 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form RX-37 or equivalent indicating the periods of time for which data are not available.

ii. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the regulations in Part D in effect before October 9, 1995. Further, occupational exposure histories obtained and recorded on Agency Form RX-37 or equivalent before October 9, 1995, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

e. 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 shall assume:

   i. In establishing administrative controls pursuant to D.201f. 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

   ii. That the individual is not available for planned special exposures.

f. The licensee or registrant shall retain the records on Agency Form RX-37 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form RX-37 or equivalent for 3 years after the record is made.

Sec. D.206 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 D.201 provided that each of the following conditions is satisfied:

a. The licensee or registrant has secured written permission from the Agency prior to the planned special exposure.

b. 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.

c. 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.

d. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

   i. Informed of the purpose of the planned operation; and

   ii. 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

   iii. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

e. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by D.205b. during the lifetime of the individual for each individual involved.

f. Subject to D.201b., the licensee or registrant shall 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:

   i. The numerical values of any of the dose limits in D.201a. in any year; and

   ii. Five times the annual dose limits in D.201a. during the individual's lifetime.

g. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with D.1106 and submits a written report in accordance with D.1204.

h. 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 shall not be considered in controlling future occupational dose of the individual pursuant to D.201a. but shall be included in evaluations required by D.206d. and e.

Sec. D.207 Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in D.201.

Sec. D.208 Dose to an Embryo/Fetus.

a. The licensee or registrant shall 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 D.1107 for recordkeeping requirements.

b. The licensee or registrant shall make efforts to avoid substantial variation[1] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in D.208a.

c. The dose equivalent to the embryo/fetus is the sum of:

   i. The deep dose equivalent to the declared pregnant woman; and

[1] 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 anyone month.

ii. The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

d. If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

Sec. D.209 Determination of Effective Dose Equivalent for Interventional/Therapeutic Fluoroscopy.

a. When a protective apron is worn while working as described in Section D.101(e) with C-arm Interventional/Therapeutic medical fluoroscopic equipment and monitoring is conducted as specified in D.502(a), the effective dose equivalent for external radiation shall be determined as follows:

i. 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 shall be the effective dose equivalent for external radiation; or

ii. 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 percent of the limit specified in D.201(a), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

iii. 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 shall 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.

b. Compliance with the following procedures provide a registrant with continuing automatic approval for such usage as described in D.209(a)(ii) and (iii) under the following conditions:

i. When an individual's external (collar) badge exceeds 25% (1.25 rem) of the 5 rem annual limit, a facility may automatically apply one of the alternative methodologies in D.209(a)(ii) and (iii) for calculating the effective dose equivalents.

ii. Once an individual's effective dose equivalent has reached 80% (4 rem) of the annual effective dose equivalent limit, the registrant shall notify the Agency, provide to the Agency the information listed in subsection (b)(ii)(1) – (3) below, and continue to apply the selected alternative methodology for calculating the effective dose equivalent:

(1) A copy of the two most recent Radiation Safety Committee Meeting minutes that discuss issues identified in radiation safety involving occupational workers and the practice of achieving the "as low as reasonably achievable (ALARA)" principle and corrective actions taken for issues identified. The meeting notes must be detailed in regard to the film badge program, which can be satisfied by including the following information:

(a) Individuals required to wear film badges are wearing their badges correctly;

(b) Badges are being returned on time and handed out promptly to wearers at least 90% of the time;

(c) Badges are being worn at least 90% of the time before the start of a procedure by individuals required to wear film badges;

(d) Appropriate radiation protective tools including lead or lead equivalent protection are being utilized; and

(e) For any individual who reached or exceeded 80% of the effective annual dose limit, the badge information is being reviewed to detect any anomalies in the film badge pattern of use, such as if the individual had a zero or very low reading if a fluoroscope was utilized and a high number of fluoroscopic minutes were identified; and

(2) Assurance that the badge readings are being expedited in order for the registrant to effectively monitor the readings to ensure that the occupational worker does not exceed the annual dose limit; and

(3) A notification to the Agency of the next scheduled Radiation Safety Committee Meeting so that Agency representatives may attend.

c. The Agency will inform the facility within two weeks of receipt of the required documentation in D.209(b)(ii) whether the information submitted by the registrant is deficient and therefore does not support continued approval of use of the weighting factor in D.209(a)(ii) and (iii).

i. In the event of such notification, the registrant shall immediately cease use of the selected weighting factor for the badged individual and discontinue its use until the deficiencies are corrected.

ii. If the registrant is not notified that the information submitted is deficient within the two week period specified in this subsection, the badged individual may

(1) continue to utilize the alternative methodology in D.209(a)(ii) and (iii) for calculating the effective dose equivalent for the remainder of the calendar year or

(2) until the 5 rem effective dose annual limit is met, whichever occurs earlier.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

Sec. D.301 Dose Limits for Individual Members of the Public.

a. Each licensee or registrant shall conduct operations so that:

i. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) 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 under G.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with D.1003, and

ii. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Sec. G.75, does not exceed 0.002 rem (0.02 mSv) in any one hour.

b. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

c. 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.

d. Notwithstanding paragraph (a)(i) of this section, a licensee may permit visitors to an individual who cannot be released, under Sec. G.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

i. The radiation dose received does not exceed 0.5 rem(5 mSv); and

ii. The authorized user, as defined in Part G, has previously determined that the visit is appropriate.

e. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

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Sec. D.302 Compliance with Dose Limits for Individual Members of the Public.

a. The licensee or registrant shall 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 D.301.

b. At intervals not to exceed twelve months, a licensee or registrant shall show compliance with the annual dose limit in D.301a.i. for each calendar year by:

i. Demonstrating compliance with D.101a.; and

ii. (1) Demonstrating by measurement, or calculation, or appropriate simulation model that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered source of radiation does not exceed the annual dose limit of D.301; 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 B; and

(b) If an individual were continually present in an unrestricted area, at the point of highest potential exposure from the licensed or registered source of radiation, the dose to that individual would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in any year.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

Sec. D.401 Testing for Leakage or Contamination of Sealed Sources.

a. Each sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, shall be tested for leakage or contamination prior to initial use and, unless otherwise authorized by the Agency, at intervals not to exceed 6 months. If, at any other time, there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use. In the absence of a certificate from a transferor indicating that a test for leakage has been made within 6 months prior to the transfer, the sealed source shall not be put into use until tested and the results received.

i. Tests for leakage for all sealed sources, except those manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate.

ii. The test for leakage for sources manufactured to contain radium shall 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.

iii. Test samples shall also be taken from the interior surfaces of the container in which sealed sources of radium are stored. This test shall be capable of detecting the presence of 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than 4 days.

iv. Notwithstanding the periodic test for leakage required, any sealed source is exempt from such tests for leakage when the sealed source contains 3.7 MBq (100 μCi) or less of beta or gamma emitting material or 370 KBq (10 μCi) or less of alpha emitting material.

b. Tests for leakage or contamination shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

c. The following shall be considered evidence that the sealed source is leaking:

i. The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample. If the test of a sealed source, other than radium, reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, and cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with Part D.

ii. Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for sealed sources manufactured to contain radium. If the test of a sealed source manufactured to contain radium reveals the presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium-226, the licensee or registrant shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with Part D.

d. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.

e. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to D.1206.

SURVEYS AND MONITORING

Sec. D.501 General.

a. Each licensee or registrant shall make, or cause to be made, surveys of areas that:

   i. Are necessary for the licensee or registrant to comply with Part D; and

   ii. Are reasonable under the circumstances to evaluate:

      (1) The magnitude and extent of radiation levels; and

      (2) Concentrations or quantities of residual radioactivity; and

      (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.

   iii. Each survey related to radiation machines shall be performed by a qualified expert as defined in F.2.

b. For radioactive materials licensees, surveys as described in D.501a. shall include surface and subsurface areas.

c. Notwithstanding the requirements of D.1103(a), 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 Section C.29(f).

d. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated for the radiation measured at intervals not to exceed 12 months.

e. 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 D.201, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

   i. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

   ii. 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.

f. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

Sec. D.502 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D. As a minimum:

a. Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee or registered and unregistered radiation machines under the control of the registrant and shall supply and require the use of individual monitoring devices by:

   i. Adults who potentially may receive, in 1 year, from sources external to the body, a dose in excess of 10 percent of the limits in D.201a;

   ii. Minors who potentially may receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

   iii. Declared pregnant women who potentially may receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);[a] and

   iv. Individuals entering a high or very high radiation area.

b. Each licensee shall monitor, to determine compliance with D.204, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

   i. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B;

   ii. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

   iii. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

Sec. D.601 Control of Access to High Radiation Areas.

a. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

   i. 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 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

   ii. 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

   iii. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

[a] All the occupational doses in Section D.201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

b. In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by D.601a.

c. The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.

d. The licensee or registrant shall establish the controls required by D.601a. and c. in a way that does not prevent individuals from leaving a high radiation area.

e. The licensee 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:

   i. The packages do not remain in the area longer than 3 days; and

   ii. The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

f. 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 Part D and to operate within the ALARA provisions of the licensee's radiation protection program.

Sec. D.602 Control of Access to Very High Radiation Areas.

a. The provisions of D.602 do not apply to sources of radiation that are used in teletherapy, field radiography, diagnostic x-ray, or in self-shielded irradiators.

b. In addition to the requirements in D.601, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to very high radiation areas. This requirement includes, but is not limited to the following provisions:

   i. Each entrance or access point that is large enough to admit a person shall be equipped with entry control devices which:

      (1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

      (2) 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

(3) 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; and

(4) Display a conspicuously visible warning light, activated by the physical detection of radiation, that operates when, and only when, the very high levels of radiation exist inside the area.

ii. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by D.602b.i.:

(1) 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

(2) Conspicuously 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.

iii. The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(1) 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

(2) Conspicuously 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.

iv. When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

v. 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 D.602b.iii. and iv.

vi. Each area shall 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.

vii. Each area shall 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.

viii. Each area shall 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) in1 hour.

ix. The entry control devices required in D.602b.i. shall be tested for proper functioning.

(1) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(2) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(3) The licensee or registrant shall submit with each application for license or registration an acceptable schedule for periodic tests of the entry control and warning systems and shall meet that schedule following approval.

(4) Records of these tests shall be kept in accordance with D.1110.

x. The licensee or registrant shall 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.

xi. Exit portals that are used for transporting material from the irradiation area shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically prevent loose radioactive material from being carried out of the area.

c. Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of D.602 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 D.602b., such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in D.602b. At least one of the alternative measures shall

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.

d. The entry control devices required by D.602b. and c. shall 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

Sec. D.701 Use of Process or Other Engineering Controls. The licensee shall use, to the extent practical, process or other engineering controls, such as containment or ventilation, to control the concentrations of radioactive material in air.

Sec. D.702 Use of Other Controls.

a. 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 shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

   i. Control of access; or

   ii. Limitation of exposure times; or

   iii. Use of respiratory protection equipment; or

   iv. Other controls.

b. 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.

Sec. D.703 Use of Individual Respiratory Protection Equipment.

If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material:

a. The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as provided in D.703(ii).

b. 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 shall submit an application to the Agency for authorized use of this equipment. 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.

c. The licensee shall implement and maintain a respiratory protection program that includes:

i. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

ii. Surveys and bioassays, as necessary, to evaluate actual intakes; and

iii. Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use; and

iv. Written procedures regarding:

(1) Monitoring, including air sampling and bioassays;

(2) Supervision and training of respirator users;

(3) Fit testing;

(4) Respirator 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.

v. Determination by a physician that the individual user is medically fit to use respiratory protection equipment:

(1) Before the initial fitting of a face sealing respirator;

(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.

vi. Fit testing, with fit factor " 10 times the APF for negative pressure devices, and a fit factor " 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 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

d. The licensee shall 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.

e. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

f. 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 himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall 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.

g. 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). Grade D quality air criteria include:

   i. Oxygen content (v/v) of 19.5-23.5%;

   ii. Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

   iii. Carbon monoxide(CO) content of 10 ppm or less;

   iv. Carbon dioxide content of 1,000 ppm or less; and

   v. Lack of noticeable odor.

h. The licensee shall 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.

i. 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.

Sec. D.704 Further Restrictions on the Use of Respiratory Protection Equipment.

The Agency may impose restrictions in addition to the provisions of D.701, D.702, D.703 and Appendix A to Part D, in order to:

a. 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

b. Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

Sec.D.705ApplicationfortheUseofHigherAssignedProtectionFactors.

The licensee shall obtain authorization from the Agency before using assigned protection factors in excess of those specified in Appendix A to Part D. The Agency may authorize a licensee to use higher assigned protection factors on receipt of an application that:

a. Describes the situation for which a need exists for higher protection factors; and

b. 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

Sec. D.801 Security of Stored Sources of Radiation. Sources of radiation shall be secured against unauthorized removal or access from the place of storage.

Sec. D.802 Control of Sources of Radiation Not in Storage.

a. The licensee shall control and maintain constant surveillance of licensed radioactive material that is in an unrestricted area and that is not in storage or in a patient.

b. The registrant shall maintain control of radiation machines that are in an unrestricted area and that are not in storage.

Section D.803 Security Requirements for Portable Gauges.

a. Each portable gauge licensee shall 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.

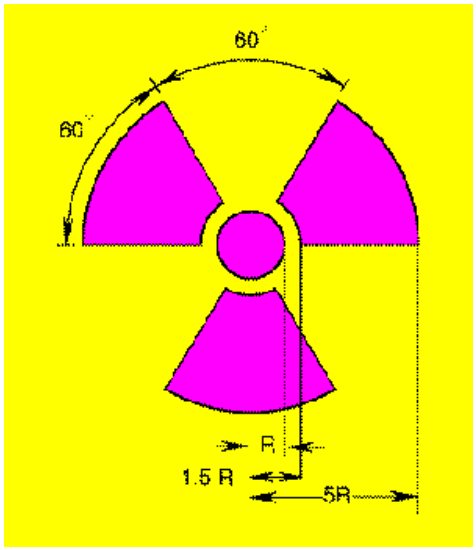
b. The licensee shall ensure that the source locking mechanism for each device is engaged in the secured and fully shielded position during storage and transport.

Sec.D.901CautionSigns.

a. Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by D.901 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

i. Cross-hatched area is to be magenta, or purple, or black, and
ii. The background is to be yellow.



b. Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of D.901a., 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.

c. Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Part D, the licensee or registrant shall 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.

Sec. D.902 Posting Requirements.

a. Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

b. Posting of High Radiation Areas. The licensee or registrant shall 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."

c. Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

d. Posting of Airborne Radioactivity Areas. The licensee shall 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."

e. Posting of Areas or Rooms in which Licensed Radioactive Material is Used or Stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Sec. D.903 Exceptions to Posting Requirements.

a. A licensee is not required to post caution signs in areas or rooms containing radioactive material for periods of less than 8 hours, if each of the following conditions is met:

   i. The radioactive material is constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in Part D; and

   ii. The area or room is subject to the licensee's control.

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to D.902 provided that the patient could be released from license control pursuant to G.25.

c. Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under D.902 if:

   i. Access to the room is controlled pursuant to Section G.51; and

   ii. 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 this part.

d. Rooms or other areas which contain only therapeutic x-ray machines or diagnostic x-ray machines are not required to be posted with caution signs pursuant to D.902.

Sec. D.904 Labeling Containers and Radiation Machines.

a. The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall 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.

b. Each licensee shall, 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.

c. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

Sec. D.905 Exemptions to Labeling Requirements. A licensee is not required to label:

a. Containers holding licensed material in quantities less than the quantities listed in Appendix C; or

b. Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or

c. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part D; or

d. Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation[2]; or

e. 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 those 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 shall be retained as long as the containers are in use for the purpose indicated on the record; or

f. Installed manufacturing or process equipment, such as chemical process equipment, piping and tanks.

Sec. D.906 Procedures for Receiving and Opening Packages.

a. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in T.2 and Appendix A of Part T of these regulations, shall make arrangements to receive:

   i. The package when the carrier offers it for delivery; or

   ii. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

b. Each licensee shall:

   i. Monitor the external surfaces of a labeled[3] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in A.2 of these regulations; and

   ii. Monitor the external surfaces of a labeled[3] 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 T.2 and Appendix A to Part T of these regulations.

[2] 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 the U.S. Dept. of Transportation regulations 49 CFR 173.403 (m) and (w) and 173.421-424.

[3] 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.

iii. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of package degradation, such as packages that are crushed, wet, or damaged.

c. The licensee shall perform the monitoring required by D.906b. as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

d. The licensee shall immediately notify the final delivery carrier and the Agency by telephone and telegram, mailgram, or facsimile, when:

   i. Removable radioactive surface contamination exceeds the limits of T.87(i) of these regulations; or

   ii. External radiation levels and surface temperatures exceed the limits of T.87(j) and (k) of these regulations.

e. Each licensee shall:

   i. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

   ii. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

f. 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 D.906b., but are not exempt from the monitoring requirement in D.906b. for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

Sec. D.1001 General Requirement. No licensee shall dispose of any radioactive material except:

a. By transfer to an authorized recipient as provided in D.1007 and C.40 of these regulations, or

b. As authorized pursuant to D.301, D.302, D.1002, D.1003, D.1005, or D.1006.

c. Notwithstanding the provisions of D.1001a and b, the Agency may prohibit by rule, regulation or order any transfer or disposal of radioactive material.

d. For materials that will be managed as biomedical waste after they have been released from the licensee, a licensee must remove or obliterate all radiation labels, except for radiation labels on materials that are within containers, before release from the licensee's control.

Sec. D.1002 Method of Obtaining Approval of Proposed Disposal Procedures.

Any person may apply to the Agency for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this Part. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application, where appropriate, should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

Sec. D.1003 Disposal by Release into Sanitary Sewerage.

a. No licensee shall discharge licensed material into sanitary sewerage unless each of the following conditions is satisfied.

   i. The material is readily soluble, or is a readily dispersible biological material, in water; and

   ii. The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 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 B; and

   iii. If more than one radionuclide is released, the following conditions must also be satisfied.

      (1) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

      (2) The sum of the fractions for each radionuclide required by D.1002a.iii.(1) does not exceed unity; and

   iv. The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage 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.

b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in D.1003a.

Sec. D.1004 RESERVED.

Sec. D.1005 Treatment or Disposal by Incineration. No licensee shall treat or dispose of licensed material by incineration except for materials listed under Sec. D.1006 or as specifically approved by the Agency pursuant to Sec. D.1002.

Sec. D.1006 Disposal of Specific Wastes.

a. Any licensee may dispose of the following radioactive material without regard to its radioactivity:

   i. 0.05 microcurie (1.85 kBq) or less of hydrogen-3, or carbon-14 per gram of medium used for liquid scintillation counting, and

   ii. 0.05 microcurie (1.85 kBq) or less of hydrogen-3, or carbon-14 per gram of animal tissue averaged over the weight of the entire animal; provided, however, tissue may not be disposed of under D.1006 in a manner that would permit its use either as food for humans or as animal feed.

b. Nothing in D.1006(a), however, relieves the licensee of maintaining records showing the receipt, transfer and disposal of such radioactive material as specified in A.4 of these regulations.

c. Nothing in D.1006(a) relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.

Sec. D.1007 Transfer for Disposal and Manifests.

a. The requirements of D.1007 are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

b. The above requirements shall be conducted in accordance with the requirements in Appendix D and E to this Part.

c. Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2 intended for ultimate disposal at a land disposal facility licensed under NRC regulation 10 CFR Part 61 must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G of 10 CFR Part 20.

Sec. D.1008 Compliance with Environmental and Health Protection Regulations.

Nothing in Part D 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 Part D.

Sec. D.1009 Disposal of Certain Byproduct Material.

a. Licensed material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2 may be disposed of in accordance with NRC's 10 CFR Part 61, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under NRC's 10 CFR Part 61, must meet the requirements of Section D.1007.

b. A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2, at a disposal facility authorized to dispose of such 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.

RECORDS

Sec. D.1101 General Provisions.

a. Each licensee or registrant shall use the units curie, disintegrations per minute, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part D.

b. In the records required by this Part, the licensee or registrant may record quantities in SI units in parentheses following each of the units specified in D.1101(a).

c. Notwithstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in Section D.1007, information must be recorded in the International System of Units (SI) or in SI and units as specified in D.1101(a).

d. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

Sec. D.1102 Records of Radiation Protection Programs.

a. Each licensee or registrant shall maintain records of the radiation protection program, including:

   i. The provisions of the program; and

   ii. Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by D.1102a.i. until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by D.1102a.ii. for 3 years after the record is made.

Sec. D.1103 Records of Surveys.

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by D.501 and D.906b. The licensee or registrant shall retain these records for 3 years after the record is made.

b. The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

   i. 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; and

   ii. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

   iii. Records showing the results of air sampling, surveys, and bioassays required pursuant to D.703(c)(i) and (ii); and

   iv. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

Sec. D.1104 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by D.401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency or until the sealed source is transferred or disposed.

Sec. D.1105 Records of Prior Occupational Dose.

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in D.205 on Agency Form MDE 217 or equivalent until the Agency terminates each pertinent license or registration requiring this record or for such time as the Agency shall determine.

b. The licensee or registrant shall retain records used in preparing Agency Form MDE 217 or equivalent for 3 years after the record is made or for such time as the Agency shall determine.

Sec. D.1106 Records of Planned Special Exposures.

a. For each use of the provisions of D.206 for planned special exposures, the licensee or registrant shall maintain records that describe:

   i. The exceptional circumstances requiring the use of a planned special exposure; and

   ii. The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

   iii. What actions were necessary; and

   iv. Why the actions were necessary; and

   v. What precautions were taken to assure that doses were maintained ALARA; and

   vi. What individual and collective doses were expected to result; and

   vii. The doses actually received in the planned special exposure.

   viii. The written permission received from the Agency under D.206a.

b. The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

Sec. D.1107 Records of Individual Monitoring Results.

a. Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to D.502, 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 9, 1995 need not be changed. These records shall include, when applicable:

   i. 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

ii. The estimated intake of radionuclides (see D.202); and

iii. The committed effective dose equivalent assigned to the intake of radionuclides; and

iv. The specific information used to assess the committed effective dose equivalent pursuant to D.204c.; and

v. The total effective dose equivalent when required by D.202; and

vi. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

b. Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in D.1107a. at intervals not to exceed 1 year.

c. Recordkeeping Format. The licensee or registrant shall maintain the records specified in D.1107a. on Agency Form 217, in accordance with the instructions for Agency Form 217, or in clear and legible records containing all the information required by Agency Form 217.

d. The licensee or registrant shall 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, shall also be kept on file, but may be maintained separately from the dose records.

e. The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record, or for such time as the Agency shall determine.

Sec. D.1108 Records of Dose to Individual Members of the Public.

a. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See D.301.

b. The licensee shall retain the records required by D.1108a. until the Agency terminates each pertinent license or registration requiring the record, or for such time as the Agency shall determine.

Sec. D.1109 Records of Waste Disposal.

a. Each licensee shall maintain records of the disposal of licensed materials made pursuant to D.1002, D.1003, D.1004 or D.1005 of these regulations, and disposal by burial in soil, including burials authorized before September 21, 1986.

b. The licensee shall retain the records required by D.1109 until the Department terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in §C.38 for activities licensed under this part.

Sec. D.1110 Records of Testing Entry Control Devices for Very High Radiation Areas.

a. Each licensee or registrant shall maintain records of tests made pursuant to D.602 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records required by D.1110a. for 3 years after the record is made or for such time as the Agency shall determine.

Sec. D.1111 Form of Records.

Each record required by Part D shall be legible throughout the specified retention period. The record shall 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 or 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, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

Sec. D.1201 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

a. Immediate Report.
   i. Each licensee or registrant shall report by telephone immediately and in writing within 24 hours to the Agency the theft or loss of any source of radiation immediately after such occurrence becomes known.
   ii. All other licensees shall make reports by telephone to the Agency at 410-537-3300 or 800-633-6101 ext. 3300.

b. Following Report. Each licensee or registrant required to make a report pursuant to D.1201a. shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

   i. 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; and

   ii. A description of the circumstances under which the loss or theft occurred; and

iii. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

iv. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

v. Actions that have been taken, or will be taken, to recover the source of radiation; and

vi. 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.

c. Subsequent to filing the written report required in D.1201(b), the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the Agency pursuant to D.1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

Sec. D.1202 Notification of Incidents.

a. Immediate Notification. In addition to other requirements for notification, each licensee or registrant shall immediately report by telephone 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:

i. An individual to receive:

(1) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(2) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(3) A shallow dose equivalent to the skin or extremities 2.5 Gy (250 rad) or more; or

ii. 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 ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

iii. All other licensees shall make the reports required by section a (i) and (ii) of this section and twenty-four hour notification by telephone to the Agency as specified in D.1201(a)(ii).

b. Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency in writing by telegram, mailgram or facsimile, 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:

i. An individual to receive, in a period of 24 hours:

(1) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(2) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

(3) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

ii. 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.

c. The licensee or registrant shall prepare each report filed with the Agency pursuant to D.1202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

d. The provisions of D.1202 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 to D.206a and D.1204.

Sec. D.1203 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

a. Reportable Events. In addition to the notification required by D.1202, each licensee or registrant shall submit a written report to the Agency within 30 days after learning of any of the following occurrences:

i. Incidents for which notification is required by D.1202; or

ii. Doses in excess of any of the following:

(1) The occupational dose limits for adults in D.201; or

(2) The occupational dose limits for a minor in D.207; or

(3) The limits for an embryo/fetus of a declared pregnant woman in D.208; or

(4) The limits for an individual member of the public in D.301; or

(5) Any applicable limit in the license or registration; or

(6) The ALARA constraints for air emissions established under D.101(d); or

iii. Levels of radiation or concentrations of radioactive material in a restricted or unrestricted area in excess of the applicable limits set forth in any license or registration condition.

b. Contents of Reports.

i. Each report required by D.1203a. shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(1) Estimates of each individual's dose; and

(2) The levels of radiation and concentrations of radioactive material involved; and

(3) The cause of the elevated exposures, dose rates, or concentrations; and

(4) 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.

ii. Each report filed pursuant to D.1203a. shall 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 D.208, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

Sec. D.1204 Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with D.206, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Sec. D.1106.

Sec D.1205 Reports to Individuals of Exceeding Dose Limits.

When a licensee or registrant is required pursuant to D.1203 to report to the Agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to the Agency to the individual. This report shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of J.13a. of these regulations.

Sec. D.1206 Reports of Leaking or Contaminated Sealed Sources.

If the test for leakage or contamination required pursuant to D.401 indicates a sealed source is leaking or contaminated, a written report of the test shall be filed within 5 days with the Agency describing the equipment involved, the test results and the corrective action taken.

Sec. D.1207 Annual Reports from General Licensees.

a. A licensee granted a general license under Section C.22(e), (g), (i), or (j) shall report annually, the following information on a form provided by the Agency:

   i. The amount and kind of radioactive material received during the previous year;

   ii. The form of the radioactive material;

   iii. The amount possessed by the licensee at the time of the report; and

   iv. The pathways and amounts of radioactive material disposed of by that person during the previous year.

b. The information required by D.1207a.iv. shall be estimated using a technique that is acceptable to the Department.

c. The report required by D.1207a. shall cover the calendar year from January 1 to December 31 and shall be forwarded to the Department not later than March 1 of the following year.

Sec. D.1208 Report and Notification of a Misadministration.

a. Licensees and registrants shall establish appropriate procedures, through compliance with the written directive, to prevent the occurrence of a misadministration.

b. A licensee or registrant shall report any misadministration in which the administration of byproduct material, or radiation from byproduct material or a radiation machine, except for an event that results from patient intervention, results in:

   i. A dose from byproduct material that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

      (1) The total dose delivered differs from the prescribed dose by 20 percent or more;

      (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

      (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

   ii. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

      (1) An administration of a wrong radioactive drug containing byproduct material;

      (2) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

      (3) An administration of a byproduct material dose or dosage to the wrong individual or human research subject;

      (4) An administration of a byproduct material dose or dosage delivered by the wrong mode of treatment; or

      (5) A leaking sealed source.

iii. A byproduct material dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent 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).

iv. For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(1) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(2) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(3) An administration that includes any of the following:
(a) The wrong radionuclide;
(b) The wrong individual or human research subject;
(c) Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or
(d) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

v. A radiation therapy dose or dose from a radiation machine:

(1) Involving the wrong individual, wrong mode of treatment, or wrong treatment site, or of a type other than the one intended; or

(2) When the treatment consists of three or fewer fractions, a difference of the calculated total administered dose from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(3) A calculated weekly administered dose that is 30 percent greater than the weekly prescribed dose; or

(4) A calculated total administered dose that differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

c. The licensee or registrant shall notify by telephone the Agency no later than the next calendar day after discovery of the misadministration.

d. The licensee or registrant shall submit a written report to the Agency within 15 days after discovery of the misadministration.

i. The written report must include:

(1) The licensee's or registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

(5) The effect, if any, on the individual(s) who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) A certification signed by the appropriate authorized user or registrant that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if +not, why not.

ii. The report may not contain the individual's name or any other information that could lead to identification of the individual.

e. The licensee or registrant shall 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 or registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or 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 licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or 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 this paragraph, 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 or registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee or registrant upon request. The licensee or registrant shall provide such a written description if requested.

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f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees, registrants or physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

g. A licensee or registrant shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the individual who is the subject of the misadministration; and

(2) Identification number or, if no other identification number is available, the social security number of the individual who is the subject of the event; and

ii. Provide the appended report in Sec. D.1208g.i. to the referring physician, if other than the licensee or registrant, no later than 15 days after the discovery of the misadministration.

h. Each licensee or registrant shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), identification number or if no other identification number is available, the social security number of the individual, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

Sec. D.1209 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

a. The licensee shall notify by telephone the Agency, the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in G.204(a) at the time of generator elution. The telephone report to the Agency must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

b. By an appropriate method listed in 10 CFR § 30.6(a), the licensee shall submit a written report to the Agency listed in 10 CFR § 30.6 within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution; and to Agency, to the address listed in Section A.12. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by D.1209(a).

Sec. D.1210 Report and Notification of a Dose to an Embryo/fetus or a Nursing Child.

a. A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) 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.

b. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(i). Is greater than 5 rem (50 mSv) total effective dose equivalent; or

(ii). Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210(a) or (b).

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210(a) or (b).

(i). The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

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(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) 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.

(ii) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the misadministration 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 a misadministration that would require reporting under D.1210(a) or (b), unless the referring physician personally informs the licensee either that he or she 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 shall 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 misadministration, because of any delay in notification. To meet the requirements of D.1210(e), 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 shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

(i). Append to a copy of the report provided to the Agency the:

(1) Name of the pregnant individual or the nursing child who is the subject of the misadministration; and

(2) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

(ii). Provide the appended report in D.1210f(i) to the referring physician, if other than the licensee, no later than 15 days after the discovery of the misadministration.

Sec. D.1211 Additional Reporting Requirements for Radioactive Materials.

a. Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 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 release of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four-hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

i. An unplanned contamination event that:

(1) 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;

(2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

(3) 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.

ii. An event in which equipment is disabled or fails to function as designed when:

(1) 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;

(2) The equipment is required to be available and operable when it is disabled or fails to function; and

(3) No redundant equipment is available and operable to perform the required safety function.

iii. 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.

iv. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

(2) The damage affects the integrity of the licensed material or its container.

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

i. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(1) The caller's name and call back number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

ii. Written report. Each licensee who makes a report required by paragraph a. or b. of this section shall 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 reports must be sent to the Agency. The reports must include the following:

(1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of event;

(5) Corrective actions taken or planned and the results of any evaluations or assessments; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

d. Each specific licensee shall notify the Agency 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:

i. The licensee;

ii. 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

iii. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

e. The notification specified in D.1211d. shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

f. A specific licensee shall notify the Agency in writing of the possession of a device containing a sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, that has not been used for a period longer than 3 years.

Sec. D.1220 Notification of Failure To Comply or Existence of a Defect and Its Evaluation.

a. Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to--

i. Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(ii) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected;

ii. Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Department through a director or responsible officer or designated person as discussed in Sec. D.1220(d)(v). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply; and

iii. Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in Sec. D.1220(a)(i) or Sec. D.1220(a)(ii) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity--

(1) Fails to comply with COMAR 26.12.01.01 Regulations for the Control of Ionizing Radiation (1994), or any applicable rule, order, or license of the Department relating to a substantial safety hazard, or

(2) Contains a defect.

b. If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to Sec. D.1220(a).

c. A dedicating entity is responsible for--

i. Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

ii. Maintaining auditable records for the dedication process.

d. i. A director or responsible officer subject to the regulations of this part or a person designated under Sec. D.1220(d)(v) must notify the Department when he or she obtains information reasonably indicating a failure to comply or a defect affecting--

(1) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Part C of these regulations, or the equivalent regulations of the NRC or another Agreement State, and that is within his or her organization's responsibility; or

(2) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Part C of these regulations, or the equivalent regulations of the NRC or another Agreement State.

ii. The notification to the Department of a failure to comply or of a defect under paragraph (d)(i) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(i) and (a)(ii) of this section, are not required if the director or responsible officer has actual knowledge that the Department has been notified in writing of the defect or the failure to comply.

iii. Notification required by paragraph (d)(i) of this section must be made as follows--

(1) Initial notification by facsimile, which is the preferred method of notification, to the Department at (410) 537-3198 or by telephone at (410) 537-3300 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(i) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the Department. This paragraph does not apply to interim reports described in Sec. D.1220(a)(ii).

(2) Written notification to the Department at the address specified in Sec. A.12 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(iii) of this section, on the identification of a defect or a failure to comply.

iv. The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(1) Name and address of the individual or individuals informing the Department.

(2) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(3) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(4) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(5) The date on which the information of such defect or failure to comply was obtained.

(6) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.

(7) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(8) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

v. The director or responsible officer may authorize an individual to provide the notification required by this paragraph. However, such authorization does not relieve the director or responsible officer of his or her responsibility under this paragraph.

e. Individuals subject to this part may be required by the Department to supply additional information related to a defect or failure to comply. Department action to obtain additional information may be based on reports of defects from other reporting entities.

ADDITIONAL REQUIREMENTS

Sec. D.1301 Vacating Premises. (See also C.32, "Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas")

Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises or other authorized use location which may have been contaminated with radioactive material as a result of his activities, notify in writing of intent to vacate and submit a written decontamination survey to the Agency. Records required by COMAR 26.12.01.01C.38 shall be forwarded to the Agency. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

Sec. D.1401 General Provisions and Scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under Part C of this regulation, as well as other facilities subject to the Department's jurisdiction. For low- level waste disposal facilities (COMAR 26.13.05 through .10), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(b) The criteria in this subpart do not apply to sites which:

(1) Have been decommissioned prior to the effective date of this regulation in accordance with criteria identified in the Site Decommissioning Management Plan (SDMP) Action Plan of April 16, 1992 (57 FR 13389);

(2) Have previously submitted and received Agency approval on a license termination plan (LTP) or decommissioning plan that is compatible with the SDMP Action Plan criteria; or

(3) Submit a sufficient LTP or decommissioning plan prior to the [effective date of this regulation] and such LTP or decommissioning plan is approved by the Department before March 1, 2001 and in accordance with the criteria identified in the SDMP Action Plan, except that if an EIS is required in the submittal, there will be a provision for day-for-day extension.

(c) After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the Department will require additional cleanup only if, based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(d) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

Sec. D.1402 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 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.

Sec. D.1403 Criteria for License Termination Under Restricted Conditions. A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of C.1402 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;

(b) 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 25 mrem (0.25 mSv) per year;

(c) 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--

(1) Funds placed into a trust 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 1 percent real rate of return on investment;

(2) A statement of intent in the case of Federal, State, or local Government licensees, as described in Sec. C.29(e)(4) of this chapter; or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with Sec.C.32 and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or 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.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning--

(i) 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 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.

(ii) 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;

(2) In seeking advice on the issues identified in Sec. 20.1403(d)(1), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning. The scope of participation and persons representing community interests must be pre-approved by the Agency;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) 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

(e) 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--

(1) 100 mrem (1 mSv) per year; or

(2) 500 mrem (5 mSv) per year provided the licensee--

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of paragraph (e)(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) 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 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of Sec. D.1403(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in paragraph (c) of this section.

Sec. D.1404 Alternate Criteria for License Termination.

(a) The Department may terminate a license using alternate criteria greater than the dose criterion of D.1402 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 subpart D, 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 D.1403 in minimizing exposures at the site;

(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 or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with Sec. C.32(c) of this chapter, specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP 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 shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning. The scope of participation and persons representing community interests must be pre-approved by the Agency;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented;

(iii) 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) 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.

(b) The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Agency staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to Sec. D.1405.

Sec. D.1405 Public Notification and Public Participation.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Sec. D.1404, D.1403 or whenever the Department deems such notice to be in the public interest, the Department shall:

(a) Notify and solicit comments from:

(1) 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

(2) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to Sec. D.1404.

(b) Publish a notice in the Maryland Register and in a forum, such as local newspapers, letters to State or local organizations, posting of the site or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

Sec. D.1406 Minimization of Contamination.

Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with existing radiation protection requirements in D.101 and radiological criteria for license termination in D.1401 through D.1406.

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PART D		
APPENDIX A		
ASSIGNED PROTECTION FACTORS FOR RESPIRATORS[a]		
	Operating Mode	**Assigned Protection Factors**
I. Air Purifying Respirators [Particulate[b] only][c]:		
Filtering faceplate 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 vapors[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	(1) Assigned protection factor for type and mode of operation as listed above.	

See next page for footnotes.

FOOTNOTES

[a] These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Part. 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 Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to Section D 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 percent efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97 percent efficient.

[c] The licensee may apply to the Agency 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 Sections D.701 through D.705 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 (e.g., 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 percent efficient and all other requirements of this Part 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 (i.e., Section D.701 through D.705).

[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 shall 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.

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PART D

APPENDIX 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. 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 D.3. 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.

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 non-stochastic 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, Σ (intake (in μCi) of each radionuclide/ALI_{ns}) ≤ 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 ≤ 1.0.

> 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.

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:

$$DAC = ALI(\text{in } \mu Ci)/(2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \times 2 \times 10^4 \text{ ml per minute}) = [ALI/2.4 \times 10^9] \ \mu Ci/ml,$$

where 2×10^4 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 D.202. 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 D.302. 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 0.50 mSv (0.05 rem).

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 they were in Appendix A of Part D of the eighth edition of Volume I of the Suggested State Regulations for Control of Radiation.

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 2.4×10^9, 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 compo-

nents: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 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, that is, 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 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 D.1003. 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 rem.

LIST OF ELEMENTS

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Actinium	Ac	89	Molybdenum	Mo	42
Aluminum	Al	13	Neodymium	Nd	60
Americium	Am	95	Neptunium	Np	93
Antimony	Sb	51	Nickel	Ni	28
Argon	Ar	18	Niobium	Nb	41
Arsenic	As	33	Nitrogen	N	7
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Oxygen	O	8
Berkelium	Bk	97	Palladium	Pd	46
Beryllium	Be	4	Phosphorus	P	15
Bismuth	Bi	83	Platinum	Pt	78
Bromine	Br	35	Plutonium	Pu	94
Cadmium	Cd	48	Polonium	Po	84
Calcium	Ca	20	Potassium	K	19
Californium	Cf	98	Praseodymium	Pr	59
Carbon	C	6	Promethium	Pm	61
Cerium	Ce	58	Protactinium	Pa	91
Cesium	Cs	55	Radium	Ra	88
Chlorine	Cl	17	Radon	Rn	86
Chromium	Cr	24	Rhenium	Re	75
Cobalt	Co	27	Rhodium	Rh	45
Copper	Cu	29	Rubidium	Rb	37
Curium	Cm	96	Ruthenium	Ru	44
Dysprosium	Dy	66	Samarium	Sm	62
Einsteinium	Es	99	Scandium	Sc	21
Erbium	Er	68	Selenium	Se	34
Europium	Eu	63	Silicon	Si	14
Fermium	Fm	100	Silver	Ag	47
Fluorine	F	9	Sodium	Na	11
Francium	Fr	87	Strontium	Sr	38
Gadolinium	Gd	64	Sulfur	S	16
Gallium	Ga	31	Tantalum	Ta	73
Germanium	Ge	32	Technetium	Tc	43
Gold	Au	79	Tellurium	Te	52
Hafnium	Hf	72	Terbium	Tb	65
Holmium	Ho	67	Thallium	Tl	81
Hydrogen	H	1	Thorium	Th	90
Indium	In	49	Thulium	Tm	69
Iodine	I	53	Tin	Sn	50
Iridium	Ir	77	Titanium	Ti	22
Iron	Fe	26	Tungsten	W	74
Krypton	Kr	36	Uranium	U	92
Lanthanum	La	57	Vanadium	V	23
Lead	Pb	82	Xenon	Xe	54
Lutetium	Lu	71	Ytterbium	Yb	70
Magnesium	Mg	12	Yttrium	Y	39
Manganese	Mn	25	Zinc	Zn	30
Mendelevium	Md	101	Zirconium	Zr	40
Mercury	Hg	80			

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases 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, Ti, 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
		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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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
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	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			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 (9E+4)	Bone surf (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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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	-	-
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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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
		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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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	-	-
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 St wall	2E+5	9E-6	3E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			(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
3	4Selenium-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	-	-
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,

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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
		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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation DAC (μCi)	Table I Occupational Values Col. 3 Inhalation Air (μCi/ml)	Table II Effluent Concentrations Col. 1 ALI (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
			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	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
38	Strontium-80[2]	D, all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and SrTi0	-	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	2E+1	8E-9	-	-	-
			Bone surf (4E+1)	Bone surf (2E+1)	-	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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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	-	-
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	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			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	-	-
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-89m[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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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
		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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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
		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	-	E+1	2E-8	8E-11	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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	-	-
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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases 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 (4E+1)	Kidneys (4E+0)	-	5E-12	5E-7	5E-6
		W, see ^{104}Cd	-	8E+0	4E-9	-	-	-
			-	Kidneys (1E+1)	-	2E-11	-	-
		Y, see ^{104}Cd	-	1E+1	5E-9	2E-11	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
48	Cadmium-113	D, see ^{104}Cd	2E+1	2E+0	9E-10	-	-	-
			Kidneys (3E+1)	Kidneys (3E+0)	-	5E-12	4E-7	4E-6
		W, see ^{104}Cd	-	8E+0	3E-9	-	-	-
			-	Kidneys (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	2E-8	-	4E-6	4E-5
			-	Kidneys (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	1E+3	6E-7	2E-9	-	-
			LLI wall (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	6E+1	3E-8	9E-11	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		W, see ^{109}In	-	1E+2	4E-8	1E-10	-	-
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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	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	1E+3	5E-7	2E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-117m	D, see ^{110}Sn	2E+3	1E+3	5E-7	-	-	-
			LLI wall (2E+3)	Bone surf (2E+3)	-	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	2E+3	1E-6	3E-9	-	-
			LLI wall (4E+3)	-	-	-	6E-5	6E-4
		W, see ^{110}Sn	-	1E+3	4E-7	1E-9	-	-
50	Tin-121m	D, see ^{110}Sn	3E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-121	D, see ^{110}Sn	6E+3	2E+4	6E-6	2E-8	-	-
			LLI wall (6E+3)	-	-	-	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	6E+2	3E-7	9E-10	-	-
			LLI wall (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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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
		W, see ^{115}Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m[2]	D, see ^{115}Sb	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	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	2E+3	9E-7	3E-9	-	-
			LLI wall (8E+2)	-	-	-	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	4E+5	2E-4	5E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			(1E+5)	-	-	-	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	- Bone surf -	4E+2 (1E+3)	2E-7 -	- 2E-9	- -	- -
52	Tellurium-125m	D, see ^{116}Te	1E+3 Bone surf (1E+3)	4E+2 Bone surf (1E+3)	2E-7 -	- 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 Bone surf (4E+2)	1E-7 -	- 6E-10	9E-6 -	9E-5 -
		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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
52	Tellurium-131m	D, see ^{116}Te	3E+2 Thyroid (6E+2)	4E+2 Thyroid (1E+3)	2E-7 -	- 2E-9	- 8E-6	- 8E-5
		W, see ^{116}Te	- -	4E+2 Thyroid (9E+2)	2E-7 -	- 1E-9	- -	- -
52	Tellurium-131[2]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- 8E-5	- 8E-4
		W, see ^{116}Te	- -	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- -	- -
52	Tellurium-132	D, see ^{116}Te	2E+2 Thyroid (7E+2)	2E+2 Thyroid (8E+2)	9E-8 -	- 1E-9	- 9E-6	- 9E-5
		W, see ^{116}Te	- -	2E+2 Thyroid (6E+2)	9E-8 -	- 9E-10	- -	- -
52	Tellurium-133m[2]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- 9E-5	- 9E-4
		W, see ^{116}Te	- -	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- -	- -
52	Tellurium-133[2]	D, see ^{116}Te	1E+4 Thyroid (3E+4)	2E+4 Thyroid (6E+4)	9E-6 -	- 8E-8	- 4E-4	- 4E-3
		W, see ^{116}Te	- -	2E+4 Thyroid (6E+4)	9E-6 -	- 8E-8	- -	- -
52	Tellurium-134[2]	D, see ^{116}Te	2E+4 Thyroid (2E+4)	2E+4 Thyroid (5E+4)	1E-5 -	- 7E-8	- 3E-4	- 3E-3
		W, see ^{116}Te	- -	2E+4 Thyroid (5E+4)	1E-5 -	- 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	6E+1 Thyroid	3E-8	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			(1E+2)	(2E+2)	-	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 Thyroid (3E+4)	5E+4 -	2E-5 -	6E-8 -	- 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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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	1E+5	6E-5	2E-7	-	-
			St wall (9E+4)	-	-	-	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	2E+5	8E-5	3E-7	-	-
			St wall (1E+5)	-	-	-	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	1E+5	6E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	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
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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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 Liver	3E-8	-	2E-4	2E-3
			-	(7E+1)	-	1E-10	-	-
		W, see ^{131}La	-	3E+2 Liver	1E-7	-	-	-
			-	(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	-	-
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	-	-
			(4E+4) St wall	-	-	-	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	-	-
			(6E+2) LLI wall	-	-	-	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	-	-
			(2E+3) LLI wall	-	-	-	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	-	-
			(2E+3) LLI wall	-	-	-	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	-	-
			(1E+3) LLI wall	-	-	-	2E-5	2E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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	-	-
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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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, 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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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 (1E+4)	Bone surf (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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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	8E-3	3E-12	-	-	-
			Bone surf (2E+1)	Bone surf (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	1E-2	4E-12	-	-	-
			Bone surf (3E+1)	Bone surf (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	3E+2	1E-7	-	-	-
			LLI wall (5E+4)	Bone surf (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	2E+3	7E-7	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI DAC (μCi)	Table I Occupational Values Col. 3 Inhalation ALI Air (μCi/ml)	Table II Effluent Concentrations Col. 1 (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
			LLI wall (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 (E+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

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 LLI wall	2E+3	8E-7	3E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			(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	-	-
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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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	-	-
72	Hafnium-172	D, see ^{170}Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
			-	Bone surf (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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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	8E-1	3E-10	-	-	-
			Bone surf (4E+2)	Bone surf (2E+0)	-	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	-	-
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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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-182m2	W, see ^{172}Ta	2E+5	5E+5	2E-4	8E-7	-	-
			St wall (2E+5)	-	-	-	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	1E+3	5E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	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	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	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
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	-	-
		W, oxides, hydroxides,	St wall (1E+5)	-	-	-	2E-3	2E-2

		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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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 St wall (2E+3)	2E+3 St wall (2E+3)	7E-7 -	- 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 St wall (9E+5)	4E-4 -	- 1E-6	8E-3 -	8E-2 -
		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	-	-
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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			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
		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+2	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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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
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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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
		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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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
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	6E1	2E1	1E-10	-	-	-
			Bone surf (1E+0)	Bone surf (4E-1)	-	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	3E+1	1E-8	5E-11	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation DAC (μCi)	Table I Occupational Values Col. 3 Inhalation Air (μCi/ml)	Table II Effluent Concentrations Col. 1 (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
			Bone surf (1E+2)	-	-	-	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	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, all other compounds	-	1E+5	4E-5	1E-7	-	-
83	Bismuth-201[2]	D, see ^{200}Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{200}Bi	-	4E+4	2E-5	5E-8	-	-
83	Bismuth-202[2]	D, see ^{200}Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{200}Bi	-	8E+4	3E-5	1E-7	-	-
83	Bismuth-203	D, see ^{200}Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
		W, see ^{200}Bi	-	6E+3	3E-6	9E-9	-	-
83	Bismuth-205	D, see ^{200}Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{200}Bi	-	1E+3	5E-7	2E-9	-	-
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	5E+0	2E-9	-	-	-
			Kidneys (6E+1)	Kidneys (6E+0)	-	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	1E-7	-	1E-5	1E-4
			-	Kidneys (4E+2)	-	5E-10	-	-
		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	8E+2	3E-7	1E-9	-	-
			St wall (2E+4)	-	-	-	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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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
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 Bone surf (9E+0)	7E-1 -	3E-10 -	9E-13 -	- 1E-7	- 1E-6
88	Radium-224	W, all compounds	8E+0 Bone surf (2E+1)	2E+0 -	7E-10 -	2E-12 -	- 2E-7	- 2E-6
88	Radium-225	W, all compounds	8E+0 Bone surf (2E+1)	7E-1 -	3E-10 -	9E-13 -	- 2E-7	- 2E-6
88	Radium-226	W, all compounds	2E+0 Bone surf (5E+0)	6E-1 -	3E-10 -	9E-13 -	- 6E-8	- 6E-7
88	Radium-227[2]	W, all compounds	2E+4 Bone surf (2E+4)	1E+4 Bone surf (2E+4)	6E-6 -	- 3E-8	- 3E-4	- 3E-3
88	Radium-228	W, all compounds	2E+0 Bone surf (4E+0)	1E+0 -	5E-10 -	2E-12 -	- 6E-8	- 6E-7
89	Actinium-224	D, all compounds except those given for W and Y	2E+3 LLI wall (2E+3)	3E+1 Bone surf (4E+1)	1E-8 -	- 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 LLI wall (5E+1)	3E-1 Bone surf (5E-1)	1E-10 -	- 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 LLI wall (1E+2)	3E+0 Bone surf (4E+0)	1E-9 -	- 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	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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 (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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
				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	-	-
91	Protactinium-231	W, see ^{227}Pa	2E-1	2E-3	6E-13	-	-	-
			Bone surf	Bone surf				
			(5E-1)	(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	Bone surf				
			(6E+0)	(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	Bone surf				
			(4E+0)	(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	Bone surf				
			(2E+1)	(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	Bone surf				
			(2E+1)	(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	Bone surf				
			(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-236	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	-	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	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	-	-
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	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (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	2E-2	9E-12	-	-	-
			Bone surf (6E+0)	Bone surf (5E-2)	-	8E-14	9E-8	9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3	3E+1	1E-8	-	-	-
			Bone surf (4E+3)	Bone surf (7E+1)	-	1E-10	5E-5	5E-4
93	Neptunium-237	W, all compounds	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (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	-	-
93	Neptunium-239	W, all compounds	2E+3	2E+3	9E-7	3E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation DAC (μCi)	Table I Occupational Values Col. 3 Inhalation Air ALI (μCi/ml)	Table II Effluent Concentrations Col. 1 (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
			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 (2E+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-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
		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	-	-
			LLI wall (4E+2)	-	-	-	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
			-	Bone surf (6E+3)	-	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	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242m	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (9E+1)	-	1E-10	-	-
95	Americium-243	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-244m[2]	W, all compounds	6E+4	4E+3	2E-6	-	-	-
			St wall (8E+4)	Bone surf (7E+3)	-	1E-8	1E-3	1E-2
95	Americium-244	W, all compounds	3E+3	2E+2	8E-8	-	4E-5	4E-4
			-	Bone surf (3E+2)	-	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	2E+5	8E-5	3E-7	-	-
			St wall (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	6E-1	2E-10	-	-	-
			Bone surf (8E+1)	Bone surf (6E-1)	-	9E-13	1E-6	1E-5
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	3E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	4E-13	7E-7	7E-6
96	Curium-243	W, all compounds	1E+0	9E-3	4E-12	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			Bone surf (2E+0)	Bone surf (2E-2)	-	2E-14	3E-8	3E-7
96	Curium-244	W, all compounds	1E+0	1E-2	5E-12	-	-	-
			Bone surf (3E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
96	Curium-245	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-246	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-247	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-248	W, all compounds	2E-1	2E-3	7E-13	-	-	-
			Bone surf (4E-1)	Bone surf (3E-3)	-	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	3E-4	1E-13	-	-	-
			Bone surf (6E-2)	Bone surf (5E-4)	-	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	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
97	Berkelium-249	W, all compounds	2E+2	2E+0	7E-10	-	-	-
			Bone surf (5E+2)	Bone surf (4E+0)	-	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	-	-
			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	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
			-	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
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

Atomic Radionuclide No.	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
- 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 radio-nuclide 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. (See D.203)

[3]For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see § D.201(e)). 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 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 > 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

Atomic Radionuclide No.	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)
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, 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

Atomic Number	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I 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 Releases to Sewers Monthly Average Concentration (μCi/ml)

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 Appendix B to Part D 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:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} < 1$$

PART D

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity µCi)*	Radionuclide	Quantity µCi)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-11	1,000	Manganese-51	1,000
Carbon-14	1,000	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62m	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100
Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Gallium-66	100	Krypton-81	1,000
Gallium-67	1,000	Krypton-83m	1,000
Gallium-68	1,000	Krypton-85m	1,000
Gallium-70	1,000	Krypton-85	1,000
Gallium-72	100	Krypton-87	1,000
Gallium-73	1,000	Krypton-88	1,000
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82m	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-92	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000
Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000		

* To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Niobium-88	1,000	Palladium-101	1,000
Niobium-89m (66 min)	1,000	Palladium-103	100
Niobium-89 (122 min)	1,000	Palladium-107	10
Niobium-90	100	Palladium-109	100
Niobium-93m	10	Silver-102	1,000
Niobium-94	1	Silver-103	1,000
Niobium-95m	100	Silver-104m	1,000
Niobium-95	100	Silver-104	1,000
Niobium-96	100	Silver-105	100
Niobium-97	1,000	Silver-106m	100
Niobium-98	1,000	Silver-106	1,000
Molybdenum-90	100	Silver-108m	1
Molybdenum-93m	100	Silver-11Om	10
Molybdenum-93	10	Silver-111	100
Molybdenum-99	100	Silver-112	100
Molybdenum-101	1,000	Silver-115	1,000
Technetium-93m	1,000	Cadmium-104	1,000
Technetium-93	1,000	Cadmium-107	1,000
Technetium-94m	1,000	Cadmium-109	1
Technetium-94	1,000	Cadmium-113m	0.1
Technetium-96m	1,000	Cadmium-113	100
Technetium-96	100	Cadmium-115m	10
Technetium-97m	100	Cadmium-115	100
Technetium-97	1,000	Cadmium-117m	1,000
Technetium-98	10	Cadmium-117	1,000
Technetium-99m	1,000	Indium-109	1,000
Technetium-99	100	Indium-110m (69.1m)	1,000
Technetium-101	1,000	Indium-11O (4.9h)	1,000
Technetium-104	1,000	Indium-111	100
Ruthenium-94	1,000	Indium-112	1,000
Ruthenium-97	1,000	Indium-113m	1,000
Ruthenium-103	100	Indium-114m	10
Ruthenium-105	1,000	Indium-115m	1,000
Ruthenium-106	1	Indium-115	100
Rhodium-99m	1,000	Indium-116m	1,000
Rhodium-99	100	Indium-117m	1,000
Rhodium-100	100	Indium-117	1,000
Rhodium-101m	1,000	Indium-119m	1,000
Rhodium-101	10	Tin-110	100
Rhodium-102m	10	Tin-111	1,000
Rhodium-102	10	Tin-113	100
Rhodium-103m	1,000	Tin-117m	100
Rhodium-105	100	Tin-119m	100
Rhodium-106m	1,000	Tin-121m	100
Rhodium-107	1,000	Tin-121	1,000
Palladium-100	100		

* To convert µCi to kBq, multiply the µCi value by 37

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Tin-123m	1,000	Tellurium-133	1,000
Tin-123	10	Tellurium-134	1,000
Tin-125	10	Iodine-120m	1,000
Tin-126	10	Iodine-120	100
Tin-127	1,000	Iodine-121	1,000
Tin-128	1,000	Iodine-123	100
Antimony-115	1,000	Iodine-124	10
Antimony-116m	1,000	Iodine-125	1
Antimony-116	1,000	Iodine-126	1
Antimony-117	1,000	Iodine-128	1,000
Antimony-118m	1,000	Iodine-129	1
Antimony-119	1,000	Iodine-130	10
Antimony-120		Iodine-131	1
(16m)	1,000	Iodine-132m	100
Antimony-120		Iodine-132	100
(5.76d)	100	Iodine-133	10
Antimony-122	100	Iodine-134	1,000
Antimony-124m	1,000	Iodine-135	100
Antimony-124	10	Xenon-120	1,000
Antimony-125	100	Xenon-121	1,000
Antimony-126m	1,000	Xenon-122	1,000
Antimony-126	100	Xenon-123	1,000
Antimony-127	100	Xenon-125	1,000
Antimony-128		Xenon-127	1,000
(10.4m)	1,000	Xenon-129m	1,000
Antimony-128		Xenon-131m	1,000
(9.O1h)	100	Xenon-133m	1,000
Antimony-129	100	Xenon-133	1,000
Antimony-130	1,000	Xenon-135m	1,000
Antimony-131	1,000	Xenon-135	1,000
Tellurium-116	1,000	Xenon-138	1,000
Tellurium-121m	10	Cesium-125	1,000
Tellurium-121	100	Cesium-127	1,000
Tellurium-123m	10	Cesium-129	1,000
Tellurium-123	100	Cesium-130	1,000
Tellurium-125m	10	Cesium-131	1,000
Tellurium-127m	10	Cesium-132	100
Tellurium-127	1,000	Cesium-134m	1,000
Tellurium-129m	10	Cesium-134	10
Tellurium-129	1,000	Cesium-135m	1,000
Tellurium-131m	10	Cesium-135	100
Tellurium-131	100	Cesium-136	10
Tellurium-132	10	Cesium-137	10
Tellurium-133m	100	Cesium-138	1,000

*To convert µCi to kBq, multiply the µCi value by 37

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-144	10
Barium-131	100	Promethium-145	10
Barium-133m	100	Promethium-146	1
Barium-133	100	Promethium-147	10
Barium-135m	100	Promethium-148m	10
Barium-139	1,000	Promethium-148	10
Barium-140	100	Promethium-149	100
Barium-141	1,000	Promethium-150	1,000
Barium-142	1,000	Promethium-151	100
Lanthanum-131	1,000	Samarium-141m	1,000
Lanthanum-132	100	Samarium-141	1,000
Lanthanum-135	1,000	Samarium-142	1,000
Lanthanum-137	10	Samarium-145	100
Lanthanum-138	100	Samarium-146	1
Lanthanum-140	100	Samarium-147	100
Lanthanum-141	100	Samarium-151	10
Lanthanum-142	1,000	Samarium-153	100
Lanthanum-143	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100
Cerium-143	100	Europium-150	
Cerium-144	1	(12.62h)	100
Praseodymium-136	1,000	Europium-150	
Praseodymium-137	1,000	(34.2y)	1
Praseodymium-138m	1,000	Europium-152m	100
Praseodymium-139	1,000	Europium-152	1
Praseodymium-142m	1,000	Europium-154	1
Praseodymium-142	100	Europium-155	10
Praseodymium-143	100	Europium-156	100
Praseodymium-144	1,000	Europium-157	100
Praseodymium-145	100	Europium-158	1,000
Praseodymium-147	1,000	Gadolinium-145	1,000
Neodymium-136	1,000	Gadolinium-146	10
Neodymium-138	100	Gadolinium-147	100
Neodymium-139m	1,000	Gadolinium-148	0.001
Neodymium-139	1,000	Gadolinium-149	100
Neodymium-141	1,000	Gadolinium-151	10
Neodymium-147	100	Gadolinium-152	100
Neodymium-149	1,000	Gadolinium-153	10
Neodymium-151	1,000	Gadolinium-159	100

* To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Terbium-147	1,000	Ytterbium-162	1,000
Terbium-149	100	Ytterbium-166	100
Terbium-150	1,000	Ytterbium-167	1,000
Terbium-151	100	Ytterbium-169	100
Terbium-153	1,000	Ytterbium-175	100
Terbium-154	100	Ytterbium-177	1,000
Terbium-155	1,000	Ytterbium-178	1,000
Terbium-156m		Lutetium-169	100
(5.Oh)	1,000	Lutetium-170	100
Terbium-156m		Lutetium-171	100
(24.4h)	1,000	Lutetium-172	100
Terbium-156	100	Lutetium-173	10
Terbium-157	10	Lutetium-174m	10
Terbium-158	1	Lutetium-174	10
Terbium-160	10	Lutetium-176m	1,000
Terbium-161	100	Lutetium-176	100
Dysprosium-155	1,000	Lutetium-177m	10
Dysprosium-157	1,000	Lutetium-177	100
Dysprosium-159	100	Lutetium-178m	1,000
Dysprosium-165	1,000	Lutetium-178	1,000
Dysprosium-166	100	Lutetium-179	1,000
Holmium-155	1,000	Hafnium-170	100
Holmium-157	1,000	Hafnium-172	1
Holmium-159	1,000	Hafnium-173	1,000
Holmium-161	1,000	Hafnium-175	100
Holmium-162m	1,000	Hafnium-177m	1,000
Holmium-162	1,000	Hafnium-178m	0.1
Holmium-164m	1,000	Hafnium-179m	10
Holmium-164	1,000	Hafnium-180m	1,000
Holmium-166m	1	Hafnium-181	10
Holmium-166	100	Hafnium-182m	1,000
Holmium-167	1,000	Hafnium-182	0.1
Erbium-161	1,000	Hafnium-183	1,000
Erbium-165	1,000	Hafnium-184	100
Erbium-169	100	Tantalum-172	1,000
Erbium-171	100	Tantalum-173	1,000
Erbium-172	100	Tantalum-174	1,000
Thulium-162	1,000	Tantalum-175	1,000
Thulium-166	100	Tantalum-176	100
Thulium-167	100	Tantalum-177	1,000
Thulium-170	10	Tantalum-178	1,000
Thulium-171	10	Tantalum-179	100
Thulium-172	100	Tantalum-180m	1,000
Thulium-173	100	Tantalum-180	100
Thulium-175	1,000	Tantalum-182m	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Tantalum-182	10	Iridium-188	100
Tantalum-183	100	Iridium-189	100
Tantalum-184	100	Iridium-190m	1,000
Tantalum-185	1,000	Iridium-190	100
Tantalum-186	1,000	Iridium-192m	
Tungsten-176	1,000	(1.4m)	1
Tungsten-177	1,000	Iridium-192	
Tungsten-178	1,000	(74.2d)	10
Tungsten-179	1,000	Iridium-194m	10
Tungsten-181	1,000	Iridium-194	100
Tungsten-185	100	Iridium-195m	1,000
Tungsten-187	100	Iridium-195	1,000
Tungsten-188	10	Platinum-186	1,000
Rhenium-177	1,000	Platinum-188	100
Rhenium-178	1,000	Platinum-189	1,000
Rhenium-181	1,000	Platinum-191	100
Rhenium-182		Platinum-193m	100
(12.7h)	1,000	Platinum-193	1,000
Rhenium-182		Platinum-195m	100
(64.Oh)	100	Platinum-197m	1,000
Rhenium-184m	10	Platinum-197	100
Rhenium-184	100	Platinum-199	1,000
Rhenium-186m	10	Platinum-200	100
Rhenium-186	100	Gold-193	1,000
Rhenium-187	1,000	Gold-194	100
Rhenium-188m	1,000	Gold-195	10
Rhenium-188	100	Gold-198m	100
Rhenium-189	100	Gold-198	100
Osmium-180	1,000	Gold-199	100
Osmium-181	1,000	Gold-200m	100
Osmium-182	100	Gold-200	1,000
Osmium-185	100	Gold-201	1,000
Osmium-189m	1,000	Mercury-193m	100
Osmium-191m	1,000	Mercury-193	1,000
Osmium-191	100	Mercury-194	1
Osmium-193	100	Mercury-195m	100
Osmium-194	1	Mercury-195	1,000
Iridium-182	1,000	Mercury-197m	100
Iridium-184	1,000	Mercury-197	1,000
Iridium-185	1,000	Mercury-199m	1,000
Iridium-186	100	Mercury-203	100
Iridium-187	1,000		

* To convert µCi to kBq, multiply the µCi value by 37

APPENDIX C

QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Thallium-194m	1,000	Francium-223	100
Thallium-194	1,000	Radium-223	0.1
Thallium-195	1,000	Radium-224	0.1
Thallium-197	1,000	Radium-225	0.1
Thallium-198m	1,000	Radium-226	0.1
Thallium-198	1,000	Radium-227	1,000
Thallium-199	1,000	Radium-228	0.1
Thallium-200	1,000	Actinium-224	1
Thallium-201	1,000	Actinium-225	0.01
Thallium-202	100	Actinium-226	0.1
Thallium-204	100	Actinium-227	0.001
Lead-195m	1,000	Actinium-228	1
Lead-198	1,000	Thorium-226	10
Lead-199	1,000	Thorium-227	0.01
Lead-200	100	Thorium-228	0.001
Lead-201	1,000	Thorium-229	0.001
Lead-202m	1,000	Thorium-230	0.001
Lead-202	10	Thorium-231	100
Lead-203	1,000	Thorium-232	100
Lead-205	100	Thorium-234	10
Lead-209	1,000	Thorium-natural	100
Lead-210	0.01	Protactinium-227	10
Lead-211	100	Protactinium-228	1
Lead-212	1	Protactinium-230	0.1
Lead-214	100	Protactinium-231	0.001
Bismuth-200	1,000	Protactinium-232	1
Bismuth-201	1,000	Protactinium-233	100
Bismuth-202	1,000	Protactinium-234	100
Bismuth-203	100	Uranium-230	0.01
Bismuth-205	100	Uranium-231	100
Bismuth-206	100	Uranium-232	0.001
Bismuth-207	10	Uranium-233	0.001
Bismuth-210m	0.1	Uranium-234	0.001
Bismuth-210	1	Uranium-235	0.001
Bismuth-212	10	Uranium-236	0.001
Bismuth-213	10	Uranium-237	100
Bismuth-214	100	Uranium-238	100
Polonium-203	1,000	Uranium-239	1,000
Polonium-205	1,000	Uranium-240	100
Polonium-207	1,000	Uranium-natural	100
Polonium-210	0.1	Neptunium-232	100
Astatine-207	100	Neptunium-233	1,000
Astatine-211	10	Neptunium-234	100
Radon-220	1	Neptunium-235	100
Radon-222	1	Neptunium-236	
Francium-222	100	(11.5y)	0.001

* To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX C
QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Neptunium-236 (22.5h)	1	Curium-242	0.01
Neptunium-237	0.001	Curium-243	0.001
Neptunium-238	10	Curium-244	0.001
Neptunium-239	100	Curium-245	0.001
Neptunium-240	1,000	Curium-246	0.001
Plutonium-234	10	Curium-247	0.001
Plutonium-235	1,000	Curium-248	0.001
Plutonium-236	0.001	Curium-249	1,000
Plutonium-237	100	Berkelium-245	100
Plutonium-238	0.001	Berkelium-246	100
Plutonium-239	0.001	Berkelium-247	0.001
Plutonium-240	0.001	Berkelium-249	0.1
Plutonium-241	0.01	Berkelium-250	10
Plutonium-242	0.001	Californium-244	100
Plutonium-243	1,000	Californium-246	1
Plutonium-244	0.001	Californium-248	0.01
Plutonium-245	100	Californium-249	0.001
Americium-237	1,000	Californium-250	0.001
Americium-238	100	Californium-251	0.001
Americium-239	1,000	Californium-252	0.001
Americium-240	100	Californium-253	0.1
Americium-241	0.001	Californium-254	0.001
Americium-242m	0.001	Einsteinium-250	100
Americium-242	10	Einsteinium-251	100
Americium-243	0.001	Einsteinium-253	0.1
Americium-244m	100	Einsteinium-254m	1
Americium-244	10	Einsteinium-254	0.01
Americium-245	1,000	Fermium-252	1
Americium-246m	1,000	Fermium-253	1
Americium-246	1,000	Fermium-254	10
Curium-238	100	Fermium-255	1
Curium-240	0.1	Fermium-257	0.01
Curium-241	1	Mendelevium-257	10
		Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

* To convert µCi to kBq, multiply the µCi value by 37.

NOTE: For purposes of D.902e., D.905a., and D.1201a. where there is involved a combination of radionuclides in known amounts, the limit for the combination shall 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.

[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 B to Part D, 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 E+9 years, except rhenium, 37 MBq (1,000 µCi), to take into account their low specific activity.

*To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX D

REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

For the purpose of Part D of these regulations, the requirements for transfer of low-level radioactive waste for disposal at land disposal facilities and manifests shall be as specified by Appendix G to 10 CFR Part 20 ("Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests").

APPENDIX E

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

For the purpose of Part D of these regulations, the classification and characteristics of low-level radioactive waste shall be as specified by COMAR 26.15 "Disposal of Controlled Hazardous Substances--Radioactive Hazardous Substances."

PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subpart A - General Provisions

Sec. E.1 Purpose. The regulations in this part establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations.

Sec. E.2 Scope. The regulations in this part apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for those regulations of this part clearly applicable only to sealed sources of radiation, both radiation machines and sealed sources of radiation are covered by this part.

Sec. E.3 Definitions.

"Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

"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 (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head).

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in D.301 of these regulations.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being radiated, provide radiation attenuation, and exclude personnel from its interior during generation of the 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. An 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.

"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 10 CFR 34 Appendix A or the equivalent regulations of an Agreement State.

"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 (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 to and from the exposure device.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

"Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched.

"Guide tube (Projection sheath)" means a flexible or rigid tube (i.e., "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.

"Independent certifying organization" means an independent organization that meets all of the criteria of 10 CFR 34 Appendix A or the equivalent regulations of an Agreement State.

"Industrial radiography (radiography)" means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

"Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

"Lixiscope" means a portable light intensified imaging device using a sealed source.

"Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

"Practical Examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

"Radiation Safety Officer (RSO)" for industrial radiography means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of Sec. E.42.

"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 for assuring compliance with the requirements of the Department's regulations and the conditions of the license.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses a radiation machine, radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device (also called a camera, or a 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 associated with the use of a radiation machine, or with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used 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, including those also used for transporting and storage of sealed sources.

"Storage area" means any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

"Storage container" means a container in which sealed sources are secured and stored.

"Underwater radiography" means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

Subpart B - Exemptions and Cabinet Radiography

Sec. E.4 Exemptions.

(a) Except for the requirements of E.5, certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part.

(b) Industrial uses of lixiscopes are exempt from the requirements of this part.

Sec. E.5 Special Requirements for Cabinet Radiography.

(a) Systems for cabinet radiography designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this part and D.301 of these regulations. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this part and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed 1 year to assure compliance with the applicable requirements of Part E. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation.

(b) Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part except that:

(1) Operating personnel must be provided with and required to wear either film badges or thermoluminescent dosimeters, and reports of the results of such monitoring shall be maintained for inspection by the Agency.

(2) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the Agency until disposition is authorized by the Agency.

(3) The registrant shall perform an evaluation, at intervals not to exceed 1 year, to determine conformance with D.301 of these regulations. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation.

(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Agency pursuant to Part A.3(a) of these regulations.

Subpart C - Equipment

Sec. E.20 Performance Requirements for Industrial Radiography Equipment Using Sealed Sources of Radiation.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) (1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone: (212) 642-4900.

(2) Notwithstanding the provisions of paragraph E.308(a)(1), engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography components. Upon review, the Agency may find this an acceptable alternative to actual testing of the component pursuant to the referenced standard.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the--

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model (or product code) and serial number of the sealed source;

(iv) Manufacturer's identity of the sealed source; and

(v) Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71.

(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.

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, 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) (i) 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."

(ii) 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 assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSIN432-1980.

(9) Source changers 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.

(d) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section.

(e) Notwithstanding paragraph (a)(1) of this section, equipment used in industrial radiographic operations need not comply with Sec. 8.9.2(c) of the Endurance Test in American National Standards Institute 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 realistically exert on the lever or crankshaft of the drive mechanism.

Sec. E.21 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 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

Sec. E.23 Locking of Radiation Machines, Radiographic Exposure Devices, Storage Containers and Source Changers.

(a) Each radiation machine and radiographic exposure device must have a lock to prevent unauthorized use, or have an outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The radiation machine or 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 Sec. E.51. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(b) 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 aradiographer's assistant.

Sec. E.25 Radiation Survey Instruments.

(a) The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where a radiation machine or radioactive material is present to make the radiation surveys required by this part and by Part D of this regulation. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 sievert (1 rem) per hour.

(b) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated--

(1) At intervals not to exceed 6 months and 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 millirems) per hour; and

(3) So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

(c) The licensee shall maintain records of the results of the instrument calibrations in accordance with Sec. E.65.

Sec. E.27 Leak Testing and Replacement of Sealed Sources.

(a) 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 Agency, the NRC or an Agreement State.

(b) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the NRC or an Agreement State.

(c) Testing and recordkeeping requirements.

(1) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Agency, the NRC or an 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 Bq (0.005 microcurie) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the NRC or an Agreement State to perform the analysis.

(2) The licensee shall maintain records of the leak tests in accordance with Sec. E.67.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 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 6 months.

(d) Any test conducted pursuant to paragraphs (b) and (c) of this section which reveals the presence of 185 Bq (0.005 microcurie) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Commission regulations. A report must be filed in accordance with D.1206.

(e) 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 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the NRC or an Agreement State to perform the analysis. Should such testing reveal the presence of 185 Bq (0.005 microcuries) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that 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 in storage and not in use. 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 Sec. E.67.

Sec. E.29 Quarterly Inventory.

(a) Each licensee shall conduct a quarterly physical inventory to account for all radiation machines, sealed sources and for devices containing depleted uranium received and possessed under this license.

(b) The licensee shall maintain records of the quarterly inventory in accordance with Sec. E.69.

Sec. E.31 Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) The licensee shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

(b) Each licensee shall have written procedures for:

(1) 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 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

(2) Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The 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.

(c) Records of equipment problems and of any maintenance performed under paragraphs (a) and (b) of this section must be made in accordance with Sec. E.73.

Sec. E.33 Permanent Radiographic Installations.

(a) 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 Sec. D.601 of these regulations that reduces the radiation level upon entry into the area, or

(2) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the radiation machine is on. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the radiation machine is on.

(b) 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 (designated in paragraph (a)(1) of this section) 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 7-day period, provided the licensee implements the continuous surveillance requirements of Sec. E.51 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarm must be maintained in accordance with Sec. E.75.

Sec. E.35 Labeling, Storage, and Transportation.

(a) The licensee may not use a source changer or a container to store licensed 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, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording

CAUTION[1]
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")

(b) The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part T of these regulations.

(c) Locked radiation machines, radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(d) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

[1] The Licensee may use the word “DANGER”

Subpart D - Radiation Safety Requirements

Sec. E.41 Conducting Industrial Radiographic Operations.

(a) 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 Sec. E.43(c). The additional qualified individual shall 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.

(b) All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the Agency.

(c) A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the NRC or by an Agreement State.

(d) Each licensee or registrant shall provide as a minimum two radiographic personnel when sealed sources of radiation are used at temporary jobsites. If one of the personnel is a radiographer assistant, the other person shall be a radiographer.

Sec. E.42 Radiation Safety Officer for Industrial Radiography.

The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(a) The minimum qualifications, training, and experience for RSOs for industrial radiography are as follows:

(1) Completion of the training and testing requirements of Sec. E.43(a);

(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 protection program.

(b) The Department will consider alternatives when the RSO has appropriate training and/or 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.

(c) The specific duties and authorities of the RSO include, but are not limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part D of this chapter, and reviewing them regularly to ensure that the procedures in use conform to current Part D procedures, conform to other Agency regulations and to the license conditions;

(2) Overseeing and approving all phases of the training program for radiographic personnel, ensuring 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 and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Sec. D.1203 of this chapter; and

(5) Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

(d) Licensees will have until May 28, 2000 to meet the requirements of paragraph (a) or (b) of this section.

Sec. E.43 Training.

(a) The licensee may not permit any individual to act as a radiographer until the individual--

(1) Has received training in the subjects in paragraph (g) of this section, in addition to a minimum of 2 months of on-the-job training, and is certified through a radiographer certification program by a certifying entity that has been approved by the NRC or an Agreement State (an independent organization that would like to be recognized as a certifying entity shall submit its request to the Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001), or

(2) The licensee may, until May 28, 2000, allow an individual who has not met the requirement of paragraph (a)(1) of this section, to act as a radiographer after the individual has received training in the subjects outlined in paragraph (g) of this section and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Department.

(b) In addition, the licensee may not permit any individual to act as a radiographer until the individual--

(1) Has received copies of and instruction in:

(a) The regulations governing industrial radiography contained in Part E of this chapter, or the equivalent regulations of an Agreement State or the NRC;

(b) The regulations governing radiation protection standards and notices, instructions, and reports to workers contained in Parts D and J of this chapter, or the equivalent regulations of the NRC or an Agreement State;

(c) Applicable DOT regulations as referenced in 10 CFR Part71;

(d) The Agency, NRC or Agreement State license(s) under which the radiographer will perform industrial radiography; and

(e) The licensee's operating and emergency procedures.

(2) Has demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material.

(3) Has received training in the use of 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.

(4) Has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described in paragraphs (b)(1) and (b)(3) of this section by successful completion of a practical examination covering this material.

(c) The licensee may not permit any individual to act as a radiographer's assistant until the individual--

(1) Has received copies of and instruction in:

(a) The regulations governing industrial radiography contained in Part E of this chapter, or the equivalent regulations of an Agreement State or the NRC;

(b) The regulations governing radiation protection standards and notices, instructions, and reports to workers contained in Parts D and J of this chapter, or the equivalent regulations of the NRC or an Agreement State;

(c) Applicable DOT regulations as referenced in 10 CFR Part71;

(d) The Agency, NRC or Agreement State license(s) under which the radiographer's assistant will perform industrial radiography; and

(e) The licensee's operating and emergency procedures.

(2) Has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

(3) Has demonstrated understanding of the instructions provided under (c)(1) of this section by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in (c)(2) of this section by successful completion of a practical examination on the use of such hardware.

(d) The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in paragraph (e)(4), the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the regulations governing industrial radiography contained in Part E of this chapter, or the equivalent regulations of the NRC or an Agreement State, the license 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 6 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of Sec. E.43(b)(3) and the radiographer's assistant must re-demonstrate knowledge of the training requirements of Sec. E.43(c)(2) 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 RSO.

(4) In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

(f) The licensee shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with Sec. E.79.

(g) The licensee shall include the following subjects required in paragraph (a) of this section:

(1) Fundamentals of radiation safety including--

(i) Characteristics of x-ray and gamma radiation;

(ii) Units of radiation dose and quantity of radioactivity;

(iii) Hazards of exposure to radiation;

(iv) Levels of radiation from radiation machines and licensed material; and

(v) Methods of controlling radiation dose (time, distance, and shielding);

(2) Radiation detection instruments including--

(i) Use, operation, calibration, and limitations of radiation survey instruments;

(ii) Survey techniques; and

(iii) Use of personnel monitoring equipment;

(3) Equipment to be used including--

(i) Operation and control of radiation machines, radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

(ii) Storage, control, and disposal of licensed material and radiation machines; and

(iii) Inspection and maintenance of equipment;

(4) The requirements of pertinent Agency regulations; and

(5) Case histories of accidents in radiography.

(h) Licensees will have until May 28, 2000 to comply with the additional training requirements specified in paragraphs (b)(1) and (c)(1) of this section.

Sec. E.45 Operating and Emergency Procedures.

(a) Operating and emergency procedures must include, as a minimum, instructions in the following:

(1) Appropriate handling and use of radiation machines, licensed sealed sources and radiographic exposure devices so that no person is likely to be exposed to radiation doses in excess of the limits established in Part D of this chapter "Standards for Protection Against Radiation";

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

(5) Personnel monitoring and the use of personnel monitoring equipment;

(6) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation (refer to Part T of these regulations);

(7) The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, 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 alarm ratemeter alarms unexpectedly;

(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by COMAR 26.12.01.01D.1220 of this chapter;

(10) The procedure for notifying proper persons in the event of an accident;

(11) Minimizing exposure of persons in the event of an accident;

(12) Source recovery procedure if licensee will perform source recovery;

(13) Maintenance of records.

(b) The licensee shall maintain copies of current operating and emergency procedures in accordance with Secs. E.81 and E.89.

Sec. E.46 Supervision of Radiographers' Assistants.

Whenever a radiographer's assistant uses radiation machines, radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by Sec. E.49(b) to determine that the sealed source has returned to the shielded position or the radiation machine has turned off after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision must include:

(a) The radiographer's physical presence at the site where the radiation machines or sealed sources are being used;

(b) The availability of the radiographer to give immediate assistance if required; and

(c) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

Sec. E.47 Personnel Monitoring.

(a) The licensee 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 alarm ratemeter, and a personnel dosimeter. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to 2 millisieverts (200 millirems) and must be recharged at the start of each shift. Electronic personnel 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 that require replacement must be replaced at periods not to exceed thirty (30) days. All personnel dosimeters shall be evaluated thirty (30) days or promptly after replacement, whichever is more frequent.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personnel dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with Sec. E.82.

(c) Pocket dosimeters, or electronic personnel dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with Sec. E.82. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personnel dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use or radiation machines until a determination of the individual's radiation dose has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with Sec. E.82.

(e) If the personnel dosimeter that is required by Sec. E.47(a) is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in Sec. E.47(a) 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 Sec. E.82.

(f) Dosimetry results must be retained in accordance with Sec. E.82.

(g) Each alarm ratemeter must--

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent 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 shall maintain records of alarm ratemeter calibrations in accordance with Sec. E.82(b).

Sec. E.49 Radiation Surveys.

The licensee shall:

(a) Not conduct a radiographic operation unless at least one calibrated and operable radiation survey instrument, as described in Sec. E.25, is available and used by each radiographic person at the site of each exposure.

(b) Survey with a radiation survey instrument after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube. If using a radiation machine, a similar survey shall be performed to determine if the machine has turned off.

(c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in Sec. E.3), to ensure that the sealed source is in its shielded position.

(d) Maintain records in accordance with Sec. E.85.

Sec. E.51 Surveillance.

During each radiographic operation the radiographer, or the other individual present, as required by Sec. E.41, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part D of this chapter except at permanent radiographic installations where all entryways are locked and the requirements of Sec. E.33 are met.

Sec. E.53 Posting.

All areas in which industrial radiography is being performed must be conspicuously posted as required by Sec. D.902 of this chapter. Exceptions listed in Sec. D.903 of this chapter do not apply to industrial radiographic operations.

Subpart E - Recordkeeping Requirements

Sec. E.61 Records of the Specific License for Industrial Radiography.

Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license.

Sec. E.63 Records of Receipt and Transfer of Sealed Sources

(a) Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using depleted uranium for shielding and retain each record for 3 years after it is made.

(b) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for depleted uranium), and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

Sec. E.65 Records of Radiation Survey Instruments.

Each licensee shall maintain records of the calibrations of its radiation survey instruments that are required under Sec. E.25 and retain each record for 3 years after it is made.

Sec. E.67 Records of Leak Testing of Sealed Sources and Devices Containing Depleted Uranium.

Each licensee shall maintain records of leak test results for sealed sources and for devices containing depleted uranium. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

Sec. E.69 Records of Quarterly Inventory.

(a) Each licensee shall maintain records of the quarterly inventory of sealed sources and of devices containing depleted uranium as required by Sec. E.29 and retain each record for 3 years after it is made.

(b) 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 sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

Sec. E.71 Utilization Logs.

(a) Each licensee shall maintain utilization logs showing for each radiation machine or sealed source the following information:

(1) A description, including the make, model, and serial number of the radiation machine, radiographic exposure device or transport or storage container in which the sealed source is located;

(2) The identity and signature of the radiographer to whom assigned; and

(3) The plant or site where used and dates of use, including the dates removed and returned to storage.

(b) The licensee shall retain the logs required by paragraph (a) of this section for 3 years after the log is made.

Sec. E.73 Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) Each licensee shall maintain records specified in Sec. E.31 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 3 years after it is made.

(b) 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 done.

Sec. E.75 Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations.

Each licensee shall maintain records of alarm system and entrance control device tests required under Sec. E.33 and retain each record for 3 years after it is made.

Sec. E.79 Records of Training and Certification.

Each licensee shall maintain the following records (of training and certification) for 3 years after the record is made:

(a) 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, and names of individuals conducting and receiving the oral and practical examinations; and

(b) Records of annual refresher safety training and quarterly 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-compliances observed by the Radiation Safety Officer.

Sec. E.81 Copies of Operating and Emergency Procedures.

Each licensee shall maintain a copy of current operating and emergency procedures until the Department terminates the license. Superseded material must be retained for 3 years after the change is made.

Sec. E.82 Records of Personnel Monitoring Procedures.

Each licensee shall maintain the following exposure records specified in Sec. E.47:

(a) Direct reading dosimeter readings and yearly operability checks required by Sec. E.47(b) and (c) for 3 years after the record is made.

(b) Records of alarm ratemeter calibrations for 3 years after the record is made.

(c) Personnel dosimeter results until the Department terminates the license.

(d) Records of estimates of exposures as a result of: off-scale personnel direct reading dosimeters, or lost or damaged personnel dosimeters, until the Department terminates the license.

Sec. E.85 Records of Radiation Surveys.

Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in Sec. E.49(c), if that survey is the last one performed in the workday. Each record must be maintained for 3 years after it is made.

Sec. E.87 Form of Records.

Each record required by this part 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 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 shall maintain adequate safeguards against tampering with and loss of records.

Sec. E.89 Location of Documents and Records.

(a) Each licensee or registrant subject to Part E shall maintain copies of records required by this part and other applicable parts of this chapter at the location specified in the person's license or registration.

(b) Each licensee or registrant subject to Part E shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary job site:

(1) The license or registration authorizing the use of sources of radiation;

(2) A copy of COMAR 26.12.01.01 Regulations for Control of Ionizing Radiation (1994);

(3) Utilization records for each radiation machine or radiographic exposure device dispatched from that location as required by Sec. E.71;

(4) Records of equipment problems identified in daily checks of equipment as required by Sec. E.73(a);

(5) Records of alarm system and entrance control checks required by Sec. E.75, if applicable;

(6) Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeter readings as required by Sec. E.82;

(7) Operating and emergency procedures required by Sec. E.81;

(8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by Sec. E.65;

(9) Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by Sec. E.82;

(10) Latest survey records required by Sec. E.85;

(11) The shipping papers for the transportation of radioactive materials required by Sec. T.5 of this chapter; and

(12) When operating under reciprocity pursuant to Sec. C.90, a copy of the NRC or Agreement State license authorizing the use of licensed materials.

Subpart F - Notifications

Sec. E.101 Notifications.

(a) In addition to the reporting requirements specified in Sec. D.1201 through D.1206, D.1211, and D.1220 of these regulations, each licensee or registrant shall immediately notify the Department and shall provide a written report to the Maryland Department of the Environment, Radiological Health Program, 1800 Washington Boulevard,

Baltimore, MD 21230 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; or

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function;

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section, and in each report of overexposure submitted under D.1203 which involves failure of safety components of radiography equipment:

(1) A 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) Qualifications of personnel involved in the incident.

(c) Any person conducting radiographic operations or storing radiation machines or radioactive material at any location not listed on the registration or license for a period in excess of 180 days in a calendar year, shall notify the Agency prior to exceeding the 180 days.

Appendix A –NRC 10 CFR Part 34 Radiographer Certification

I. Requirements for an Independent Certifying Organization

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;

2. Make its membership available to the general public nationwide that is not 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 fields 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 NRC 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 NRC 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 Sec. E.43(g) or equivalent Agreement State 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 Sec. E.43(g) or equivalent Agreement State regulations;

(b) satisfactorily completed a minimum period of on-the-job training; and

(c) received verification by an Agreement State or a NRC 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, revoking, suspending, and reinstating a certificate;

5. Provide a certification period of not less than 3 years nor more than 5 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;

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:

1. Be designed to test an individual's knowledge and understanding of the topics listed in Sec. E.43(g) or equivalent Agreement State requirements;

2. Be written in a multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in Sec. E.43(g).

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PART F

X RAYS IN THE HEALING ARTS

Sec. F.1 Scope. This part establishes requirements, for which a registrant is responsible, 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 healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

Sec. F.2 Definitions. As used in this part, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"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 the owner’s 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 at least 20 centimeters (cm) by 20 centimeters (cm) by 3.8 centimeters (cm) that is large enough to intercept the entire x-ray beam, of type 1100 aluminum alloy[1] or other materials having equivalent attenuation.

"Authorized provider" means a licensed healing arts practitioner, which is limited to the following professions: physician, podiatrist, chiropractor, dentist, and veterinarian.

"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 (See also "Phototimer").

“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.

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[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"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 which provides a means to restrict the dimensions of the x-ray field.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

“C-arm fluoroscope” means a fluoroscopic x-ray system in which the image receptor and the x-ray tube 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.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified 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.

"Certified system" means any x-ray system which has one or more certified component(s).

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

"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:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}}\left[\sum_{i=1}^{n} \frac{(X_i - \bar{X})^2}{n-1}\right]^{1/2}$$

where:

s = Estimated standard deviation of the population.
$\bar{x}$ = Mean value of observations in sample.
X_i = i^{th} observation sampled.
n = Number of observations in sample.

"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. "CT"

(See "Computed tomography").

“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.

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

“Dental tomographic x-ray unit” means any unit or system used for taking tomograms of parabolically curved objects such as the dentition, jawbones and other bony structures of the head and dento-facial region. Systems may include the capability and software for 3-D imaging.

"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 body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

“Electronic brachytherapy” means a method of radiation therapy using electrically-generated x-rays to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal, or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

“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.

"Entrance exposure rate" means the exposure per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (See "X-ray equipment")

"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 absorb preferentially selected radiations.

“Fluoroscopic air kerma display device” means a device, subsystem, or component that provides the display of AKR and cumulative air kerma. It includes radiation detectors, if any, and electronic and computer components, and 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.

"Focal spot" 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, or 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.

"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")

“High energy facility” means a facility with equipment utilizing energies in excess of 150 keV.

"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" means, for mammographic systems, that part of the system designed to support the image receptor in a plane perpendicular to the beam during a mammographic examination and to provide a primary protective barrier.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly

"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 as defined by the International Commission of 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”.

“Kilo electron volt (keV)” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

"Kilovolts peak" (See "Peak tube potential")

"kV" means kilovolts.

"kVp" (See "Peak tube potential")

"kWs" means kilowatt second. It is equivalent to 10^3 (kV)(mA)(s).

“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.

"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 factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

(l) 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 "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl 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. It is calculated using the following equation:

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.

"Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

"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 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.

"Patient" means an individual subjected to 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.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

"PID" (See "Position indicating device")

"Portable x-ray equipment" (See "X-ray equipment")

"Position indicating device" 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.

“Positive beam limitation” means automatic collimation for fluoroscopy or radiography in which the collimator allows exposure only after specific criteria such as distance, or field size compared to receptor size and tube angle, are met.

"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 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:

(1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

(2) "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 has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"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 radiographic, fluoroscopic, or CT 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.

"Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Radiological physicist" means an individual who

(1) is certified by the American Board of Radiology or other comparable organization acceptable by the Department in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or

(2) has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology or other comparable organization acceptable by the Department. The work duties shall include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

(3) has a Master's or a Doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had 1 year's full-time training in therapeutic radiological physics; and has had 1 year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a retrievable form of an image resulting from x-ray photons.

“Registered cardiovascular invasive specialist (RCIS)” means an individual who is credentialed by Cardiovascular Credentialing International or another credentialing body approved by the Maryland Board of Physicians to assist in cardiac catheterization procedures under the direct, in-person supervision of a licensed physician.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

"Secondary protective barrier" (See "Protective barrier")

"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.

"SID" (see "Source-image receptor distance")

“Solid state x-ray imaging device” means the 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 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 an image intensifier for the purpose of making a radiograph.

"SSD" (see “Source-skin distance”)

"Stationary x-ray equipment" (See "X-ray equipment")

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

(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.

"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.

“Thyroid shielding” means a collar or shield consisting of ≥0.5 mm lead equivalent which is effective in protecting a patient’s thyroid gland from direct exposure to the useful x-ray beam.

"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 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.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

"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.

(3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location, and includes x-ray equipment permanently installed in a vehicle.

"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, or 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.

"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 tube" means any electron tube which is designed to be used primarily for the production of x rays.

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Sec. F.3 General Requirements.

(a) Administrative Controls.

(l) Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the x-ray system(s).

(i) An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes.

(ii) Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.

(iii) A registrant must demonstrate that a dental radiation technologist employed by the registrant is adequately trained and competent to use a radiation machine as required under COMAR 10.44.19.03, and must conspicuously display the technologist's certificate as required under COMAR 10.44.19.11.

(iv) A registrant must demonstrate that a radiation therapist employed by the registrant is adequately trained and competent to use a radiation machine for medical diagnostic or therapeutic purposes as required under COMAR 10.32.10.05-1,and must conspicuously display each radiation therapist's certificate.

(v) A registrant must demonstrate that a Registered Cardiovascular Invasive Specialist (RCIS) employed by the registrant or allowed to work at the registrant's facility is adequately trained and competent to assist in a physician's performance of fluoroscopy during cardiac catheterization procedures as required under Section 14-306(f)(1) of the Health Occupations Article, Annotated Code of Maryland, and COMAR 10.32.12.06, and must conspicuously display each RCIS's certificate.

(vi) A chart shall 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:

(a) Patient's body part and anatomical size or body part thickness, or age (for pediatrics) versus technique factors to be utilized;

(b) Type and size of the film or film-screen combination to be used, if applicable;

(c) Type and focal distance of the grid to be used, if any;

(d) Source to image receptor distance to be used;

(e) Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

(f) For mammography, indication of kVp/target/filter combination.

(vii) Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(viii) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by no less than 0.5 milli- meter lead equivalent.

(b) All persons shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

(c) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall 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.

(ix) Gonad shielding of not less than 0.5 millimeter lead equivalent shall be used for 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.

(x) Thyroid shielding consisting of a ≥0.5 mm lead equivalent thyroid collar or shield shall be provided to and used for all patients upon request or whenever the useful beam is expected to or may strike the thyroid gland, so long as such shielding does not interfere with diagnostic x-ray procedures.

(xi) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision also prohibits deliberate exposure for the purpose of training, demonstration, or other non-healing-arts purposes.

(xii) When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by Section F.3(a)(1)(iv), shall list individual projections where holding devices cannot be utilized;

(b) Written safety procedures, as required by Section F.3(a)(l)(iv), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(c) The human holder shall be protected as required by Section F.3(a)(1)(v);

(d) No individual shall be used routinely to hold film or patients; and

(e) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

(f) The beam defining light, if present, shall be turned on during all exposures for which a human holder is used. The operator shall not initiate the exposure except on permission from the holder.

(g) No individual who is occupationally exposed to radiation shall be required to hold patients during radiographic exposures.

(xiii) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. Such procedures and equipment shall include, but are not limited to the following requirements:

(a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations;

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality;

(c) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation; or

(d) X-ray systems subject to Section F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

(e) Filmless diagnostic x-ray systems shall use technique factors not to exceed the maximum of the technique range recommended by manufacturers' specifications to generate images.

(xiv) All individuals who are associated with the operation of an x-ray system are subject to the requirements of Part D of these regulations. In addition:

(a) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(1) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

(2) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded as required in Section D.1107 of these regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

(b) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(2) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system:

(i) Maximum rating of technique factors;

(ii) Model and serial numbers of all certified components;

(iii) Aluminum equivalent filtration of the useful beam, including any routine variation;

(iv) Tube rating charts and cooling curves;

(v) Records of surveys, calibrations, maintenance, and effective modifications performed on the x-ray system(s) after October 9, 1995 with the names of persons who performed such services;

(vi) For x-ray systems regulated by Sections F.5, F.6, F.7, F.10, or F.11, a schedule of the maintenance necessary to keep the equipment in compliance, as required by Section B.12(d);

(a) Documentation, including logs, service tickets or completed work orders, indicating compliance with the manufacturer's recommended maintenance schedule;

(b) For fluoroscopic x-ray systems manufactured on or after June 10, 2006, the registrant shall maintain documentation, provided by the manufacturer, of the 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, and, if the capability for user calibration of the display is provided, adequate instructions for such calibration;

(vii) For x-ray systems manufactured on or after June 10, 2006 that produce images using the fluoroscopic image receptor, the manufacturer's information describing each mode of operation 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;

(viii) A scale drawing 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 shall include:

(a) 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

(b) A copy of the plan review submitted to the Agency under B.4 and the Agency's letter of approval; and

(ix) A copy of all correspondence with this Agency regarding that x-ray system.

(3) X-Ray Log.

(i) Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed.

(ii) When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded in a retrievable format.

(b) Image Production.

(1) All hard copy film shall be processed in such a fashion as to achieve adequate sensitometric performance. "Adequate sensitometric performance" means:

(i) A measured processing speed of greater than or equal to 80 percent; and

(ii) The base plus fog of the facility's film shall not exceed 0.3 OD, as measured by the Sensitometric Technique for the Evaluation of Processing (STEP) test.[2]

[2] This test is described by Suleiman, O. H. et al. in the article "Automatic Film Processing: Analysis of 9 Years of Observation." Radiology 1992 Vol. 185, pp. 25-28.

(2) Manual Processing of Film.

(i) Where film is developed manually, a system shall be available which consists of at least one three-sectional tank made of mechanically rigid, corrosion resistant material (each section of which shall be constructed so as to retain its solution separate from the other two) and has the overall temperature controlling capability of maintaining each solution such that the temperature of each solution will always fall within the range of 60°F to 80°F (16-27°C).

(ii) Devices shall be available which will:

(a) Give the actual temperature of the developer, plus or minus 2°F (or 1°C if SI units are used),

(b) Give an audible or visible signal after a preset time, plus or minus 10% of the preset time, and

(iii) Film shall be developed in accordance with the appropriate time and temperature charts. Time and temperature charts matched to the film types in use in the facility shall be available and posted in the development work area.

(3) Chemical-Film Processing Control.

(i) Chemicals shall be mixed in accordance with the chemical manufacturer's recommendations.

(ii) Replenishing of chemicals shall be sufficient to maintain the standards of Section F.3(b)(1) above.

(iii) All processing chemicals shall be completely replaced at least every 3 months.

(4) Automatic Processors and Other Closed Processing Systems. Preventive maintenance shall be performed on the unit, except for extended periods of non-use, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good film quality.

(5) Film Fog Prevention.

(i) Film processing areas and devices shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through a proper safelight filter.

(ii) That light which remains in a film processing area or device following compliance with F.3(b)(5)(i) shall, when exposed to film in a two minute fog test, produce an increase in fog of not more than 0.05 density units.

(iii) In determining compliance with F.3(b)(5)(ii), fog measurements are to be made at exposed film densities of 1.0 plus base plus fog.

(6) Soft Copy Image Production.

(i) Display monitors. The registrant shall use only appropriate display monitors that meet the manufacturer's recommended specifications for diagnostic interpretation for image quality parameters.

(ii) Lasers. The registrant shall use only appropriate lasers that meet the manufacturer's recommended specifications for image quality parameters.

(iii) Replacement devices for electronic image retrieval or duplication instrumentation shall meet manufacturers' recommended specifications.

(c) Quality Assurance.

The registrant shall be responsible for establishing and operating an effective program for radiographic or fluoroscopic imaging quality control. This program shall be designed to fulfill the following goals:

(1) That the diagnostic quality of radiographic or fluoroscopic images will be maintained at the highest level;

(2) That film processing systems, including electronic imaging collection systems, will be maintained at the highest quality level;

(3) That radiographic or fluoroscopic images will be produced using the minimum radiation doses to patients; and

(4) That the above three goals will be consistently met.

(d) Machine Maintenance.

(1) A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended maintenance specifications.

(2) If documentation regarding the recommended maintenance schedule is not available from the manufacturer, maintenance shall be performed at intervals not to exceed 12 months.

(3) A registrant shall maintain documentation that the machine manufacturer's recommended maintenance schedule has been met. Documentation to satisfy the requirements of this section shall include a detailed service report that includes the results of all tests performed by the registered service company. Such documentation shall clearly designate the registrant name and facility registration number, service date and provider of maintenance service, Department-assigned machine number, if present, and tube serial number, and room name or number in which the machine is located, for each machine for which preventive maintenance has been provided.

(4) Each registrant shall provide to the Agency written documentation as described in (d)(3) sufficient to demonstrate that the maintenance required under (d)(1) and (2) has been performed. Such documentation shall be provided to the Agency no later than thirty (30) days following performance of this maintenance.

Diagnostic X-Ray Systems

Sec. F.4 General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

(a) 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."

(b) Battery Charge Indicator. On battery-powered x-ray 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.

(c) 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 100 milliroentgens (25.8 μC/kg), or 0.88 milligray, in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(d) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 μC/kg), or 0.02 milligray, 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.

(e) Beam Quality.

(1) Half-Value Layer.

(i) The half-value layer of the useful beam for a given x-ray tube potential shall 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.

Table I.

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

(ii) In addition to the requirements of Section F.4(e)(1)(i), all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.

(iii) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(iv) For capacitor energy storage equipment, compliance with the requirements of Section F.4(e) shall be determined with the maximum quantity of charge per exposure.

(v) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

[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.

(vi) 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 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. 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.

(2) Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by Section F.4(e)(1) is in the useful beam for the given kVp which has been selected.

(f) 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 prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected. Non-certified equipment is exempt from this requirement.

(g) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(h) Technique Indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of Section F.4(h)(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(i) Diagnostic Medical Radiation Event.

(1) Definition. A diagnostic medical radiation event has taken place when the administration of radiation from a radiation machine being used to detect or diagnose illness, injury, or for another non-therapeutic purpose results in irradiation of the wrong individual, or of the wrong part of an individual’s body, or when the wrong mode of diagnostic x-ray examination has been used, or when the diagnostic radiation exposure is of a type other than the one intended. Any diagnostic x-ray procedure performed on an individual that has not been specifically prescribed or ordered by a licensed practitioner of the healing arts is a diagnostic medical radiation event.

(2) Standard Operating Procedures. Registrants shall establish appropriate written procedures to prevent the occurrence of a diagnostic medical radiation event, and shall ensure that these procedures are adhered to at all times by all facility personnel.

(3) Prescription or Order Required. No diagnostic x-ray procedure shall be performed on an individual unless a prescription or order for such procedure has been written by a licensed practitioner of the healing arts. Any diagnostic x-ray procedure performed on an individual shall not vary from the diagnostic x-ray procedure prescription or order. If a previously written prescription or order has been superseded by a later prescription or order, the latest prescription or order written shall be followed.

(4) Reporting Requirements.

(i) A registrant shall report each diagnostic medical radiation event to the Agency by telephone no later than the next business day after discovery of the event.

(ii) The registrant shall submit a report providing details relating to the diagnostic medical radiation event, in the form of the Agency-published Form RX-38 "Diagnostic Medical Event Occurrence Log" completed in its entirety, to the Agency within 15 days following discovery of the event.

(5) Notification Requirements. Within the next business day following discovery of a diagnostic medical radiation event, the registrant shall provide notification of the event to both the individual who was the subject of the event and to the prescribing physician. To meet the requirements of notification to the individual, such notification may instead be made to the individual's responsible relative or guardian.

(6) Recordkeeping Requirements. The registrant shall retain an occurrence log book of events at the registrant's physical location and make this log book, and all completed Form RX-38's, available to licensed private inspectors or Department inspectors for review for a period of not less than three years from the date of report of each event.

Sec. F.5 Fluoroscopic X-Ray Systems Except for Computed Tomography X-Ray Systems. All fluoroscopic imaging x-ray systems used shall be image intensified and meet the following requirements:

(a) Limitation of Useful Beam.

(1) Primary Barrier.

(i) 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.

(ii) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopy and Radiography Using the Fluoroscopic Imaging Assembly with Inherently Circular Image Receptors.

(i) For certified fluoroscopic systems manufactured before June 10, 2006, 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 shall 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 shall be no greater than 4 percent of the SID.

(ii) For uncertified fluoroscopic systems manufactured before June 10, 2006, with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters tabletop to the film plane distance.

(iii) For uncertified fluoroscopic systems manufactured before June 10, 2006, without a spot film device, the requirements of Section F.5(a)(2)(i) apply.

(iv) Other requirements for fluoroscopic beam limitation on fluoroscopic systems include:

(a) Means shall 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 shall be provided with means for stepless adjustment of the x-ray field;

(b) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall 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;

(c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field size from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;

(d) For equipment manufactured after February 25, 1978, when the angle between 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;

(e) For non-circular x-ray fields used with circular image receptors, 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.

(v) For fluoroscopic equipment manufactured on or after June 10, 2006, using inherently circular image receptors, the maximum area of the x-ray field on the plane of the image receptor shall conform with one of the following requirements:

(a) 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 centimeters in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor; or

(b) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 centimeters 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 centimeters.

(3) Fluoroscopy and Radiography Using the Fluoroscopic Imaging Assembly with Inherently Rectangular Image Receptors.

For fluoroscopy and radiography x-ray systems manufactured on or after June 10, 2006, using the fluoroscopic imaging assembly with inherently rectangular image receptors, the following applies:

(i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall 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 shall be no greater than 4 percent of the SID.

(ii) 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.

(4) Spot-film Beam Limitation. Spot-film devices shall meet the following requirements:

(i) Means shall 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 that has been selected on the spot film selector. Such adjustment shall 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 shall be only at the operator's option;

(ii) 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;

(iii) It shall 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 shall be equal to, or less than, 5 centimeters by 5 centimeters;

(iv) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of SID; and

(v) 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.

(5) Override. If a means exists to override any of the automatic x-ray field size adjustments required in Sections F.5(a)(2) and F.5(a)(3), this means that it:

(i) Shall be designed for use only in the event of system failure;

(ii) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(iii) Shall be clearly and durably labeled or indicated as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

(b) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial radiographic images from a fluoroscopic image receptor, the fluoroscopist 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.

(c) Exposure Rate Limits.

(1) Entrance Exposure Rate, or AKR, Allowable Limits.

(i) Fluoroscopic equipment manufactured before May 19, 1995 that is provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current which will result in the exposure rate in excess of 10 roentgens (2.58 mC/kg) per minute, or in excess of an AKR of 88 mGy per minute, at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images; or

(b) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute, or in excess of an AKR of 44 mGy 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 shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(ii) Fluoroscopic equipment manufactured before May 19, 1995 which is not provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute, or in excess of an AKR of 44 mGy per minute, at the point where the center of the useful beam enters the patient, except:

(a) During the recording of fluoroscopic images; or

(b) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal to the fluoroscopist shall indicate that the high level control is being employed.

(iii) Fluoroscopic equipment manufactured before May 19, 1995 which is provided with both an automatic exposure rate control (AERC) mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.58 mC/kg) per minute, or in excess of an AKR of 88 mGy per minute, in either mode at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images; or

(b) When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute, or in excess of an AKR of 44 mGy 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 shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(iv) Any fluoroscopic equipment manufactured on or after May 19, 1995 operable at any combination of tube potential and current that results in an exposure rate greater than 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure rate control (AERC). Provision for manual selection of technique factors may be provided.

(v) Fluoroscopic equipment manufactured between May 19, 1995 and June 9, 2006 shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute, or in excess of an AKR of 88 mGy per minute, at the point where the center of the useful beam enters the patient except:

(a) 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; or

(b) When a mode of operation has an optional high-level control and the control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 roentgens (5.2 mC/kg) per minute, or in excess of an AKR of 176 mGy per minute, at the measurement point specified in Section F.5(c)(1)(vii). Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(vi) Fluoroscopic equipment manufactured on or after June 10, 2006, shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute, or in excess of an AKR of 88 mGy per minute, at the point where the center of the useful beam enters the patient, except:

(a) 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; or

(b) When a mode of operation has an optional high-level control and the control is activated, the equipment shall not be operable in any combination of tube potential and current that will result in an exposure rate in excess of 20 roentgens (5.2 mC/kg) per minute, or in excess of an AKR of 176 mGy per minute, at the measurement point specified in Section F.5(c)(1)(vii). Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(vii) Compliance with the requirements of Sections F.5(c)(1)(i) through F.5(c)(1)(vi) shall be determined as follows:

(a) If the source is below the table, the exposure rate or AKR shall be measured 1 centimeter above the tabletop or cradle;

(b) If the source is above the table, the exposure rate or AKR shall 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;

(c) For a C-arm type of fluoroscope, the exposure rate or AKR shall 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 spacer or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(d) For a lateral type fluoroscope, the exposure rate or AKR shall 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 shall 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; or

(e) In a C-arm type of fluoroscope having an SID less than 45 centimeters, the exposure rate or AKR shall be measured at the minimum SSD, which must be documented.

(2) Periodic measurement of entrance exposure rate or AKR shall be performed as follows:

(i) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate or AKR.

(ii) Results of measurements from Sections F.5(c)(2)(iv) and F.5(c)(2)(v) shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in Section F.3(a)(2)(v). The measurement results shall be stated in roentgens per minute or mGy per minute 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 shall be included in the results.

(iii) Area monitoring devices may be used to perform the measurements required by Section F.5(c)(2)(i), provided the measurements are made as described in Section F.5(c)(2)(iv).

(iv) Conditions of periodic measurement of entrance exposure rate or AKR are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of Section F.5(c)(1)(vii);

(b) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of posted clinical use of the x-ray system;

(c) The x-ray system(s) that incorporates automatic exposure control (AEC) shall have sufficient attenuative material placed in the useful beam to produce a milliamperage typical of posted use of the x-ray system;

(d) The x-ray system(s) that does not incorporate an automatic exposure control (AEC) shall utilize a milliamperage typical of the clinical use of the x-ray system; and

(e) Components, such as moveable grids and compression devices, shall be removed from the useful beam during the measurement.

(v) Conditions of periodic measurement of maximum entrance exposure rate or AKR are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of F.5(c)(1)(vii);

(b) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate or AKR;

(c) The x-ray system(s) that incorporates automatic exposure rate control (AEC) shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

(d) Barrier Transmitted Radiation Rate Limits.

(1) The exposure rate, or AKR, 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, shall not exceed 2 milliroentgens (0.516 μC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate, or AKR.

(2) Measuring Compliance of Barrier Transmission.

(i) The exposure rate, or AKR, due to transmission through the primary protective barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(ii) 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.

(iii) 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.

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(v) The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate, or AKR, and between this point and the input surface of the fluoroscopic imaging assembly.

(e) Indication of Potential and Current. During fluoroscopy and cine fluorography, the kVp and the mA shall be continuously indicated. Deviation of tube potential and current from indicated values shall not exceed the limits specified for that system by its manufacturer.

(f) Source-to-Skin Distance. The SSD shall not be less than:

(1) 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(2) 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(3) 30 centimeters on all mobile and portable fluoroscopes; and

(4) 20 centimeters for fluoroscopes used for specific surgical applications as long as written safety procedures providing manufacturer's precautionary measures are:

(i) Adhered to during the use of this device; and

(ii) Available for reference at all times.

(5) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, the SSD shall not be less than:

(i) 19 centimeters for systems having a maximum source-image receptor distance of less than 45 centimeters. Such systems shall be utilized and labeled for extremity use only;

(ii) 10 centimeters for fluoroscopes used for specific surgical applications as long as written safety procedures providing the manufacturer's precautionary measures are:

(a) Adhered to during the use of this device; and

(b) Available for reference at all times.

(6) Mobile fluoroscopes specifically manufactured for imaging extremities are exempt from SSD limitations.

(g) Fluoroscopic Irradiation Time, Display, and Signal.

(1) Fluoroscopic equipment manufactured before June 10, 2006, shall be provided with means to preset the cumulative irradiation time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. One of the following must occur:

(i) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while x-rays are produced until the timing device is reset; or

(ii) If there is no means for an audible signal, x-ray production must terminate automatically at the end of the preset time.

(2) For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

(i) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in Section F.5(g)(2)(ii). The following requirements apply:

(a) 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 (six) seconds;

(b) The fluoroscopic irradiation time shall also be displayed within 6 (six) seconds of termination of an exposure and remain displayed until reset; and

(c) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

(ii) A signal audible to the fluoroscopist shall 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.

(h) Mobile Fluoroscopes. In addition to the other requirements of Section F.5, mobile fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

(i) Control of Scattered Radiation.

(1) Fluoroscopic table designs, when combined with procedures utilized, shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration, when combined with procedures, shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(i) Is at least 120 centimeters from the center of the useful beam, or

(ii) Is in a location such that 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 Section F.3(a)(1)(v).

(3) The Agency may grant exemptions to Section F.5(i)(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of pre-fitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption.

(j) Spot Film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of Section F.6(d) or F6(g)(1), as appropriate.

(k) Display of Last-Image-Hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of fluoroscopic exposure.

(1) For a 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 shall be indicated prior to initiation of the fluoroscopic exposure.

(2) For a LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

(3) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall 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.

(4) The predetermined or selectable options for producing the LIH radiograph shall be described in the information required in Section F.3(a)(1)(iii). The information shall include a description of any technique factors applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.

(l) Displays of Values for AKR and Cumulative Air Kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working positions, including the operator's console, 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 shall be continuously displayed and updated at least once every second.

(2) The cumulative air kerma in units of mGy shall be displayed 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 shall be clearly distinguishable from the display of the cumulative air kerma.

(4) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users, according to Section F.3(a)(2)(vi).

(i) For fluoroscopes with x-ray sources below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in Sections F.5(c)(1)(vii)(a), F.5(c)(1)(vii)(b), or F.5(c)(1)(vii)(d) for measuring compliance with air kerma limits.

(ii) For C-arm fluoroscopes, the reference location shall be 15 centimeters from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall 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 shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(6) The displayed AKR and cumulative air kerma shall 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 shall be determined with an irradiation time greater than 3 seconds.

(m) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of Sections F.5(a), F.5(c), F.5(d), and F.5(g) provided that:

(1) 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; and

(2) Systems which do not meet the requirements of Section F.5(g) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(n) Qualifications for Users who Energize Fluoroscopic System.

(1) The registrant shall ensure that only a licensed practitioner of the healing arts or a radiological technologist be allowed to energize fluoroscopic x-ray systems. In addition, all persons energizing these systems shall have completed at least four hours of training as specified in Section F.5(n)(2) prior to clinical use of a fluoroscopic system, or provide documentation to demonstrate completion of four hours of training as specified in Section F.5(n)(2) prior to clinical use of a fluoroscopic system.

(2) Training to meet the requirements of Section F.5(n)(1) shall include, but is not limited to the following:

(i) Biological effects of x-ray;

(ii) Principles of radiation protection;

(iii) Factors affecting fluoroscopic outputs;

(iv) Dose reduction techniques;

(v) Principles and operation of the specific fluoroscopic x-ray system(s) to be used;

(vi) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used; and

(vii) Applicable requirements of these regulations.

(3) The registrant shall maintain records to demonstrate a minimum of one hour of in-service training or continuing medical education training for all users who energize fluoroscopic equipment every twenty-four months in fluoroscopic radiation safety and patient dose management.

(4) The registrant shall maintain documentation pertaining to the requirements of Sections F.5(n)(1), F.5(n)(2) and F.5(n)(3) for review for three years.

(5) Documentation to meet the requirements of Sections F.5(n)(1), F.5(n)(2) and F.5(n)(3) are not registrant specific and should be transferable to other work areas if authorized between the users who energize fluoroscopic radiation machines and the registrant(s).

(6) The registrant may exempt from the requirements of Sections F.5(n)(1) through F.5(n)(4):

(i) Radiologists, if the registrant verifies initially, and biennially thereafter, via original documentation of continued certification by an accepted professional organization; or

(ii) Licensed practitioners of the healing arts and radiation therapy technologists exclusively energizing fluoroscopic radiation machines for the purpose of therapy simulation. The registrant shall maintain records verifying exempt status per user a minimum of every twenty-four months.

(o) Equipment Operation.

(1) Fluoroscopy shall not be used as a positioning tool for radiographic examinations, except for therapy simulation.

(2) By the registrant's first certification date and biennially thereafter, the registrant shall perform an evaluation that will span no less than three months of cumulative electrophysiological and interventional, including cardiac catheterization, fluoroscopic exposure times by procedure and by licensed practitioner. The report shall include the number of fluorographic images recorded for examination.

Sec. F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, or Medical, Computed Tomography X-Ray Systems.

(a) Beam Limitation. The useful beam shall be limited to the area of clinical interest.

(1) General Purpose Stationary and Mobile X-Ray Systems.

(i) There shall be provided a means for stepless adjustment of the size of the x-ray field.

(ii) A method shall 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 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.

(2) Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of F.6(a)(1), stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

(i) A method 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;

(ii) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(iii) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, 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.

(3) 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.

(4) Systems Designed for Mammography.

(i) Radiographic systems designed only for mammography 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 which performs as prescribed in F.6(a)(5)(iii). 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 F.6(a)(5)(iii)(a) and (b) shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(ii) Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography.

(5) X-Ray Systems Other Than Those Described in F.6(a)(1),(2),(3), and (4).

(i) Means shall 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 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Podiatry units with a circular beam are exempted from the 2% limit provided the diameter of the x-ray field shall not exceed the diagonal dimension of the image receptor.

(ii) 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.

(iii) F.6(a)(5)(i) and (ii) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.6(a)(1) or, when alignment means are also provided, may be met with either:

(a) 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

(b) 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.

(6) Source to Image Distance

Except for certified systems, a method shall be provided to indicate the SID to within 2 inches.

(7) Positive Beam Limitation (PBL). This regulation applies only to radiographic systems which contain PBL.

(i) PBL shall prevent the production of x-rays when:

(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by F.6(a)(5)(iii), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

(b) The sum of the length and width differences as stated in F.6(a)(7)(i)(a) without regard to sign exceeds 4 percent of the SID; or

(c) The beam limiting device is at an SID for which PBL is not designed for sizing;

(ii) PBL systems shall function as described in Section F.6(a)(5)(i) 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 centimeters;

(c) 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 is within ± 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters 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;

(iii) Compliance with F.6(a)(5)(i) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and no sooner than 5 seconds after insertion of the image receptor;

(iv) The PBL system shall 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 shall be equal to or less than 5 centimeters by 5 centimeters; and

(v) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in F.6(a)(5)(i), then any change of image receptor size or SID must cause the automatic return.

(b) Radiation Exposure Control Devices.

(1) Timers.

(i) Means shall 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. Such means shall provide that the resulting time interval product of current and time, number of pulses or radiation exposure is accurate to within ten percent of the true value.

(ii) 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.

(iii) Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.

(2) X-Ray Control.

(i) An x-ray control with a dead-man switch shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(a) Dental cone beam CT/3D (CBCT) machines installed prior to August 31, 2016, or

(b) during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(ii) An x-ray exposure switch shall be located in such a way as to meet the following requirements:

(a) stationary x-ray systems shall be required to have the x-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(b) mobile and portable x-ray systems which are:

(1) used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of F.6(b)(2)(ii)(a);

(2) used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirement of F.6(b)(2)(ii)(a) or the operator shall be protected by 6.5 feet (1.98 m) high or greater protective barrier with a minimum lead equivalent of 0.25 mm which is placed so as to intercept both direct radiation from the tube housing and radiation scattered from the patient; or

(3) used for less than 1 hour at the same location to make an exposure(s) of a patient, shall meet the requirement of F.6(b)(2)(ii)(a) or (b)(2) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure; and

(iii) means shall be provided so that the operator can view the patient during the exposure.

(iv) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(v)Accuracy. Except for certified systems, means shall be provided to terminate an exposure at a preset time interval, preset product of current and time, or preset number of pulses. Such means shall produce a time interval, product of current and time, or number of pulses within 10 percent of the indicated preset value.

(2) 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) if the x-ray tube potential is equal to or greater than 51 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 2 pulses;

(iii) the minimum exposure time for all equipment other than that specified in F.6(b)(3)(ii) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

(iv) either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 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 that, when the x-ray tube potential is less than 51 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(v) a visible signal shall indicate when an exposure has been terminated at the limits required by F.6(b)(3)(iv), and manual resetting shall be required before further automatically timed exposures can be made.

(3) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$\overline{T} \geq 5\ (T_{max} - T_{min})$$

(4) Linearity. When the equipment allows a choice of current settings, for any fixed x-ray tube potential within the range of 40-100 percent of the maximum rating, the average ratio of exposure, or air kerma, to the indicated milliamp-second product obtained at any two consecutive tube current settings shall not differ by more than 0.20 times their sum:

$$|\overline{Y}_1 - \overline{Y}_2| \leq 0.20\ (\overline{Y}_1 + \overline{Y}_2),$$

where $\overline{Y}_1 - \overline{Y}_2$ are the average mR/mAs (microcoulomb/kilogram per mAs, or milligray/mAs) values obtained at each of 2 consecutive tube current settings.

(c) Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.

(d) Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\overline{E} \geq 5\ (E_{max} - E_{min})$$

(e) kVp Accuracy. Except for certified systems, the true value of kVp shall not be different from the indicated value by greater than ten percent.

(f) Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 μC/kg or 0.02 milligray) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(g) Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure, or air kerma, to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10\,(\bar{X}_1 + \bar{X}_2),$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs (average microcoulomb/kilogram per mAs or milligray per mAs) values obtained at each of 2 consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

(i) There shall 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 shall be equal to or less than 5 centimeters by 5 centimeters.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall 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.

(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 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 shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(iv) A method shall be provided to indicate the SID to within 2 percent of its true value when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(5) Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of F.6(a)(1) and F.6(g)(4).

(6) Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978 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 exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Sec. F.7 Intraoral Dental Radiographic Systems. In addition to the provisions of F.3 and F.4, the requirements of F.7 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in F.6.

(a) Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

(b) Field Limitation.

(1) Radiographic systems 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) An open ended, shielded position indicating device shall be used.

(c) Timers. Means shall 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:

(1) 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.

(2) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\bar{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$\bar{T} \geq 5(T_{max} - T_{min}).$$

(3) Accuracy. Except for certified systems, means shall be provided to terminate exposure at a preset time interval, preset product of current and time, or preset number of pulses. Such means shall produce a time interval, product of current and time, or number of pulses within ten percent of the indicated preset value.

(d) X-Ray Control.

(1) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.

(2) Each x-ray control shall be located in such a way as to meet the following requirements:

(i) stationary x-ray systems shall 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; and

(ii) mobile and portable x-ray systems which are:

(a) used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of F.7(d)(2)(i);

(b) used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirements of F.7(d)(2)(ii)(a) or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least 6 feet (1.83 m) from the tube housing assembly and at least 6 feet (1.83 m) from the patient; or

(c) used to make an exposure(s) of a patient at the use location shall meet the requirement of F.7(d)(2)(ii)(a) or (b) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.

(3) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(e) Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure ($\bar{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure(E_{min}):

$$\bar{E} \geq 5(E_{max} - E_{min}).$$

(f) kVp Accuracy. Except for certified systems, the true value of kVp shall not be different from the indicated value by greater than ten percent.

(g) Administrative Controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) Except where dental x-ray devices are specifically designed to be hand-held, the tube housing and the PID of intra-oral machines shall not be hand-held during an exposure.

(3) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of F.7(b)(1).

(4) Dental fluoroscopy without image intensification shall not be used.

(h) Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10\,(\bar{X}_1 + \bar{X}_2),$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(5) Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.4(e)(1).

(i) Additional Requirements Applicable to Systems Designed Specifically to be Hand-Held.

(1) Each hand-held diagnostic x-ray device shall be FDA approved for use in the United States and registered with the Department for hand-held operation as part of the facility registration. Registration shall include a description of how the hand-held device(s) will be secured in accordance with F.7(i)(4)(i) below.

(2) Each individual operating a hand-held diagnostic x-ray device shall, before using the device, complete the manufacturer's training for use of the device. The registrant shall maintain training certificates for operators of hand-held devices and make them available for inspection at the registered facility.

(3) Hand-held diagnostic x-ray devices shall comply with the following requirements:

(i) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(ii) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10\,(\bar{X}_1 + \bar{X}_2),$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(iii) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(iv) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(v) Beam Quality. All certified hand-held dental x-ray devices shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.4(e)(1).

(4) The use of hand-held diagnostic x-ray devices shall be in accordance with the following:

(i) The device shall be secured between planned uses from unauthorized use or removal. A description of where and how the device will be secured shall be provided to the Department before first use of the device.

(ii) The device shall have an inherent safety mechanism to prevent accidental exposures when the device is "on" but not active between imaging procedures. The device shall be maintained in lock down (safety engaged) mode at all times between patient exposures so that the device cannot be accidentally operated.

(iii) The device shall have a permanent non-removable shield in order to protect the operator from backscatter of radiation.

(iv) Only persons who are licensed, registered or certified to operate radiographic equipment in Maryland may make exposures using the device.

(v) The operator of a device shall wear a whole-body dosimeter at all times when taking an exposure. ALARA practices shall be in place during use of the device.

(vi) The device shall not be operated if a person other than the patient, operator, and others directly involved in providing care, are present in the room in which the x-ray device will be operated. As provided in F.3(a)(1)(v), if such person(s) are required to be present for the purpose of aiding in the procedure, such person(s) shall be provided with and required to wear full body shielding of no less than 0.25 millimeter lead equivalent and shall be required to remain out of the direct beam. If other persons are present in the room who are not being treated and cannot be removed from the room, the shielding and distance requirements in F.3(a)(1)(v) shall apply.

(vii) Use of a hand-held device is allowed in dental offices as a replacement for or in addition to the use of permanent wall-mounted or free-standing portable dental x-ray machines, when it is determined by the authorized provider that it is not possible or is not safe to attempt to expose a radiograph using a wall mounted or portable stand mounted x-ray machine. A device designed to be hand-held may be permanently installed in an appropriate support frame and used as a free-standing portable dental x-ray machine.

(viii) Use of a hand-held device in a school or group environment for screening purposes is prohibited, except hand-held devices may be used for health diagnostic purposes only after an authorized practitioner's oral examination of a patient as part of an overall screening procedure and finding of clinical indication for device use. Provisions for protection of persons other than the patient set forth in F.3(a)(1)(v) shall be enforced.

(ix) The registrant shall keep a log of the hand-held device's usage on a form as provided by the Department. Devices shall only be transported to and from the registered facility in accordance with the provisions of D.802(b). Commercial transportation is permitted only for receipt and repair of the device.

(x) The Department reserves the right to perform an unannounced audit limited to the use of hand-held devices at facilities that are registered to use such devices in order to ensure that hand-held devices at the facility are being utilized and stored in accordance with these regulations.

(xi) Missing or stolen hand-held devices shall be reported to the Department immediately. A written report of the loss including all available details shall be submitted to the Department within 24 hours.

(xii) Hand-held devices shall only be used with dental film speeds E or faster or with digital imaging.

(j) Requirements for Patient Safety.

Thyroid shielding consisting of a ≥0.5 mm lead equivalent thyroid collar or shield shall be provided to and used for all patients, so long as such shielding does not interfere with diagnostic x-ray procedures.

Therapeutic X-Ray Systems

Sec. F.8 Therapeutic X-Ray Systems of Less Than One MeV Including Electronic Brachytherapy Systems.

(a) Equipment Requirements.

(1) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.

(i) Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 μC/kg) per hour at 5 centimeters from the surface of the tube housing assembly.

(ii) 0-150 kVp Systems. Systems which were manufactured or installed prior to December 6, l982 shall have a leakage radiation which does not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source.

(iii) 0-150 kVp Systems. Systems which are manufactured on or after December 6, l982 shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour at 1 meter from the source.

(iv) 151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam 1 meter from the source.

(2) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(3) Removable and Adjustable Beam Limiting Devices.

(i) Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(ii) Adjustable beam limiting devices installed after December 6, l982 shall meet the requirements of F.8(a)(3)(i).

(iii) Adjustable beam limiting devices installed before December 6, l982 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

(4) Filter System. The filter system shall be so designed that:

(i) the filters cannot be accidentally displaced at any possible tube orientation;

(ii) the radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions; and

(iii) each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

(5) Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.

(6) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Beam Monitor System. Systems of greater than 150 kVp manufactured after December 6, l982 shall be provided with a beam monitor system which:

(i) shall have the detector of the monitor system interlocked to prevent incorrect positioning;

(ii) shall not allow irradiation until a pre-selected value of exposure has been made at the treatment control panel;

(iii) shall independently terminate irradiation when the preselected exposure has been reached;

(iv) shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

(v) shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;

(vi) shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and

(vii) shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

(9) Timer.

(i) A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

(ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(iii) The timer shall terminate irradiation when a pre-selected time has elapsed if any dose monitoring system present has not previously terminated irradiation.

(iv) The timer shall permit accurate presetting and determination of exposure times as short as 1 second.

(v) The timer shall not permit an exposure if set at zero.

(vi) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

(10) Control Panel Functions. The control panel, in addition to the displays required in other provisions of F.8, shall have:

(i) an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(ii) an indication of whether x rays are being produced;

(iii) means for indicating x-ray tube potential and current;

(iv) means for terminating an exposure at any time;

(v) a locking device which will prevent unauthorized use of the x-ray system; and

(vi) for x-ray systems manufactured after December 6, l982, a positive display of specific filter(s) in the beam.

(11) Multiple Tubes. When a control panel may energize more than one x-ray tube:

(i) It shall be possible to activate only one x-ray tube at any time.

(ii) There shall be an indication at the control panel identifying which x-ray tube is energized.

(iii) There shall be an indication at the tube housing assembly when that tube is energized.

(12) Source-to-Skin Distance. There shall be means of determining the SSD to within 1 centimeter.

(13) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,

(i) after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and

(ii) an indication of shutter position shall appear at the control panel.

(14) Low-Filtration X-Ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(b) Facility Design Requirements for X-Ray Systems Capable of Operating Above 50 kVp.

(1) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

(2) Viewing Systems.

(i) Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(ii) When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

(3) Shielding and Safety Design Requirements. Shielding and safety design must be adequate to meet the following requirements:

(i). Each therapeutic radiation machine shall be provided with such shielding barriers as are necessary to assure compliance with Part D of these regulations.

(4) Additional Requirements for X-Ray Systems Capable of Operation Above 150 kVp.

(i) All protective barriers shall be fixed except for entrance doors or beam interceptors.

(ii) The control panel shall be located outside the treatment room.

(iii) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(iv) When any door referred to in F.8(b)(3)(iii) is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens (25.8 μC/kg) per hour.

(c) Surveys, Calibrations, Spot Checks, and Operating Procedures.

(1) Surveys.

(i) All new facilities, and existing facilities not previously surveyed, shall have a survey made in accordance with D.501. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(ii) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.

(iii) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations.

(2) Calibrations.

(i) The calibration of an x-ray system shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output.

(ii) The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.

(iii) Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated at intervals not to exceed 12 months.

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(iv) The calibrations shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty of 5 percent.

(v) The calibration of the x-ray system shall include, but not be limited to, the following determinations:

(a) verification that the x-ray system is operating in compliance with the design specifications;

(b) the exposure rates as a function of field size, technique factors, filter, and treatment distance used;

(c) the degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

(d) an evaluation of the uniformity of the largest radiation field used.

(vi) Records of calibration shall be maintained by the registrant for 5 years after completion of the calibration.

(vii) A copy of the most recent x-ray system calibration shall be available at or in the area of the control panel.

(3) Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

(i) The spot-check procedures shall be in writing and shall have been developed by a qualified expert. A copy of the procedures shall be submitted to the Agency prior to their implementation.

(ii) If a qualified expert does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.

(iii) The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in F.8(c)(2). The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in F.8(c)(2) shall be stated.

(iv) The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation.

(v) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in F.8(c)(2).

(vi) Records of spot-check measurements shall be maintained by the registrant for 2 years after completion of the spot-check measurements and any necessary corrective actions.

(vii) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of F.8(c)(2) or which has been intercompared with a system meeting those requirements within the previous year.

(4) Operating Procedures.

(i) X-ray systems shall not be left unattended unless the system is secured against unauthorized use.

(ii) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(iii) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

(iv) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of D.201 of these regulations. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.

(v) The x-ray system shall not be used in the administration of radiation therapy unless the requirements of F.8(c)(2) and F.8(c)(3)(v) have been met.

(vi) If applicable, provision shall be made to prevent operation of more than one therapeutic radiation medicine in a treatment room.

(vii) Access to the treatment room shall be controlled to prevent the presence of authorized parties during treatment.

(d) Training for Therapeutic Radiation Machine Authorized Providers. The registrant for any therapeutic radiation machine subject to F.8 shall require the authorized provider to be a physician who:

(1) Is certified in:

(i) Radiation oncology or therapeutic radiology by the American Board of Radiology, or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

(ii) Radiation oncology by the American Osteopathic Board of Radiology; or

(iii) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology;" or

(iv) 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, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

(i) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(d) Mathematics pertaining to the use and measurement of ionizing radiation; and

(e) Radiation biology.

(ii) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized provider and shall include:

(a) Review of the full calibration measurements and periodic quality assurance checks;

(b) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;

(c) Using administrative controls to prevent misadministrations;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(e) Checking and using radiation survey meters.

(iii) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) 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 (2) years of clinical experience in therapeutic radiology under the supervision of an authorized provider. The supervised clinical experience shall include:

(a) Examination of patients including the review of their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications.

(b) Selecting proper dose and how it is to be administered;

(c) Calculating therapeutic radiation machine doses and collaborating with the authorized provider 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

(d) Post-administration follow-up and review of case histories.

(e) Qualifications and Training of Operators.

(1) Individuals who operate a therapeutic radiation machine in Maryland shall be licensed or certified by the Maryland Department of Health to energize a radiation machine. Operation of a therapeutic radiation machine shall be by, or in accordance with, a specific order by a physician who is a licensed practitioner of the healing arts.

(2) Individuals, including physicians, who will be operating the x-ray systems shall receive adequate instruction in order to competently and safely operate the equipment. A registrant must demonstrate that a radiation therapist employed by the registrant is adequately trained and competent to use a radiation machine as required under COMAR 10.32.10.05-1 and must conspicuously display the therapist's certificate.

(3) The names and training records of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall 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.

(f) Procedures for Administrations. The registrant shall develop, implement, and maintain written procedures for administrations to ensure the following are met:

(1) Prior to the administration of each course of radiation treatments, the patient's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives. This is verified by:

(i) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and

(ii) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

Sec. F.9 X-Ray and Electron Teletherapy Systems with Energies of One MeV and Above. In addition to the provisions of Section F.9, Part I except I.11(d) and I.11(e) shall apply to medical facilities using teletherapy systems with energies 1 MeV and above.

(a) Definitions. In addition to the definitions provided in F.2, the following definitions shall be applicable to F.9:

"Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.

"Beam scattering filter" means a filter used in order to scatter a beam of electrons.

"Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

"Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

"Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

"Existing equipment" means therapy systems subject to F.9 which were manufactured on or before January 1, 1985.

"Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x rays at a specified depth.

"Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

"Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

"Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

"New equipment" means systems subject to F.9 which were manufactured after January 1, 1985.

"Normal treatment distance" means:

(1) for electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(2) for x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

"Radiation head" means the structure from which the useful beam emerges.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.

"Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

"Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

"Virtual source" means a point from which radiation appears to originate.

(b) Requirements for Equipment.

(1) Leakage Radiation to the Patient Area.

(i) New equipment shall meet the following requirements:

(a) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

(b) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in F.9(b)(1)(i)(a) for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Agency.

(ii) Existing equipment shall meet the following requirements:

(a) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meters radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(b) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in F.9(b)(1)(ii)(a) for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Agency.

(2) Leakage Radiation Outside the Patient Area for New Equipment.

(i) The absorbed dose in rads (grays) due to leakage radiation except in the area specified in F.9(b)(1)(i)(a) when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in F.9(b)(1)(i)(a).

(ii) The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in F.9(b)(2)(i) for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

(3) Beam Limiting Devices. Adjustable or interchangeable beam limiting devices shall be provided, and such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.

(4) Filters.

(i) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

(ii) If the absorbed dose rate data required by F.9(b)(16) relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

(iii) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(a) irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

(b) an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(c) a display shall be provided at the treatment control panel showing the filter(s) in use; and

(d) an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

(5) Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

(i) The absorbed dose resulting from x rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

Table III

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

(ii) Compliance with F.9(b)(5)(i) shall be determined using:

(a) a measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

(b) the largest field size available which does not exceed 15 by 15 centimeters; and

(c) a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

(iii) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

Table IV

Maximum Photon Energy In MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

(iv) Compliance with F.9(b)(5)(iii) shall be determined by measurements made:

(a) within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

(b) using a phantom whose size and placement meet the requirements of F.9(b)(5)(ii);

(c) after removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

(d) using the largest field size available which does not exceed 15 by 15 centimeters.

(v) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.

(6) Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

(i) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

(ii) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

(iii) The detector and the system into which that detector is incorporated shall meet the following requirements:

(a) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

(b) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(c) Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

(d) For new equipment, the design of the dose monitoring systems shall assure that:

(1) The malfunctioning of one system shall not affect the correct functioning of the second system; and

(2) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

(e) Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

(1) maintain a reading until intentionally reset to zero;

(2) have only one scale and no scale multiplying factors;

(3) utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

(4) in the event of power failure, the dose monitoring information required in F.9(b)(6)(iii)(e) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20- minute period of time.

(7) Beam Symmetry. In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

(8) Selection and Display of Dose Monitor Units.

(i) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

(ii) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(iii) After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

(iv) For new equipment after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

(9) Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.

(i) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

(ii) If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(iii) For new equipment, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(iv) For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

(10) Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(11) Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

(12) Timer.

(i) A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

(ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(iii) For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

(iv) The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

(13) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(i) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

(ii) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

(iii) An interlock system shall 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.

(iv) An interlock system shall be provided to prevent irradiation with x rays except to obtain a port film when electron applicators are fitted.

(v) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

(vi) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(14) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(i) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

(ii) An interlock system shall 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.

(iii) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

(iv) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

(15) Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

(i) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

(ii) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

(iii) An interlock system shall 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.

(iv) The mode of operation shall be displayed at the treatment control panel.

(v) For new equipment, an interlock system shall be provided to terminate irradiation if:

(a) movement of the gantry occurs during stationary beam therapy; or

(b) movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

(vi) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(a) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.

(b) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

(vii) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by F.9(b)(9).

(16) Absorbed Dose Rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.[3] In addition:

(i) The dose monitor unit rate shall be displayed at the treatment control panel.

(ii) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.

(17) Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

(i) The x-ray target or the virtual source of x rays; and

(ii) The electron window or the virtual source of electrons if the system has electron beam capabilities.

(18) System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

(c) Facility and Shielding Requirements. In addition to Parts B and D of these regulations, the following design requirements shall apply:

(1) Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

(2) Control Panel. The control panel shall be located outside the treatment room.

(3) Viewing Systems.

(i) Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.

(ii) When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

(4) Aural Communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.

[3] The radiation detectors specified in F.9(b)(6) may form part of this system.

(5) Room Entrances. Each treatment room entrance shall be provided with a conspicuously visible warning light, activated by the physical detection of radiation, that operates when and only when the very high levels of radiation exist inside the area.

(6) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(d) Surveys, Calibrations, Spot Checks, and Operating Procedures.

(1) Surveys.

(i) Prior to operation of the facility, and after giving two weeks written notice to the Agency, all new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(ii) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.

(iii) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations.

(2) Calibrations.

(i) The calibration of systems subject to Section F.9 shall be performed in accordance with an established calibration protocol acceptable to the Agency:[4]

(a) Before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam; and

(b) be verified and confirmed in writing by a secondary source, which shall include a second qualified expert or a separate method of calculation, before the first medical use following installation, re-installation, or re-calibration of the therapeutic radiation machine.

(ii) The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.

(iii) Calibration radiation measurements required by F.9(d)(2)(i) shall be performed using a dosimetry system:

(a) having a calibration factor for cobalt-60 gamma rays traceable to a national standard;

[4] The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the Agency for concurrence that the protocol is acceptable.

(b) which has been calibrated within the previous 2 years and after any servicing that may have affected its calibration.

(c) which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

(d) which has had constancy checks performed on the system as specified by a radiological physicist.

(iv) Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of 5 percent.

(v) The calibration of the therapy beam shall include but not be limited to the following determinations:

(a) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth,

(b) the absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam,

(c) the uniformity of the radiation field and any dependency upon the direction of the useful beam,

(d) verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions,

(e) verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

(vi) Records of calibration measurements under F.9(d)(2)(i) and dosimetry system calibrations under F.9(d)(2)(iii) shall be maintained for 5 years after completion of the full calibration.

(vii) A copy of the latest calibration and verification performed pursuant to F.9(d)(2)(i) shall be available in the area of the control panel.

(3) Spot checks. Spot checks shall be performed on systems subject to F.9 during calibrations and thereafter at intervals not to exceed 1 month. Such spot checks shall meet the following requirements:

(i) The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.

(ii) If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

(iii) The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

(iv) At intervals not to exceed 1 week, spot checks shall be made of absorbed dose measurements at a minimum of 2 depths in a phantom.

(v) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.

(vi) The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

(vii) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in F.9(d)(2).

(viii) Records of spot-check measurements shall be maintained by the registrant for a period of 2 years after completion of the spot-check measurements and any necessary corrective actions.

(ix) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of F.9(d)(2)(iii) or which has been intercompared with a system meeting those requirements within the previous year.

(4) Operating Procedures.

(i) No individual other than the patient shall be in the treatment room during treatment of a patient.

(ii) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(iii) The system shall not be used in the administration of radiation therapy unless the requirements of F.9(d)(1), (2), and (3) have been met.

(e) Personnel Requirement. All persons utilized as a qualified expert or radiological physicist shall be licensed by the Agency under COMAR 26.12.02.03.

(f) Procedures for Therapeutic Administrations. The registrant shall develop, implement, and maintain written safety procedures for therapeutic administrations.

(1) Each administration shall be in accordance with the written directive and the registrant's written safety procedures.

(2) Prior to the administration of each course of radiation treatment, the patient's identity shall be verified by more than one method as the individual named in the written directive.

(3) Therapeutic radiation machine final plans of treatment and related calculations shall include the following:

(i) Checking both manual and computer-generated dose calculations to verify they are correct; and

(ii) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units.

(4) Any misadministration shall be identified, evaluated and appropriate action taken in accordance with D.1208.

(5) The registrant shall retain a copy of the written safety procedures for administrations, including any restrictions required for the safe operation of the particular therapeutic radiation machine, in the control area of a therapeutic radiation machine for the duration of the registration.

(g) Machine Operator Records Retention. The names and the training records of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall 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.

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Other Diagnostic X-Ray Systems

Sec. F.10 Veterinary Medicine Radiographic Installations.

(a) Equipment.

(1) The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC/kg), or 0.88 milligray, in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the protective tube housing. Except for certified systems, a method shall be provided to indicate the SID to within 2 inches.

(i) A method shall 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 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, or

(ii) 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.

(3) The total filtration permanently in the useful beam shall 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) Means shall 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. Such means shall provide that the resulting time interval, product of current and time, number of pulses or radiation exposure is accurate to within ten percent of the true value.

(i) 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) Timer Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\bar{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$\bar{T} \geq 5\ (T_{max} - T_{min})$$

(iii) Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\bar{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5\ (E_{max} - E_{min})$$

(iv) kVp Accuracy. Except for certified systems, the true value of kVp shall not be different from the indicated value by greater than ten percent.

(5) A dead-man type of exposure switch shall be provided, together with an approved electrical actuator cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83 m) from the animal during all x-ray exposures.

(6) Beam Limitation for Portable or Stationary X-Ray Systems. Beam limitation for portable and stationary veterinary x-ray systems shall meet the beam limitation requirements of F.10(a)(2)(i) and

(i) There shall 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 shall be equal to or less than 5 centimeters by 5 centimeters.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall 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.

(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 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 shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(iv) A method shall be provided to indicate the SID to within 2 percent of its true value when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with D.201, D.207, and D.301 of these regulations.

(c) Operating Procedures.

(1) Except when using hand-held devices, the operator shall stand well away from the useful beam and the animal during radiographic exposures.

(2) No individual other than the operator shall 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 shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

(4) At no time shall minors be used as animal holders for positioning, restraint or assistance during a radiographic or fluoroscopic examination.

(d) Additional Requirements Applicable to Hand-Held Radiographic Devices.

(1) Equipment.

(i) The protective tube housing shall meet the requirements of F.4(c).

(ii) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall meet the requirements of Sections F.6(a)(1)(ii) or F.6(a)(5), and F.6(a)(6), and shall provide the same degree of protection as is required of the protective tube housing.

(iii) The total filtration permanently in the useful beam shall 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.

(iv) A device shall be provided to terminate the exposure after a preset time or exposure.

(2) Conditions of Use.

(i) A hand-held radiation machine is allowed in veterinary offices as a replacement for or in addition to the use of a standard radiographic machine, or may be used as a portable veterinary radiation machine in the field at remote locations.

(ii) A device designed to be hand-held may be permanently installed in an appropriate support frame and used as a free-standing portable x-ray machine.

(3) Additional Requirements Applicable to Systems Specifically Designed to be Hand-Held.

(i) Each hand-held diagnostic x-ray device shall be FDA approved and registered with the Agency for hand-held operation as part of the facility registration. Registration shall include a description of how the hand-held device(s) will be secured in accordance with F.10(d)(4)(v).

(ii) Each individual operating a hand-held diagnostic x-ray device shall, before using the device, complete the manufacturer's training for use of the device. The registrant shall maintain training certificates for operators of hand-held devices and make them available for inspection at the registered facility.

(iii) Hand-held diagnostic x-ray devices shall comply with the following requirements:

(a) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(b) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10\ (\bar{X}_1 + \bar{X}_2),$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(c) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(d) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(e) Beam Quality. All certified hand-held x-ray devices shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.4(e)(1).

(4) Hand Held Operating Procedures.

(i) A log of hand-held usage must be maintained on a form provided by the Agency.

(ii) Hand-held radiation machines require film speeds of 400 ASA or faster or with digital imaging.

(iii) Each individual operating a hand-held device must complete the manufacturer's training and submit the training certificate(s) to the Agency. The records will be maintained by the Agency as part of the facility registration.

(iv) When registering the device, the facility must indicate to the Agency that the intended manner of use is hand-held operation.

(v) The device shall be locked up after use and a description of where and how the device will be stored must be provided to the Agency.

(vi) The device must be in lock down (Safety) mode when it is not active so that exposures cannot be taken.

(vii) The device shall have a permanently mounted non-removable shield in order to protect the operator from backscatter radiation.

(viii) Only those persons licensed to operate radiographic equipment in the State of Maryland are permitted to make exposures using this device.

(ix) The operator must wear a whole-body dosimeter when taking an exposure.

(x) If the device is missing or stolen, the facility must immediately report such loss or theft to the Agency.

Sec. F.11 Computed Tomography X-Ray Systems.

(a) Definitions. In addition to the definitions provided in A.2 and F.2 of these regulations, the following definitions shall be applicable to F.11:

"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:

$$CTDI = (1/nT) \int_{-7T}^{+7T} D(z)dz$$

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.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:
μ_x = Linear attenuation coefficient of the material of interest.
μ_w = Linear attenuation coefficient of water.
$(CTN)_x$ = CTN of the material of interest.
$(CTN)_w$ = CTN of water.

"CS" (See "Contrast scale")

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in F.2.

"CTDI" (See "Computed tomography dose index")

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number")

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant[5]

μ_x = Linear attenuation coefficient of the material of interest
μ_w = Linear attenuation coefficient of water

"Dose profile" means the dose as a function of position along a line.

"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".)

"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.

"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:

$$S_n = \frac{100 \times CS \times s}{\mu_w}$$

where:

CS = Contrast scale
μ_w = Linear attenuation coefficient of water
s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image

"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.

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"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.

[5] The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(b) Requirements for Equipment.

(1) Termination of Exposure.

(i) Means shall 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 shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

(ii) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by F.11(b)(1)(i).

(iii) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

(2) Tomographic Plane Indication and Alignment.

(i) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(ii) For any multiple tomogram system, means shall 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.

(iii) If a device using a light source is used to satisfy F.11(b)(2)(i) or (ii), the light source shall 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.

(i) The CT x-ray control and gantry shall provide visual indication whenever x rays are produced and, if applicable, whether the shutter is open or closed.

(ii) Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall 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 shall be visible from any position from which scan initiation is possible.

(5) Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by F.4(c).

(6) Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall 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.

(i) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

(ii) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall 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.

(iii) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall 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.

(iv) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

(c) Facility Design Requirements.

(1) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing Systems.

(i) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(ii) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(d) Surveys, Calibrations, Spot Checks, and Operating Procedures.

(1) Surveys.

(i) All CT x-ray systems installed after October 9, 1995 and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(ii) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Agency upon request.

(2) Radiation Calibrations.

(i) The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

(ii) The calibration of a CT x-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

(iii) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

(iv) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(a) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall 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.

(b) CT dosimetry phantom(s) shall 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.

(c) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall 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.

(d) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(v) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(vi) Calibration shall meet the following requirements:

(a) 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 shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.

(b) The CTDI[6] along the two axes specified in F.11(d)(2)(iv)(b)shall be measured. The CT dosimetry phantom shall 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

[6] 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.

of operation shall correspond to typical values used by the registrant.

(c) The spot checks specified in F.11(d)(3) shall be made.

(vii) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.

(3) Spot Checks.

(i) The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

(ii) The spot-check procedures shall 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.

(iii) All spot checks shall be included in the calibration required by F.11(d)(2) and at time intervals and under system conditions specified by a qualified expert.

(iv) Spot checks shall 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 F.11(d)(2). The images shall be retained, until a new calibration is performed, in two forms as follows:

(a) photographic copies of the images obtained from the image display device; and

(b) images stored in digital form on a storage medium compatible with the CT x-ray system.

(v) Written records of the spot checks performed shall be maintained for inspection by the Agency.

(4) Operating Procedures.

(i) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

(ii) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(a) dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(b) 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;

(c) the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(d) 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.

(iii) 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 qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

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Part G

USE OF RADIONUCLIDES IN THE HEALING ARTS

General Regulatory Information

Sec. G.1 Purpose and Scope. This part establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

Sec. G.2 Definitions. As used in this part, the following definitions apply:

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

"Associate Radiation Safety Officer" means an individual who:

(1) Meets the requirements in G.50 and G.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(i) A specific medical use license issued by the NRC or an Agreement State; or

(ii) A medical use permit issued by an NRC master material licensee.

"Authorized medical physicist" means an individual who:

(1) Meets the requirements in G.51(a) and G.59, or

(2) Is identified as an authorized medical physicist or teletherapy physicist on:

(i) A specific medical use license issued by the NRC or Agreement State;

(ii) A medical use permit issued by an NRC master material licensee;

(iii) A permit issued by an NRC or Agreement State broad scope medical use licensee; or

(iv) A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in G.59 and G.190(a), G.290(a), G.390(a), G.392(a), G.394(a), G.490(a), G.590(a), or G.690(a); or

(2) Is identified as an authorized user on:

(i) An Agreement State or NRC license that authorizes the medical use of radioactive material;

(ii) A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

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(iii) A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(iv) A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

"Brachytherapy" means a method of radiation therapy in which sources are used 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 area of use or a temporary job site for the purpose of providing mobile medical service in accordance with G.80.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

“High dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

“Hub” means the main office of a mobile nuclear medicine service where patient doses are received from a manufacturer or distributor, where patient doses are assayed prior to being delivered to the point of use, and where records are maintained for Agency inspection.

“Low dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

"Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee’s activities, or those persons’ delegate or delegates.

“Manual brachytherapy” means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

"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.

"Mobile medical service” means the transportation of radioactive material to and its medical use at the client's address.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

“Ophthalmic physicist” means an individual who:

(1) Meets the requirements in G.433 (a) and G.59; and

(2) Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the NRC or an Agreement State;

(ii) Permit issued by the NRC or an Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by an NRC master material licensee; or

(iv) Permit issued by an NRC master materials licensee broad scope medical use permittee.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

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“Preceptor” means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, Radiation Safety Officer, or an Associate Radiation Safety Officer.

“Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented:

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to G.100 and G.200.

"Recordable event" means the administration of:

(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) The difference between the administered dosage and the prescribed dosage exceeds 15 microcuries;

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs by more than 10 percent of the prescribed dose.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an Agency license.

“Treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

Secs. G.3 – G.5 Reserved.

Sec. G.6 Provisions for the Protection of Human Research Subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its Agency medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

Secs. G.7 – G.10 Reserved.

Sec. G.11 License Required.

(a) A person shall not manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use except in accordance with a specific license issued by the Agency, the NRC, or any other Agreement State, or as allowed in G.11(b) or G.11(c).

(b) Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in this part under the supervision of an authorized user as provided in G.27.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in this part under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.27, unless prohibited by license condition.

(d) Exemptions. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of G.12(b)(2);

(2) The provisions of G.12(b)(5) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provisions of §G.14(a);

(4) The provisions of §G.14(b)(1) for an authorized user or an authorized nuclear pharmacist; and

(5) Requesting amendments requesting sealed sources and devices manufactured and distributed in accordance with Sec. C.28(l).

Sec. G.12 License Applications and Amendments.

(a) Applications.

(1) An application for a license, license amendment, or license renewal must be signed by the applicant's or licensee's management.

(2) An application for a license, license amendment, or license renewal under this part must be made by filing the application on a form prescribed by the Agency.

(3) An applicant that satisfies the requirements specified in Sec. C.27(b) may apply for a Type A specific license of broad scope.

(b) Amendments. A licensee shall apply for and must receive a license amendment:

(1) Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part but not permitted by the license issued pursuant to this part;

(2) Before it permits anyone to work as an authorized user, ophthalmic physicist, authorized nuclear pharmacist, or authorized medical physicist under the license except an individual who is:

(i) An authorized user in each category of use certified by the organizations specified in G.51(a), G.57(a), G.190(a), G.290(a), G.390(a), G.392(a), G.394(a), G.396(a), G.490(a), G.491(a) and G.590(a);

(ii) An authorized nuclear pharmacist certified by the organization specified in G.55(a);

(iii) Identified as an authorized user or an authorized nuclear pharmacist on a license issued by the Agency, the NRC or any other Agreement State that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

(iv) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by the Agency, the NRC or any other Agreement State licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively;

(3) Before it changes Radiation Safety Officers or teletherapy physicists;

(4) Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

(5) Before it orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license; and

(6) Before it adds to or changes the areas of use or addresses of use identified in the application or on the license.

(7) Before it revises procedures required by G.610,G.642, G.643, and G.645, as applicable, where such revision reduces radiation safety; and

(8) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

Sec.G.13 Reserved. Sec.G.14

Notifications.

(a) A licensee shall provide to the Agency a copy of the board certification, the Agency or Agreement State license, or the permit issued by the licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, authorized medical physicist, ophthalmic physicist or an authorized nuclear pharmacist pursuant to G.12(b)(2)(i) through G.12(b)(2)(iv).

(b) A licensee shall notify the Agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, authorized medical physicist, ophthalmic physicist or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § C.31(b)

(4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § G.100 or § G.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(5) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in § G.13(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in Sec. A.12.

Secs. G.15 – G.23 Reserved.

General Administrative Requirements

Sec. G.24 Authority and Responsibilities for the Radiation Protection Program.

(a) In addition to the radiation protection program requirements of Sec. D.101, a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to the Agency; and

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(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist.

(b) A licensee's management shall 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, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under G.50 and G.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in G.24(g), if the licensee takes the actions required in G.24(b), G.24(e), G.24(g), and G.24(h) and notifies the Agency in accordance with G.14.

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with G.24(c) if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Reserved.

(g) A licensee shall 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.

(h) ALARA Program.

(1) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with Sec. D.1 of these regulations.

(2) To satisfy the requirement of G.24(h)(1):

(i) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the Radiation Safety Committee; or

(ii) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

(3) The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, 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 individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable.

(4) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(i) A commitment by management to keep occupational doses as low as reasonably achievable;

(ii) A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

(iii) Personnel exposure investigational levels as established in accordance with G.26(b)(9) that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

(iv) 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.

(i) A licensee shall retain a record of actions taken under G.24(a), G.24(b), and G.24(e) in accordance with G.2024.

Sec. G.25 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

(i) Authorizing the purchase of radioactive material;

(ii) Receiving and opening packages of radioactive material;

(iii) Storing radioactive material;

(iv) Keeping an inventory record of radioactive material;

(v) Using radioactive material safely;

(vi) Taking emergency action if control of radioactive material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks and calibrations of survey instruments and other safety equipment;

(ix) Disposing of radioactive material;

(x) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(xi) Keeping a copy of all records and reports required by the Agency regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; or

(4) For medical use sited at a medical institution or private medical licensee that is authorized for one or more therapeutic use, assist the Radiation Safety Committee in the performance of its duties.

Sec. G.26 Radiation Safety Committee. Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material. Each private medical licensee that is authorized for one or more therapeutic use shall also establish a Radiation Safety Committee.

(a) The Committee shall meet the following administrative requirements:

(1) Membership must consist of at least 3 individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service (if applicable), and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee shall meet at least once each calendar quarter.

(3) The minutes of each Radiation Safety Committee meeting shall include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) Documentation of any reviews required in Sec. D.101(c) and G.26(b).

(4) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Agency authorizes its disposition.

(b) To oversee the use of licensed material, the Committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review, on the basis of safety and with regard to the training and experience standards of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or teletherapy physicist before submitting a license application or request for amendment or renewal; or

(3) Review, pursuant to Sections G.12(b)(2)(i) through (iv), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(4) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(5) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;

(6) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

(7) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents and misadministrations involving radioactive material with respect to cause and subsequent actions taken;

(8) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

(9) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

Sec. G.27 Supervision.

(a) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by G.11(b)shall:

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and 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 established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of radioactive material.

(b) A licensee that permits 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 G.11(c), shall:

(1) 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, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

Secs.G.28–G.39 Reserved.

Sec. G.40 Written Directives.

(a) A written directive must be dated and signed by an authorized user before the 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.

(b) 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. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(c) The written directive must contain the patient or human research subject's name and the following information:

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(i) Before implantation: the treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or

(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(d) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(e) 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 is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(f) The licensee shall retain a copy of the written directive in accordance with G.2040.

Sec. G.41 Procedures for Administrations Requiring a Written Directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by G.41(a) must 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 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 G.600 or G.1000.

(5) Determining if a medical misadministration, as defined in D.1208, has occurred; and

(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(c) A licensee shall retain a copy of the procedures required in G.41 in accordance with G.2041.

Secs. G.42 – G.48 Reserved.

Sec. G.49 Suppliers for Sealed Sources or Devices for Medical Use. For medical use, a licensee may only use:

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under Sec. C., 10 CFR Part 30 and 10 CFR 32.74, or the equivalent requirements of an Agreement State;

(b) Sealed sources or devices noncommercially transferred from a 10 CFR Part 35 licensee or an Agreement State medical use licensee; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

Sec. G.50 Training For Radiation Safety Officer.

Except as provided in G.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in G.24 to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.50(d). The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page:

(1) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) 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;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates 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) (i) 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;

(ii) Have 2 years of full-time practical training and/or supervised 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 NRC or an Agreement State; or

(b) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in G.57, G.290 or G.390; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b) Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an NRC or Agreement State license or permit issued by an NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a NRC or an Agreement State license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(iii) Securing and controlling radioactive material;

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material;

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(vi) Using emergency procedures to control radioactive material; and

(vii) Disposing of radioactive material; and:

(3) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in G.50(b)(1) and G.50(d), and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c) (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by an Agreement State or the NRC under G.51(a) 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 or an Associate Radiation Safety Officer, and who meets the requirements in G.50(d); or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an NRC or an Agreement State license, a permit issued by an NRC master material licensee, a permit issued by an NRC or an Agreement State licensee of broad scope, or a permit issued by an NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer responsibilities; and meets the requirements in G.50(d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by an NRC master material license. The individual must also meet the requirements G.50 (d).

(d) 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, an Associate 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.

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Sec. G.51 Training for an Authorized Medical Physicist.

Except as provided in G.57, the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process has been approved by the NRC or an Agreement State and who meets the requirements in G.51(c). The names of board certifications which have been approved by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall 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 2 years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized under G.51 by the NRC or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in G.57, G.490, or G.690; and

(3) Pass an examination, administered by diplomates of the specialty board, that 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

(b) (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 1 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 type(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 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.51(b)(1) and G.51(c), 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 G.51, G.57, or equivalent Agreement State or NRC requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) 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.

Secs. G.52 – G.54 Reserved.

Sec. G.55 Training for an Authorized Nuclear Pharmacist.

Except as provided in G.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.55(b)(2). The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page. To have its certification process recognized, a specialty board shall 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 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that 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

(b) Has completed:

(1) 700 hours in a structured educational program consisting of both:

(i) 200 hours of 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

(ii) Supervised practical experience in a nuclear pharmacy involving:

(a) Shipping, receiving, and performing related radiation surveys;

(b) 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;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid misadministrations in the administration of radioactive material; and

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in G.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Sec. G.56 Reserved.

Sec. G.57 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

(a) (1) An individual identified as a Radiation Safety Officer, a teletherapy physicist or authorized medical physicist, or an authorized nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these regulations need not comply with the training requirements of G.50, G.51, or G.55, respectively except the Radiation Safety Officers and authorized medical physicists identified in G.57(a) must meet the training requirements in G.50(d) or G.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of G.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an NRC or an Agreement State license or an NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual 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 certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in G51, for those materials and uses that these individuals performed on or before October 24, 2005.

(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses 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 NRC, need not comply with the training requirements of G.50, G.51 or G.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(b) (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized before the effective date of these regulations need not comply with the training requirements of G.100 through G.690.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized on or before October 24, 2005 need not comply with the training requirements of G.100 through G.690 for those materials and uses that these individuals performed on or before October 24, 2005 as follows:

(i) For uses authorized under G.100 or G.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under G.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under G.400 orG.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under G.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed 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 NRC, need not comply with the training requirements of G.100 through G.690 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on a specific license for the same uses for which these individuals are authorized.

Sec. G.58 Reserved.

Sec. G.59 Recentness of Training.

The training and experience specified in Secs. G.24-G.59 and G.100 through G.690 must have been obtained within the 7 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.

General Technical Requirements

Sec. G.60.A Possession, Use, Calibration, and Check of Instruments to Measure Dosages of Alpha- or Beta-emitting Radionuclides.

(a) This section does not apply to unit dosages of alpha- and beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed by the Agency pursuant to Sec. C.28(j), or licensed by the NRC or any other Agreement State pursuant to provisions equivalent to Sec. C.28(j).

(b) For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- and beta-emitting radionuclides. The licensee shall have procedures for the use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- and beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(1) 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;

(2) Check each instrument for constancy and proper operation at the beginning of each day of use; and

(3) Maintain records of tests required in G.60.A(b)(1) and (2) for 3 years.

Sec. G.60B Possession, Use, Calibration, and Check of Dose Calibrators.

(a) All medical use licensees excluding certain mobile or temporary sites as described in Section G.63 authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries); and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(d) A licensee shall also perform checks and tests required by G.60.B(b) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each check and test required by G.60.B(b) for 3 years. The records required by G.60.B(b) shall include:

(1) For G.60.B(b)(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For G.60.B(b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the identity of the individual performing the test;

(3) For G.60.B(b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test; and

(4) For G.60.B(b)(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the identity of the individual performing the test.

Sec. G.61 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(b) To satisfy the requirements of G.61(a), the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(c) To satisfy the requirements of G.61(b), the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(d) A licensee shall check each survey instrument for proper operation with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each calibration required in G.61(a) for 3 years. The record shall include:

(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.

(f) To meet the requirements of G.61(a), G.61(b), and G.61(c), the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by G.61(e) shall be maintained by the licensee.

Sec. G.62 Reserved.

Sec. G.63 Determination of Dosages of Unsealed Radioactive Material for Mobile Medical Use.

(a) A licensee shall determine with a dose calibrator and record the activity of each dosage prior to medical use in accordance with G.60.B except where allowed in G.63(b)(2) and G.63(c)(2).

(b) For a unit dosage, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) For radiopharmaceuticals delivered directly to a hub, after measurement with a dose calibrator at the hub, a decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer or preparer licensed under Sec. C.28, or equivalent NRC or Agreement State requirements; or

(ii) An NRC 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

(iii) A PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC regulations.

(c) For other than unit dosages, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) For radiopharmaceuticals delivered directly to a hub, after measurement with a dose calibrator at the hub, a combination of volumetric measurements and mathematical calculations, based on the direct measurement made by:

(i) A manufacturer or preparer licensed under Sec. C.28 or equivalent Agreement State or NRC requirements; or

(ii) A PET radioactive drug producer licensed under C.26(g) or equivalent Agreement State or NRC requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required byG.2063.

Sec. G.64 Reserved.

Sec. G.65 Authorization for Calibration, Transmission, and Reference Sources. Any person authorized by G.11 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

(a) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Sec. C.28, or equivalent NRC or Agreement State requirements.

(b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Sec. C.28 or equivalent NRC or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(c) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(d) Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in Sec. D Appendix C.

(e) Technetium-99m in amounts as needed.

(f) Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in COMAR 26.12.01.01.A.2 except in accordance with the requirements in G.500; or

(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under .G.65.

(g) A licensee using calibration, transmission, and reference sources in accordance with the requirements in G.65(a) or (b) need not list these sources on a specific medical use license.

Sec.G.66 Reserved.

Sec.G.67 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the NRC or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with G.2067(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in Sec D.401; and

(2) File a report within 5 days of the leak test in accordance with Sec. D.1206.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 3.7 MBq (100 µCi) or less of beta or gamma-emitting material or 0.37 MBq (10 µCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with G.2067(b).

Sec. G.68 Reserved.

Sec. G.69 Labeling of Vials and Syringes.

Each syringe and vial that contains 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.

Sec. G.70 Surveys for Contamination and Ambient Radiation Dose Rate.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by G.70(a) and G.70(b) so as to be able to measure dose rates as low as 0.1 millirem (1 μSv) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by G.70(a) and G.70(b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by G.70(e) so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute (3.33 Bq).

(g) A licensee shall establish removable contamination action levels for the surveys required by G.70(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by G.70(a), (b), and (e) for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Secs. G.71 – G.74 Reserved.

Sec. G.75 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material 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).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including 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 has the potential to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing 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, in any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with G.2075(b).

Secs. G.76 – G.79 Reserved.

[1] The current version of 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).

Sec. G.80 Provision of Mobile Medical Service.

(a) A licensee providing mobile medical service shall--

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(3) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at the client's location of use;

(4) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(5) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the daily check for proper function required by this paragraph must include a constancy check;

(i) Test each dose calibrator for accuracy upon receipt, at intervals not to exceed 12 months thereafter, and after repair by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(ii) Test each dose calibrator for linearity upon receipt, at least quarterly thereafter, and after repair over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries); and

(iii) Test each dose calibrator for geometry dependence upon receipt and after repair over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(6) Mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(7) Carry two calibrated survey meters in each vehicle that is being used to transport radioactive material. Survey instruments shall be checked for proper operation with a dedicated check source before use at each client's address; and

(8) Before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed. Contamination smears of the client's address confirming unrestricted release of the area must be less than 220 disintegrations per minute for 100 square centimeters.

(b) Provide to the Agency a signed certification from all proposed authorized users that they are willing and able to perform the responsibilities of authorized user as described in G.11(b) and G.27.

(c) Radioactive material may be delivered to a mobile medical service client if that client has a license allowing possession of the radioactive material. Radioactive material delivered to the licensed client must be received and handled in conformance with the client's license.

(d) A mobile medical service shall have radioactive material delivered from the manufacturer or the distributor to an unlicensed client's address only if the radioactive material is directly received by mobile medical service licensed personnel in accordance with procedures approved under the mobile medical service license.

(e) A licensee providing mobile medical services shall retain the letter required in G.80(a)(1) and the record of each survey required in G.80(a)(8) in accordance with G.2080(a) and (b), respectively.

(f) A licensee conducting mobile medical services shall provide accurate advance written notification to the Agency, describing client's addresses and times of work using a method and frequency approved by the Agency.

Secs. G.81 – G.99 Reserved.

Unsealed Radioactive Material—Written Directive Not Required

Sec. G.100 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for which a Written Directive is Not Required.

Except for quantities that require a written directive under G.40(b), a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from a manufacturer or preparer licensed by the Agency pursuant to C.28(j), or licensed by the NRC or any other Agreement State pursuant to provisions equivalent to C.28(j); or

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements;or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or an individual under the supervision of either as specified in G.27. The authorization given in G.100(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

(d) Obtained from and prepared by an NRC 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

(e) 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.

Secs. G.101 – G.189 Reserved.

Sec. G.190 Training for Uptake, Dilution, and Excretion Studies.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.100 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall 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 G.190(c)(1)(i) through G.190(c)(1)(ii)(f); and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under G.290, G.390, or equivalent NRC or Agreement State requirements; or

(c) Has completed the following:

(1) 60 hours of training and experience, including a minimum of 8 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:

(i) 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

(ii) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.190, G.290, G.390, or equivalent NRC 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 misadministration 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

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.190 (c)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under G.100. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.57, G.190, G.290, or G.390, or equivalent NRC or Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.190, G.290, or G.390, or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.190 (c)(1).

Secs. G.191 – G.199 Reserved.

Sec. G.200 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.

Except for quantities that require a written directive under G.40(b), a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

(a) Obtained from a manufacturer or preparer licensed under Sec. C.28(j) or equivalent Agreement State or NRC requirements; or

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or an individual under the supervision of either as specified in G.27. The authorization given in G.200(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

(d) Obtained from and prepared by an Agreement State licensee or NRC 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

(e) 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.

Secs. G.201 – G.203 Reserved.

Sec. G.204 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

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(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with G.204(a).

(c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with G.2204.

(d) The licensee shall report any measurement that exceeds the limits in G.204(a) at the time of generator elution, in accordance with D.1209.

Secs. G.205 – G.289 Reserved.

Sec. G.290 Training for Imaging and Localization Studies.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.200 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the NRC and who meets the requirements in G.290(c)(2). The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Use Licensee Toolkit web page. To have its certification process recognized, a specialty board shall 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 G.290(c)(1)(i) through G.290(c)(1)(ii)(g); and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under G.390 and meets the requirements in G.290(c)(1)(ii)(g), or equivalent Agreement State or NRC requirements; or

(c) Has completed the following:

(1) 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:

(i) 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;

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in G.57, G.290, or G.290(c)(1)(ii)(g) and G.390, or equivalent Agreement State or NRC requirements. An authorized nuclear pharmacist who meets the requirements in G.55 or G.57 may provide the supervised work experience for G.290 (c)(1)(ii)(g). 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 involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclides purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.290(c)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under G.100 and G.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G..57, G..290, or G..390 and G..290(c)(1)(ii)(-g), or equivalent NRC requirements or Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in .G.57, G.290, or G.390 and G.290(c)(1)(ii)(g), or equivalent NRC requirements or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.290(c)(1).

Secs. G.291 – G.299 Reserved.

Unsealed Radioactive Material—Written Directive Required

Sec. G.300 Use of Unsealed Radioactive Material for Which a Written Directive is Required.

A licensee may use any unsealed byproduct material identified in G.390(b)(1)(ii)(g) prepared for medical use and for which a written directive is required that is:

(a) Obtained from a manufacturer or preparer licensed under Sec. C.28(j) or equivalent NRC requirement or Agreement State requirements; or

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent NRC requirements or Agreement State requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, G.390; or an individual under the supervision of either as specified in G.27. The authorization given in G.300(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

(d) Obtained from and prepared by an Agreement State or NRC licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(e) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Secs. G.301 – G.309 Reserved.

Sec. G.310 Safety Instruction.

In addition to the requirements of Sec. J.12:

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including:

(i) Routine visitation to hospitalized individuals in accordance with Sec. D.301(a)(1); and

(ii) Visitation authorized in accordance with Sec. D.301(d);

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

Secs. G.311 – G.314 Reserved.

Sec. G.315 Safety Precautions.

(a) For each patient or human research subject who cannot be released under G.75, a licensee shall:

(1) Quarter the patient or the human research subject either in:

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under G.75;

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

(3) 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 the human research subject's room; and

(4) Either 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 handle the materials and items as radioactive waste;

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Secs. G.316 – G.389 Reserved.

Sec. G.390 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.300 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.390(b)(1)(ii)(g) and G.390(b)(2). The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall 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 G.390(b)(1)(i) through G.390(b)(1)(ii)(e). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates 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

(b) (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:

(i) 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

(ii) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., G.390(b)(1)(ii)(g)) as the individual requesting authorized user status. 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 involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(f) [Reserved]

(g) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in G.390(b)(1)(ii)(g) . Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under G.1000. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(1) Oral administration of less than or equal to 1.22 giga becquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required;

(2) Oral administration of greater than 1.22 giga becquerels (33 millicuries) of sodium iodide I-131;[2]

(3) 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

[2] Experience with at least 3 cases in G.390(b)(1)(ii)(g)(*2*) also satisfies the requirement in Category G.390(b)(1)(ii)(g)(*1*).

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.390(b)(1)and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under G.300 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.57, G.390, or equivalent NRC or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, or equivalent NRC or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.390 (b)(1).

Sec. G.391 Reserved.

Sec. G.392 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries).

Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in G.392(c)(1) and G.392(c)(2) and whose certification process has been recognized by the NRC or an Agreement State The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.; or

(b) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(*1*) or (*2*), G.394, or equivalent Agreement State or NRC requirements; or

(c) (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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

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(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent NRC requirements or Agreement State requirements. A supervising authorized user who meets the requirements in G.390(b) must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*1*) or (*2*). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392(c)(1) and G.392(c)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under G.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.35.G.57, G.390, G.392, G.394, or equivalent NRC requirements or Agreement State requirements and has experience in administering dosages as specified in G.390(b)(1)(ii)(g)(1) or .390(b)(1)(ii)(g)(2); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent NRC requirements or Agreement State requirements, has experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.392(c)(1) and G.392(c)(2)..

Sec. G.393 Reserved.

Sec. G.394 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries).

Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in G.394(c)(1) and G.394(c)(2), and whose certification has been recognized by the NRC or an Agreement State. The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page); or

(b) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(2) or equivalent NRC requirements or Agreement State requirements; or

(c) (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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.394, or equivalent NRC requirements or Agreement State requirements. A supervising authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.394(c)(1) and G.394(c)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under G.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.57, G.390, G.394 , or equivalent Agreement State or NRC requirements, and has experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*2*); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.394 , or equivalent Agreement State or NRC requirements, has experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*2*), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.394(c)(1) and G.394(c)(2).

Sec. G.395 Reserved.

Sec. G.396 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

Except as provided in G.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(*3*) or G.390(b)(1)(ii)(g)(*4*), or equivalent Agreement State or NRC requirements; or

(b) Is an authorized user under G.490, G.690, or equivalent Agreement State or NRC requirements and who meets the requirements in G.396(d); or

(c) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under G.490 or G.690, and who meets the requirements in G.396(d).

(d) The physician—

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in G.390(b)(1)(ii)(g)(*3*). The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.396, or equivalent NRC or Agreement State requirements, in the parenteral administrations listed in G.390(b)(1)(ii)(g)(*3*). A supervising authorized user who meets the requirements in G390, G.396, or equivalent NRC or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

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(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in G.390(b)(1)(ii)(g)(*3*); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

Secs. G.397 – G.399 Reserved.

Manual Brachytherapy

Sec. G.400 Use of Sources for Manual Brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49(a) are met.

Secs. G.401 – G.403 Reserved.

Sec. G.404 Surveys after Source Implant and Removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall 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.

(c) A licensee shall retain a record of the surveys required by G.404(a) and G.404(b) in accordance with G.2404.

Sec.G.405 Reserved.

Sec. G.406 Brachytherapy Sources Accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with G.2406.

Secs. G.407 – G.409 Reserved.

Sec. G.410 Safety Instruction. In addition to the requirements of Sec. J.12,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the:

(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:

(i) Routine visitation of hospitalized individuals in accordance with Sec. D.301(a)(1); and

(ii) Visitation authorized in accordance with Sec. D.301(d); and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency oldies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

Secs. G.411 – G.414 Reserved.

Sec. G.415 Safety Precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under G.75, a licensee shall:

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) 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.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Secs. G.416–G.431 Reserved.

Sec. G.432 Calibration Measurements of Brachytherapy Sources.

(a) Before the first medical use of a brachytherapy source on or after the effective date of these regulations, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of G.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of G.432(a)(1) and G.432(a)(2).

(b) Instead of a licensee making its own measurements as required in G.432(a), the 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 G.432(a).

(c) A licensee shall mathematically correct the outputs or activities determined in G.432(a) for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with G.2432.

Sec. G.433 Decay of Strontium-90 Sources for Ophthalmic Treatments.

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in G.433(b) are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the NRC or an Agreement State; permit issued by the NRC or Agreement State broad scope medical use licensee; medical use permit issued by an NRC master material licensee; or permit issued by an NRC master material licensee broad scope medical use permittee; and

(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(a) the creation, modification, and completion of written directives;

(b) procedures for administrations requiring a written directive;

(c) performing the calibration measurements of brachytherapy sources as detailed in G.432

(b) The individuals who are identified in paragraph (a) of this section must:

(1) 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 under § G.432; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(c) A licensee shall retain a record of the activity of each strontium-90 source in accordance with G.2433.

Secs. G.434 – G.456 Reserved.

Sec. G.457 Therapy-related Computer Systems.

The licensee shall 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:

(a) The source-specific input parameters required by the dose calculation algorithm;

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(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

Secs. G.458 – G.489 Reserved.

Sec. G.490 Training for Use of Manual Brachytherapy Sources.

Except as provided in G.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G.400 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of 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; and

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.490 or equivalent NRC requirements or Agreement State requirements at a medical institution authorized to use radioactive materials under G.400, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(f) Using emergency procedures to control radioactive material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.490 or equivalent NRC requirements of Agreement State 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 the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490(b)(1)(ii); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G. 490(b)(1) and (b)(2) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under G400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in Sections G.57, G.490, or equivalent NRC requirements or Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Sections G.57, G.490, or equivalent NRC requirements or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in Sections G.490 (b)(1) and G.490(b)(2)

Sec. G.491 Training for Ophthalmic Use of Strontium-90.

Except as provided in G.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(a) Is an authorized user under G.490 or equivalent NRC requirements or Agreement State requirements; or

(b) (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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) 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:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) 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 G.57, G.490, G.491, or equivalent NRC requirements or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.491(b) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Secs. G.492 – G.499 Reserved.

Sealed Sources for Diagnosis

Sec. G.500 Use of Sealed Sources for Diagnosis.

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of G.49(a) are met.

Secs. G.501 – G.589 Reserved.

Sec. G.590 Training for Use of Sealed Sources for Diagnosis.

Except as provided in G.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in G.590(c) and G.590(d) and whose certification has been recognized by the NRC or an Agreement State (the names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page); or

(b) Is an authorized user for uses listed in G.200 or NRC or equivalent Agreement State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

Sections G.591 – G.599 Reserved.

Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Sec. G.600 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

(a) A licensee must only use sealed sources::

(1) As approved in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration (FDA) provided the requirements of G.49(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.49(a)are met

Sections G.601 – G.603 Reserved.

Sec. G.604 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey 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 safe shielded position.

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(b) A licensee shall retain a record of these surveys in accordance with G.2404.

Sec. G.605 Installation, Maintenance, Adjustment and Repair.

(a) Only a person specifically licensed by the NRC or an Agreement State shall 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).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the NRC or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the NRC or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with G.2605.

Secs. G.606 – G.609 Reserved.

Sec. G.610 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall:

(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:

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) 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.

(b) A copy of the procedures required by G.610(a)(4) must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by G.610(a)(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.

(d) (1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(i) The procedures identified in G.610(a)(4); and

(ii) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by G.610(d) in accordance with G.2310.

(g) A licensee shall retain a copy of the procedures required by G.610(a)(4) and G.610(d)(2)(ii) in accordance with G.2610.

Secs. G.611 – G.614 Reserved.

Sec. G.615 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall 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 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.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall 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.

(e) 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.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall:

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(i) 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

(ii) 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:

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) 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 or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

Secs. G.616 – G.629 Reserved.

Sec. G.630 Dosimetry Equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards 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 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty 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 indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. 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 shall 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.

(b) The licensee shall have a dosimetry system available for use 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 G.630(a). 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 G.630(a).

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with G.2630.

Sec. G.631 Reserved.

Sec. G.632 Full Calibration Measurements on Teletherapy Units.

(a) A licensee authorized to use a teletherapy unit for medical use shall 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:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) 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 1 year.

(b) To satisfy the requirement of G.632(a), full calibration measurements must include determination of:

(1) The output within +/-3 percent 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.

(c) A licensee shall use the dosimetry system described in G.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.632(b)(1) may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by G.632(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in G.632(b)(1) for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by G.632(a) and physical decay corrections required by G.632(e) must be performed by the authorized medical physicist.

(g) A licensee shall maintain a record of each calibration in accordance with G.2632.

Sec. G.633 Full Calibration Measurements on Remote Afterloader Units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) 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 1 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 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of G.633(a), full calibration measurements must include, as applicable, determination of:

(1) The output within +/- 5 percent;

(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.

(c) A licensee shall use the dosimetry system described in G.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by G.633(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.633(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with G.633(a) through G.633(e).

(g) A licensee shall mathematically correct the outputs determined in G.633(b)(1) for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by G.633(a) and physical decay corrections required by paragraph G.633(g) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with G.2632.

Sec.G.634 Reserved.

Sec. G.635 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) 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 1 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.

(b) To satisfy the requirement of G.635(a), full calibration measurements must include determination of:

(1) The output within +/-3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in G.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.635(b)(1) may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by G.635(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in G.635(b)(1) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by G.635(a) and physical decay corrections required by G.635(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with G.2632.

Secs.G.636–G.641 Reserved.

Sec. G.642 Periodic Spot–checks for Teletherapy Units.

(a) A licensee authorized to use teletherapy units for medical use shall 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 G.630(b); and

(6) The difference between the measurement made in G.642(a)(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).

(b) A licensee shall perform measurements required by G.642(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall 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.

(e) If the results of the checks required in G.642(d) indicate the malfunction of any system, a licensee shall 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.

(f) A licensee shall maintain a record of each spot check required by G.642(a) and G.642(d), and a copy of the procedures required by G.642(b), in accordance with G.2642.

Sec. G.643 Periodic Spot-checks for Remote Afterloader Units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by G.643(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of G.643(a), 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) 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.

(e) If the results of the checks required in G.643(d) indicate the malfunction of any system, a licensee shall 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.

(f) A licensee shall retain a record of each check required by G.643(d) and a copy of the procedures required by G.643(b) in accordance with G.2643.

Sec.G.644 Reserved.

Sec. G.645 Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall 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.

(b) A licensee shall:

(1) Perform the measurements required by G.645(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of G.645(a)(1), spot-checks must, at a minimum:

(1) Assure proper operation of:

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in G.630(b);

(ii) The difference between the measurement made in G.645(c)(2)(i) 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);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of G.645(a)(2) and G.645(a)(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.

(e) A licensee shall arrange for the repair of any system identified in G.645(c) that is not operating properly as soon as possible.

(f) If the results of the checks required in G.645(d) indicate the malfunction of any system, a licensee shall 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.

(g) A licensee shall retain a record of each check required by G.645(c) and G.645(d) and a copy of the procedures required by G.645(b) in accordance with G.2645.

Sec.G.646 Reserved.

Sec. G.647 Additional Technical Requirements for Mobile Remote Afterloader Units.

(a) A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments 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.

(b) In addition to the periodic spot-checks required by G.643, a licensee authorized to use mobile afterloaders for medical use shall 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.

(c) In addition to the requirements for checks in G.647(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in G.647(b) indicate the malfunction of any system, a licensee shall 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.

(e) A licensee shall retain a record of each check required by G.647(b) in accordance with G.2647.

Secs. G.648 – G.650 Reserved.

Sec. G.651 Availability of Survey Instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 μSv) per hour to 100 millirems (1000 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with G.61.

Sec. G.652 Radiation Surveys.

(a) In addition to the survey requirement in Sec. D.501, a person licensed under this part shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by G.652(a) at 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).

(c) A licensee shall retain a record of the radiation surveys required by G.652(a) in accordance with G.2652.

Secs. G.653 – G.654 Reserved.

Sec. G.655 Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

(b) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Agency, an Agreement State, or the U.S. Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with G.2655.

Sec. G.656 Reserved.

Sec. G.657 Therapy-Related Computer Systems.

The licensee shall 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:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Secs. G.658 – G.689 Reserved.

Sec. G.690 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

Except as provided in G.57, the licensee shall require an authorized user of a sealed source for a use authorized under G.600 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.690(c). The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates 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

(b) (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:

(i) 200 hours of 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; and

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or Agreement State requirements, at a medical facility that is authorized to use radioactive materials in G.600, involving:

(a) Reviewing full calibration measurements and periodic spot-checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or Agreement State 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 the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.690(b)(1)(ii); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.690(b)(1) and G.690(b)(2), and G.690(c), and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.690(b)(1) and G.690(b)(2).

(c) Has received training in device operation, safety procedures, and clinical use for 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.

Secs. G.691 – G.999 Reserved.

Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

Sec. G.1000 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material.

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in G.100 through G.690 if:

(a) The applicant or licensee has submitted the information required by G.12(a)(2) through G.12(b); and

(b) The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the material.

Secs. G.1001 – G.2023 Reserved.

Records

Sec. G.2024 Records of Authority and Responsibilities for Radiation Protection Programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with G.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by G.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

(c) For each Associate Radiation Safety Officer appointed under G.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee’s management.

Secs. G.2025 – G.2039 Reserved.

Sec. G.2040 Records of Written Directives.

A licensee shall retain a copy of each written directive as required by G.40 for 3 years.

Sec. G.2041 Records for Procedures for Administrations Requiring a Written Directive.

A licensee shall retain a copy of the procedures required by G.41(a) for the duration of the license.

Secs. G.2042 – G.2059 Reserved.

Sec. G.2060 Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

A licensee shall maintain a record of instrument calibrations required by G.60.A and G.60.B for 3 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.

Sec. G.2061 Records of Radiation Survey Instrument Calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by G.61 for 3 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.

Sec. G.2062 Reserved.

Sec. G.2063 Records of Dosages of Unsealed Radioactive Material for Medical Use.

(a) A licensee shall maintain a record of dosage determinations required by G.63 for 3 years.

(b) The record must contain:

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

Secs.G.2064–G.2066 Reserved.

Sec. G.2067 Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources.

(a) A licensee shall retain records of leak tests required by G.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by G.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

Secs. G.2068 – G.2069 Reserved.

Sec. G.2070 Records of Surveys for Ambient Radiation Exposure Rate.

A licensee shall retain a record of each survey required by G.70 for 3 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.

Secs. G.2071 – G.2074 Reserved.

Sec. G.2075 Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with G.75, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by G.75(b) were provided to a breast-feeding female 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).

(c) The records required by G.2075(a) and G.2075(b) must be retained for 3 years after the date of release of the individual.

Secs. G.2076 – G.2079 Reserved.

Sec. G.2080 Records of Mobile Medical Services.

(a) A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by G.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by G.80(a)(8) for three (3) 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.

Secs. G.2081 – G.2203 Reserved.

Sec. G.2204 Records of Molybdenum-99 Concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by G.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum-99 per millicurie of technetium-99m), the time and date of the measurement, and the name of the individual who made the measurement.

Secs. G.2205 – G.2309 Reserved.

Sec. G.2310 Records of Safety Instruction.

A licensee shall maintain a record of safety instructions required by G.310, G.410, and the operational and safety instructions required by G.610 for 3 years. The record must include a list of the 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.

Secs. G.2311 – G.2403 Reserved.

Sec. G.2404 Records of Surveys after Source Implant and Removal.

A licensee shall maintain a record of the surveys required by G.404 and G.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Sec. G.2405 Reserved.

Sec. G.2406 Records of Brachytherapy Source Accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by G.406 for 3 years.

(b) 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.

(c) 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.

Secs. G.2407 – G.2431 Reserved.

Sec. G.2432 Records of Calibration Measurements of Brachytherapy Sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by G.432 for 3 years after the last use of the source.

(b) 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 name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Sec. G.2433 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by G.433 for the life of the source.

(b) The record must include:

(1) The date and initial activity of the source as determined under G.432; and

(2) For each decay calculation, the date and the source activity as determined under G.433.

Secs. G.2434 – G.2604 Reserved.

Sec. G.2605 Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by G.605 for 3 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.

Secs. G.2606 – G.2609 Reserved.

Sec. G.2610 Records of Safety Procedures.

A licensee shall retain a copy of the procedures required by G.610(a)(4) and G.610(d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Secs. G.2611 – G.2629 Reserved.

Sec. G.2630 Records of Dosimetry Equipment used with Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with G.630 for the duration of the license.

(b) 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 G.630(a) and G.630(b);

(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.

Sec. G.2631 Reserved.

Sec. G.2632 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery full Calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by G.632, G.633, and G.635 for 3 years.

(b) 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.

Secs. G.2633 – G.2641 Reserved.

Sec. G.2642 Records of Periodic Spot-checks for Teletherapy Units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by G.642 for 3 years.

(b) 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.

(c) A licensee shall retain a copy of the procedures required by G.642(b) until the licensee no longer possesses the teletherapy unit.

Sec. G.2643 Records of Periodic Spot-checks for Remote Afterloader Units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by G.643 for 3 years.

(b) 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.

(c) A licensee shall retain a copy of the procedures required by G.643(b) until the licensee no longer possesses the remote afterloader unit.

Sec. G.2644 Reserved.

Sec. G.2645 Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by G.645 for 3 years.

(b) 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.

(c) A licensee shall retain a copy of the procedures required by G.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Sec. G.2646 Reserved.

Sec. G.2647 Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by G.647 for 3 years.

(b) 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.

Secs.G.2648–G.2651 Reserved.

Sec. G.2652 Records of Surveys of Therapeutic Treatment Units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with G.652 for the duration of use of the unit.

(b) 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.

Secs. G.2653 – G.2654 Reserved.

Sec. G.2655 Records of 5-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by G.655 for the duration of use of the unit.

(b) 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.

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PART H

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT AND X-RAY SECURITY SCREENING

Sec. H.1 Purpose and Scope. This part provides special requirements for analytical x-ray equipment and for x-ray security screening systems. The requirements of this part are in addition to, and not in substitution for, applicable requirements in other parts of these regulations.

Sec. H.2 Definitions. As used in this part, 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.

“Backscatter system” means a security screening system that makes use of radiation scattered or deflected from an object or person to form an image of the scattering object or person.

“Bystander” means any person other than the individual being screened who is not directly associated with operation of the system.

"Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

“Full-body scanner” means any security screening system that images the full body of a person. Full-body scanners include systems in which the subject stands in place, portal systems, and multi-purpose scanners used to scan humans who are vehicle occupants. Any security screening system for which at least one dimension of the scan area is greater than 50 cm shall be considered a full-body scanner.

“General use security screening system” means a security screening system that delivers a reference effective dose equal to or less than 0.25 μSv (25 μrem) per screening.

“Inspection zone” means the general area established by the operating institution for the purpose of limiting or controlling access to the area where the screening will be performed. This includes but is not limited to any ingress, egress, gate, portal, traffic path, and areas, access to which is restricted due to the presence of radiation. The ambient dose equivalent outside of the inspection zone shall not exceed 20 μSv (2 mrem) in any 1 hour.

“Limited-use security screening system” means a security screening system that is capable of delivering an effective dose greater than 0.25 µSv (25 µrem) per screening but shall not exceed a reference effective dose of 10 µSv (1 mrem) per screening.

"Local components" mean part of an analytical x-ray system and include areas that are struck by x rays such as radiation source housings, 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 shall 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.

“Operator” means any employee associated with the operation of the security screening system whose responsibilities include at least one of the following: initiating or stopping the scan, verifying the system is operating correctly, providing information and instructions to the screened individuals, and controlling access to the inspection zone.

“Portal system” means a system designed to image persons who move through the inspection zone under their own control, by a moving walkway, or within a vehicle. It does not include systems that move the individual through the inspection zone in a controlled manner, such as a moving platform on which the subject is normally required to remain still (see Stationary-subject system).

"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.

“Reference effective dose” means a quantity based on measurable parameters used by the ANSI/HPS N43.17-2009 standard for setting dose limits. It is derived from the effective dose to the average adult as defined in ICRU Report 57 (ICRU 1998) and as modified by ICRP Publication 103 (ICRP 2007). It is obtained from air kerma and HVL measurements as described in Section 6.1.3 of the ANSI/HPS standard, “Determination of the Reference Effective Dose.”

“Reference plane” means the plane containing the reference measuring point and is perpendicular to the beam direction at the reference point (used only for partial-body scanners).

“Scan” means the operation necessary to produce one image (e.g., front view) from one radiation source. One radiation source simultaneously producing multiple images also constitutes one scan. Two sources simultaneously producing two images constitute two scans. In some cases several scans may be required for a single screening of the subject.

“Scan area” means the total area on the reference plane that is covered by the primary beam as it scans.

“Screening” means the sum of radiation exposures or scans necessary to image objects concealed on all sides of the body as intended by the system design under normal conditions.

“Security screening system” means a system designed for the detection of contraband and weapons concealed on a person or in a vehicle while being occupied by one or more people.

“Stationary-subject system” means a system designed to image a person who remains stationary while a scan is occurring. This includes systems that move the individual through the inspection zone in a controlled manner, such as a moving platform on which the subject is normally required to remain still.

“Transmission security screening system” means a security screening system using the conventional means of radiographic imaging in which x-rays or gamma rays pass through a target (e.g., person or container) and create shadow-grams of enclosed objects (e.g., contraband) based on their radiation attenuating properties.

General Regulatory Provisions and Specific Requirements for Analytical X-Ray Equipment

Sec. H.3 Equipment Requirements.

(a) Safety Device. A 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 shall be provided on all open-beam configurations. A registrant or licensee may apply to the Agency for an exemption from the requirement of a safety device. Such application shall 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.

(b) Warning Devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of:

(i) x-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(ii) shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

(i) near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

(ii) in the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after October 10, 1982 warning devices shall have fail-safe characteristics.

(c) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(d) Labeling. All analytical x-ray equipment shall 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 Part D of these regulations if the radiation source is a radionuclide.

(e) Shutters. On open-beam configurations installed after October 10, 1982 each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

(1) Each x-ray tube housing shall 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.

Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface or for x-ray tubes at any specified tube rating is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour.

(g) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 μSv) in one hour.

Sec. H.4 Area Requirements.

(a) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall 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 Part D of these regulations. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(b) Surveys.

(1) Radiation surveys, as required by Part D of these regulations, of all analytical x-ray systems sufficient to show compliance with H.4(a) shall be performed:

(i) upon installation of the equipment, and at least once every 12 months thereafter;

(ii) following any change in the initial arrangement, number, or type of local components in the system;

(iii) following any maintenance requiring the disassembly or removal of a local component in the system;

(iv) 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;

(v) any time a visual inspection of the local components in the system reveals an abnormal condition; and

(vi) whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in Part D of these regulations.

(2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with H.4(a) to the satisfaction of the Agency.

(c) Posting. Each area or room containing analytical x-ray equipment shall 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 Part D of these regulations.

Sec. H.5 Operating Requirements.

(a) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

(b) Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall 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, shall be placed on the radiation source housing.

(c) Repair or Modification of X-Ray Tube Systems. Except as specified in H.5(b), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall 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, shall be used for routine shutdown in preparation for repairs.

(d) Radioactive Source Replacement, Testing, or Repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Sec. H.6 Personnel Requirements.

(a) Instruction. No individual shall be permitted to operate or maintain analytical x-ray equipment unless such individual has received 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, 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; and

(5) proper procedures for reporting an actual or suspected exposure.

(b) Personnel Monitoring.

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:

(i) analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

(ii) 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 shall not be used for the purpose of determining compliance with D.201 of these regulations unless evaluated by a qualified expert.

General Regulatory Requirements and Specific Requirements for X-Ray Security Screening

Sec. H.7 Purpose and Scope.

(a) This section applies to the operation of full-body security screening systems that are intended to expose humans to primary beam x-rays. Such systems include:

(1) Direct screening of humans to detect objects hidden within an individual's body or clothing; and

(2) Knowingly exposing human occupants to the primary beam when screening vehicles or structures.

(3) These regulations do not apply to backscatter systems.

(4) These regulations do not apply to partial-body scanning systems.

(b) All security screening systems shall apply to the dose limitation requirements of Section H.9.

Sec. H.8 Security Screening System Categories.

Security screening systems subject to this regulation are used for full-body scanning and are divided into two categories based on the radiation output:

(1) Category 1 - general-use security screening systems are systems in which low doses are delivered and engineering controls are incorporated in the system. Category 1 systems shall conform to the dose limitation requirements in Section H.9(b).

(2) Category 2 limited-use security screening systems are systems that require additional administrative controls in order to ensure that members of the public are not subjected to a cumulative effective dose in excess of the allowed annual limit. Category 2 systems shall conform to the dose limitation requirements in Section H.9(c).

Sec. H.9 Dose Limitation.

(a) Dose to Scanned Individuals**.** The radiation dose delivered to a scanned individual shall be as low as reasonably achievable (ALARA) while meeting the required detection performance.

(b) For Category 1 general-use security screening systems, the reference effective dose shall not exceed 0.25 µSv (25 µrem) per screening. The cumulative reference effective dose received by any individual shall not exceed 250 µSv (25 mrem) over a 12-month period. Compliance with this requirement shall be demonstrated by retaining records to demonstrate that:

(1) the number of screenings received by any individual does not exceed 1,000 per 12-month period; and

(2) the reference effective dose multiplied by the number of screenings does not exceed 250 µSv (25 mrem) over a 12-month period for any individual.

(3) Cumulative records per screened individual shall be maintained for Agency review.

(c) For Category 2 limited-use security screening systems, the following regulations shall apply:

(1) The radiation dose delivered to a human shall be maintained ALARA while meeting the desired detection performance. The reference effective dose shall not exceed 10 µSv (1 mrem) per screening.

(2) Administrative controls are required for the operation of all limited-use, full body scanners. Administrative controls shall be in the form of documented procedures that ensure that the effective dose to any individual screened shall be limited to 250 µSv (25 mrem) in any 12-month period. This shall be accomplished by maintaining records to demonstrate that the reference effective dose multiplied by the number of screenings to any individual in a 12-month period does not exceed 250 µSv (25 mrem).

(3) Compliance with this requirement shall be demonstrated by retaining records to demonstrate that dose limits are not exceeded. Cumulative records per screened individual shall be maintained for Agency review.

(4) Table 1 can be used to aid in meeting the annual dose requirement.

(5) Sensitive Groups. Alternative security screening methods shall be considered when a declared pregnant woman is to be screened utilizing a limited-use security screening system.

Table 1. The number of allowed screenings for one individual.*

Reference effective dose per screening (μSv)	(μrem)	Standard is met if number of screenings per year does not exceed	Standard is met if number of screenings every month does not exceed	Standard is met if number of screenings every week does not exceed	Standard is met if number of screenings every day does not exceed
0.25	25	1,000	83	19	2
0.5*	50	500	41	9	
1.0*	100	250	20	4	
2.0*	200	125	10	2	
3.0*	300	80	6	1	
4.0*	400	62	5	1	
5.0*	500	50	4		
10.0*	1,000	25	2		

*Applies to limited-use systems only.

(d) Determination of Reference Effective Dose.[1] The reference effective dose for full-body scanners shall be determined from measurements of the half-value layer (HVL) and air kerma (or exposure). One of the equations (1) or (2) below shall be used.

$$E_{REF} = K_a \times C \qquad \text{(eq.1)}$$

where
E_{REF} is the reference effective dose in Sv,
K_a is the measured air kerma in Gy, and
C in Sv/Gy is given by
$C = 0.125 \times$ HVL in mm of Al or
$C = 1.14$, whichever is smaller.

Or, when using traditional units the equivalent equation is

$$E_{REF} = X \times C_R \qquad \text{(eq. 1a)}$$

where
E_{REF} is the reference effective dose in rem,
X is the measured exposure in R, and
C_R in rem/R is given by
$C_R = 0.110 \times$ HVL in mm of Al or
$C_R = 1.00$, whichever is smaller.

Note: C and C_R achieve their maximum value at HVL = 9.1 mm Al. This corresponds to an effective photon energy slightly less than 60 keV. Therefore, a C of 1.14 Sv/Gy (C_R of 1.00 rem/R) shall be used for systems using ^{60}Co, ^{137}Cs, or any other isotope whose emissions equal or exceed 60 keV.

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1 A full description of the rationale and derivation of "Reference Effective Dose" is found in ANSI/HPS N43.17-2009. This document also contains Determination of Half-Value Layer at 6.1.3.1 and Measurement of Reference Air Kerma at 6.1.3.2.

(e) Dose to Bystanders, Operators, and Other Employees

(1) An inspection zone shall be established around the x-ray security screening system where bystanders are prohibited during the operation of the device. A means shall be provided for any operator responsible for initiating a scan to maintain full visual surveillance of the inspection zone. The ambient dose equivalent outside of this inspection zone shall not exceed 20 μSv (2 mrem) in any 1 hour.

(2) Any area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 mrem) in 1 hour at no less than 30 cm from a beam exit surface, a tunnel wall or virtual tunnel wall shall be posted with a sign displaying the radiation symbol as specified in Section D.901 and the words "CAUTION, RADIATION AREA."

(3) Any area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (100 mrem) in any 1 hour at no less than 30 cm from the beam exit surface, a tunnel wall or virtual tunnel wall shall be posted with a sign displaying the radiation symbol as specified in Section D.901 and the words "CAUTION, HIGH RADIATION AREA." Access control shall be maintained at all times as described in Section D.601.

(4) The system shall be positioned and operated such that the ambient dose equivalent at any work station does not exceed 1 mSv (100 mrem) per year.

Sec. H.10 Shielding Requirements.

Under maximum operating parameters, the leakage ambient dose equivalent at any point 30 cm from any external surface of the system, outside of the primary beam, shall not exceed 2.5 μSv (0.25 mrem) in any 1 hour. For units that employ a shutter this limit shall also apply to the region of the primary beam while the shutter is closed. For units that employ a beam stop this limit shall also apply to the region adjacent to the beam stop opposite the source of radiation.

Sec. H.11 System Requirements.

(a) Indicators.

(1) There shall be at least one indicator, clearly visible from any location from which a scan can be initiated, that indicates when a scan is in progress.

(2) There shall be at least one lighted indicator clearly visible from the inspection zone. For portal systems the indicator shall be visible from any approach to the inspection zone to indicate that a scan is in progress.

(3) For any x-ray system that normally keeps high voltage applied to the x-ray tube at times other than during a scan, there shall be at least one lighted "x-ray on" indicator at the control console where x-rays are initiated indicating when x-rays are being produced.

(b) Controls.

(1) Power to the system shall be controlled by a key switch. The key shall be captured (unable to be removed) whenever it is in a position that allows exposures to be initiated. Turning on the key switch shall never result in the external emission of radiation.

(2) Each system shall have a means for the operator to initiate the emission of radiation other than the function of an interlock or the main power control.

(3) Each system shall have a means for the operator to terminate the emission of radiation other than the function of an interlock.

(4) Means shall be provided to ensure that operators have a clear view of the scanning area. This can be a direct, mirror view, or real-time video of the scanning area. Engineering controls should be provided to ensure that individuals do not reenter the scanning area from the exit while x-rays are being produced (e.g., one way turnstile).

(5) Technique factors for each mode of operation shall be preset by the manufacturer and shall not be alterable by the system operator. If there is more than one mode, prior to each scan, a mode indicator shall be clearly visible to the operator.

(6) The following warning label shall be permanently affixed or inscribed on the x-ray system at the location of any controls used to initiate x-ray generation: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED."

(7) X-ray emission shall automatically terminate after a preset time or exposure.

(c) Safety interlocks.

(1) Failure of any single component of the system shall not cause failure of more than one safety interlock.

(2) A tool or key shall be required to open or remove access panels. Each access panel to the x-ray source shall have at least one safety interlock to terminate the x-ray production when opened.

(3) For stationary-subject systems, the scanning motion of the x-ray beam relative to the subject shall be interlocked and the exposure shall terminate when the rate of motion of the beam in any direction falls below a preset minimum speed. The minimum speed shall be chosen so that the dose during the exposure period is within the applicable limit.

(4) Operational interlocks shall terminate the primary beam in the event of any system problem that could result in abnormal or unintended radiation emission. This shall include, but is not limited to, unintended stoppage of beam motion, abnormal or unintended x-ray source output, computer safety system malfunction, termination malfunction, and shutter or beam stop mechanism malfunction.

(5) In the event of a malfunction, the system shall terminate radiation exposure rapidly enough so that no location on the subject's body shall receive an ambient dose equivalent exceeding 250 μSv (25 mrem), regardless of the size of the exposed area.

(6) Following interruption of x-ray production by the functioning of any safety interlock, resetting the interlock shall not result in the production of x-rays. Use of the normal control sequence shall be necessary for resumption of x-ray generation.

Sec. H.12 Operating Requirements.

(a) Responsible Individual. The facility operating the security screening system shall designate a person(s) responsible for ensuring compliance with the requirements of this section The person(s) shall have direct access to senior management for radiation safety issues. The person(s) shall have training and experience as required commensurate with the scope of the radiation safety program.

(b) Operating Procedures. The facility shall document its procedures for operating the system. These procedures shall be consistent with the manufacturer's operator's manual, and shall be readily available to the operator of each screening system. The procedures shall include the following topics:

(1) Warnings of potential safety hazards (including unauthorized modification of the system);

(2) The requirements for registration of the system in accordance with B.5 and B.9;

(3) Operational procedures and training required to use the system safely;

(4) Preventive maintenance requirements for safe operation in accordance with F.3(d);

(5) Technique factors for each operating mode and the beam quality of the primary beam; and

(6) The reference effective dose per screening measured by the manufacturer. This information shall include a definition of "screening" for the system (e.g., number of scans required).

(c) Information To Be Provided to Screened Individuals. The facility operating the system shall inform each person being screened that the system emits radiation. A poster or sign is an appropriate method of providing this information.

Sec. H.13 Personnel Training.

(a) Each operator shall be provided with radiation safety training in the operation and use of the security screening system. This radiation safety training must include, at minimum:

(1) The concept of and how to achieve ALARA;

(2) Instructions and hands-on training in safe operation of the radiation machine;

(3) Operational and environmental emergency procedures;

(4) Safety hazards;

(5) Awareness and control of inspection zones;

(6) Requirements for personnel dosimetry;

(7) Pre-operational checks;

(8) Subject positioning;

(9) Interpretation of images.

(b) Applicable regulatory requirements. Proficiency shall be demonstrated at the conclusion of training.

(c) Refresher training including all subjects in this section must be provided and taken by all operators at intervals not to exceed 12 months.

Sec. H.14 Radiation Surveys.

Radiation surveys shall be performed to verify the reference effective dose, radiation leakage, inspection zone, radiation area, and any other parameters specified by the manufacturer. The radiation surveys in this paragraph shall be performed at least once every 12 months, and after any maintenance that affects shielding, shutter, or x-ray production, and after any incident that may have damaged the system in such a way that unintended radiation emission occurs.

Sec. H.15 Records.

(a) Maintenance Logs. Records of upgrades, modifications, maintenance, and repair shall be maintained for the life of the system.

(b) System Operating Procedures. A complete set of operating procedures as required in H.12 shall be maintained for the life of the system.

(c) The facility operating a security screening system shall collect and maintain for a minimum of five years the following records on-site at the facility:

(1) Each operator's training records including sufficient information to show compliance with Section H13;

(2) Use logs for all screened individuals who could receive radiation doses approaching 0.25 mSv (25 mrem) in any 12month period, to include the name of each individual that was screened, reference effective dose per screening, the number of times and dates when each individual was screened, and cumulative reference effective dose for each individual screened, to demonstrate that the dose limits specified in Section H.9 are being met;

(3) Records of radiation surveys, to include the name of the person who performed the survey, survey date, survey and background measurements, and system parameters at which measurements were made;

(4) The number of scans conducted during each calendar year by month; and

(5) The name and contact information for the responsible individual to be contacted about the nature and use of the radiation machine(s) at the facility.

PART I

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

Sec. I.1 Purpose and Scope.

(a) This part establishes procedures for the registration and the use of particle accelerators.

(b) In addition to the requirements of this part, all registrants are subject to the requirements of Parts A, B, D, and J of these regulations. Registrants engaged in industrial radiographic operations are subject to the requirements of Part E of these regulations, and registrants engaged in the healing arts are subject to the requirements of Part F of these regulations. Registrants whose operations result in the production of radioactive material are subject to the requirements of Part C of these regulations.

Registration Procedure

Sec. I.2 Registration Requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to Part B of these regulations.

Sec. I.3 General Requirements for the Issuance of a Registration for Particle Accelerators. In addition to the requirements of Part B of these regulations, a registration application for use of a particle accelerator will be approved only if the Agency determines that:

(a) the applicant is qualified by reason of training and experience to use the accelerator for the purpose requested in accordance with this part and Parts D and J of these regulations in such a manner as to minimize danger to public health and safety or property;

(b) the applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

(c) the issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in I.4;

(d) the applicant has appointed a properly qualified radiation safety officer;

(e) the applicant and the applicant's staff have substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

(f) the applicant has established a radiation safety committee, whenever deemed necessary by the Agency, to approve in advance, proposals for uses of particle accelerators; and

(g) the applicant has an adequate training program for operators of particle accelerators.

Sec. I.4 Human Use of Particle Accelerators. In addition to the requirements of Part B of these regulations, a registration for use of a particle accelerator in the healing arts will be issued only if:

(a) the applicant has appointed a medical committee, whenever deemed necessary by the Agency, of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

(b) the individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

(c) the individual designated on the application as the user is a physician.

Radiation Safety Requirements for the Use of Particle Accelerators

Sec. I.5 Operating and Emergency Procedures.

Each registrant shall operate a particle accelerator in compliance with

(1) all information submitted to the Agency in the registrant's Form RX 3 "Application for Certified Registration of Particle Accelerator," including but not limited to operating and emergency procedures, and

(2) the accelerator manufacturer's operating, maintenance, and emergency procedures.

Sec. I.6 Limitations.

(a) No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) has received copies of and instruction in this part and the applicable requirements of Parts D and J of these regulations, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

(b) The radiation safety committee and the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

Sec. I.7 Shielding and Safety Design Requirements.

(a) A qualified expert, acceptable to the Agency, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with Part D of these regulations.

Sec. I.8 Particle Accelerator Controls and Interlock Systems.

(a) Instrumentation, readouts, and controls on the particle accelerator control console shall be functioning properly at all times, clearly identified, and easily discernible.

(b) Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

(c) Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

(d) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

(e) When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

(f) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

Sec. I.9 Warning Devices.

(a) Each location designated as a very high radiation area, and each entrance to such location, shall be equipped with a conspicuously visible warning light as specified in D.602.b.i.(4).

(b) Except in facilities designed for human exposure, each very high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such very high radiation area. Such warning device shall be clearly discernible in all very high radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to very high radiation areas shall be posted in accordance with D.902 of these regulations.

Sec. I.10 Operating Procedures.

(a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed 3 months. Results of such tests shall be maintained at the accelerator facility for inspection by the Agency.

(d) Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.

(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) authorized by the radiation safety committee or radiation safety officer;

(2) recorded in a permanent log and a notice posted at the accelerator control console; and

(3) terminated as soon as possible.

(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

Sec. I.11 Radiation Monitoring Requirements.

(a) Except for particle accelerators used in teletherapy, each location designated as a very high radiation area shall be surveyed immediately following each accelerator shutdown to determine that no radiation is emanating from the accelerator, before persons other than the surveyor are allowed to enter.

(b) There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for radiations being produced at the facility. Such equipment shall be tested for proper operation before each use and calibrated at intervals not to exceed 1 year and after each servicing and repair.

(c) A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(d) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

(e) All area monitors shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.

(f) Whenever applicable, surveys shall be made to determine the amount of airborne particulate radioactivity present.

(g) Whenever applicable, smear surveys shall be made to determine the degree of contamination.

(h) All surveys shall be made in accordance with the written procedures established by a qualified expert, acceptable to the Agency, or the radiation safety officer.

(i) Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the Agency.

Sec. I.12 Ventilation Systems.

(a) Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Part D, Appendix B, Table I of these regulations.

(b) A registrant shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in Part D, Appendix B, Table II of these regulations. For purposes of I.12(b), concentrations may be averaged over a period not greater than 1 year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

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PART J

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Sec. J.1 Purpose and Scope. This part 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 Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this part apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the Agency pursuant to Parts B and C of these regulations.

General Regulatory Provisions and Specific Requirements

Sec. J.11 Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this part, Part D and each applicable part of these regulations that apply to the activities authorized by the specific license or registration;

(2) The license, radiation machine certificate of registration, conditions and 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 Part A of these regulations, and any response from the licensee or registrant.

(b) If posting of a document specified in J.11(a)(1), (2), (3) or (4) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Agency MDE 279 "Notice to Employees" shall be posted by each licensee or registrant as required by these regulations.

(d) Agency documents posted pursuant to J.11(a)(4) shall be posted within two (2) working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five (5) working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 30 working days or until action correcting the violation has been completed and this correction has been verified by the Agency.

(e) Documents, notices, or forms posted pursuant to J.11 shall 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, shall be conspicuous, and shall be replaced if defaced or altered.

Sec. J.12 Instructions to Workers.

(a) All individuals who in the course of employment potentially may receive in a year an occupational dose in excess of 100 mrem (1 mSv):

(1) Shall be kept informed of the storage, transfer, or use of radiation or radioactive materials;

(2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in the precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or radioactive material;

(5) Shall be 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) Shall be advised as to the radiation exposure reports which workers may request pursuant to J.13.

(b) In determining those individuals subject to the requirements of paragraph (a) of this section, 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 licensed or registered facility. The extent of these instructions shall be commensurate with potential radiological health protection problems in the work place.

Sec. J.13 Notifications and Reports to Individuals.

(a) 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 shall be reported to the individual as specified in J.13. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations. Each notification and report shall:

(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 security number;

(3) Include the individual's exposure information; and

(4) Contain the following statement:

"This report is furnished to you under the provisions of COMAR 26.12.01.01 Part J. You should preserve this report for further reference."

(b) Each licensee or registrant shall furnish a report to each worker annually, and within 90 days following termination, of the worker's dose as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations.

(c) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly or presently engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to D.502 of these regulations. Such report shall be furnished within 30 days from date the request was made, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever

is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to D.1203 or D.1204 of these regulations to report to the Agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such report shall be transmitted at a time not later than the transmittal to the Agency.

(e) A licensee or registrant shall furnish to each worker who is terminating employment in work involving exposure to sources of radiation, a written report during the current year to each such worker, or to a worker's designee, 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 shall be provided together with a clear indication that this is an estimate.

Sec. J.14 Presence of Representatives of Licensees or Registrants and Workers During Inspection.

(a) Each licensee or registrant shall afford to the Agency, or an agent of the Agency licensed under COMAR 26.12.02.03, at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

(b) During an inspection, Agency inspectors, or agents of the Agency licensed under COMAR 26.12.02.03, may consult privately with workers as specified in J.15. The licensee or registrant may accompany Agency inspectors or agents etc. during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in J.12.

(e) 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.

(f) 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, shall be afforded the opportunity to accompany Agency inspectors or agents of the Agency etc. during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of J.14, Agency inspectors or agents of the Agency etc. are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. [Subsection J.14(g) continued next page]

With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

Sec. J.15 Consultation with Workers During Inspections.

(a) Agency inspectors or agents etc. or a State-licensed inspector performing an inspection under the authority of COMAR 26.12.01.02 may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection, any worker may bring privately to the attention of the Agency inspector or agents etc., 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, these regulations, 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 shall comply with the requirements of J.16(a).

(c) The provisions of J.15(b) shall not be interpreted as authorization to disregard instructions pursuant to J.12.

Sec. J.16 Requests by Workers for Inspections.

(a) Any worker or representative of workers believing that a violation of the Act, these regulations, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

(b) If, upon receipt of such notice, the Agency determines that the complaint meets the requirements set forth in J.16(a), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to J.16 need not be limited to matters referred to in the complaint.

(c) No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall 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 these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this part.

Sec. J.17 Inspections Not Warranted; Informal Review.

(a) (1) If the Agency determines, with respect to a complaint under J.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of such determination. The

complainant may obtain review of such determination by submitting a written statement of position with the Secretary of the Department of the Environment. The Agency will provide the licensee or registrant with a copy of such 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 with the Secretary of the Department of the Environment. The Agency will provide the complainant with a copy of such statement by certified mail.

(2) Upon the request of the complainant, the Secretary of the Department of the Environment 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 Secretary of the Department of the Environment shall affirm, modify, or reverse the determination of the Agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

(b) If the Agency determines that an inspection is not warranted because the requirements of J.16(a) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of J.16(a).

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PART T

PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

GENERAL PROVISIONS

Sec. T.1 Purpose and Scope. The regulations in this Part establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any licensee authorized by specific or general license issued by the Agency to receive, possess, use or transfer radioactive material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in its Agency license, or transports that material on public highways. No provision of this Part authorizes possession of licensed material.

Sec. T.2 Reserved.

Sec. T.3 Requirement for License. Except as authorized in a general license or a specific license issued by the Agency pursuant to T.17 through T.23 of these regulations, or as exempted in this Part, no licensee may –

(a) Deliver licensed material to a carrier for transport; or

(b) Transport licensed material.

Sec. T.4 Definitions. To ensure compatibility with international transportation standards, all limits in this Part are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this Part, either unit may be used. As used in this Part, the following definitions apply:

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package.

"A_2" means the maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a Type A package. These values are either listed in Appendix A of this Part, Table A-1, or may be derived in accordance with the procedures prescribed in Appendix A of this Part.

"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 NRC which approves the design of a package for the transportation of radioactive material.

"Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

"Contamination" means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm^2 (1X10^{-5} µCi/cm^2) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 (1X10^{-6} µCi/cm^2) for all other alpha emitters.

(1) "Fixed contamination" means contamination that cannot be removed from a surface during normal conditions of transport.

(2) "Non-fixed contamination" means contamination that can be removed from a surface during normal conditions of 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, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in T.22, T.23, and 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

"Deuterium" means, for the purposes of T.15 and T.22, 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 by a single consignor of a conveyance 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 is 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 the radionuclides 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. Certain exclusions from fissile material controls are provided in T.15.

"Graphite" means, for the purposes of T.15 and T.22, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

"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.

"Low Specific Activity (LSA) material" means radioactive material with limited specific activity which is nonfissile or is excepted under T.15, 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. The LSA material must be in one of three groups:

(1) LSA-I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides;

(ii) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;

(iii) Radioactive material other than fissile material, for which the A_2 value is unlimited; or

(iv) 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 A.

(2) LSA-II.

(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(ii) Other radioactive material in which the activity is distributed throughout and the estimated 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:

(i) 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.);

(ii) 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 by leaching when placed in water for 7 days will not exceed 0.1 A_2; and

(iii) The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2×10^{-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).

"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 the NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lb/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case 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 DOT regulations in 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 in 10 CFR Part 19.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this Part. 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 the 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.

"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.

"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-I: A solid object on which:

(i) 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} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} microcurie/cm^2) for all other alpha emitters;

(ii) 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 $4x10^4$ Bq/cm^2 (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and

(iii) 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 4×10^4 Bq/cm^2 (1 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 4×10^3 Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(i) 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} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} microcurie/cm^2) for all other alpha emitters;

(ii) 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 8 x 10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters; and

(iii) 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 8 x 10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters.

"Transport index (TI)" 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)).

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

"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 Table A-1 of this Part, or may be determined by procedures described in Appendix A of this Part.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

"Unirradiated uranium" means uranium containing not more than 2 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

"Uranium – natural, depleted, enriched":

(1) "Natural uranium" means uranium (which may be chemically separated) 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.

Sec. T.5 Transportation of Licensed Material.

(a) In addition to the requirements of this Part, each licensee who transports licensed material outside the site of usage, as specified in its Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

(1) The licensee shall particularly note DOT regulations in the following areas:

(i) Packaging--49 CFR Part 173: Subparts A, B, and I.

(ii) Marking and labeling--49 CFR Part 172: Subpart D; and §§ 172.400 through 172.407 and §§ 172.436 through 172.441 of Subpart E.

(iii) Placarding--49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519 and §172.556; and Appendices B and C.

(iv) Accident reporting--49 CFR Part 171: §§ 171.15 and 171.16.

(v) Shipping papers and emergency information--49 CFR Part 172: Subparts C and G.

(vi) Hazardous material employee training--49 CFR Part 172: Subpart H.

(vii) Security plans--49 CFR Part 172: Subpart I.

(viii) Hazardous material shipper/carrier registration--49 CFR Part 107: Subpart G.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(i) Rail--49 CFR Part 174: Subparts A through D and K.

(ii) Air--49 CFR Part 175.

(iii) Vessel--49 CFR Part 176: Subparts A through F and M.

(iv) Public Highway--49 CFR Part 177 and Parts 390 through 397.

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT 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 Maryland Department of the Environment, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230.

Secs. T.6 – T.12 Reserved.

Sec. T.13 Exemption of Physicians.

Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from Sec. T.5 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under 10 CFR Part 35 or the equivalent Maryland or other Agreement State regulations.

Sec. T.14 Exemption for Low-Level Materials.

A licensee is exempt from all requirements of this Part with respect to shipment or carriage of the following low-level materials:

(1) Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for the use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in Appendix A, Table A-2, or Table A-3 of this Part.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in Appendix A, Table A-2, or Table A-3 of this Part, or for which the consignment activity is not greater than the limit for an exempt consignment found in Appendix A, Table A-2, or Table A-3 of this Part.

(3) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in T.4.

Sec. T.15 Exemption from Classification as Fissile Material.

Fissile material meeting the requirements of at least one of the paragraphs (a) through (f) of this section 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 this Part, except as noted.

(a) Individual package containing 2 grams or less fissile material.

(b) 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.

(c) (1) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

(i) There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and

(ii) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

(2) 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.

(d) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

(e) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent 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.

(f) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

Sec. T.16 Reserved.

GENERAL LICENSES

Sec. T.17 General License: NRC-Approved Package.

(a) A general license is hereby issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, Certificate of Compliance (CoC), or other approval has been issued by the NRC.

(b) This general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of T.101 – T.137.

(c) Each licensee issued a general license under paragraph (a) of this section shall--

(1) Maintain a copy of the Certificate of Compliance, or other approval of the package, and 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 before shipment;

(2) Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of T.1 – T.5, T.81 – T.97, and T.101 – T.137; and

(3) Submit in writing before the first use of the package to: Radiological Health Program, 1800 Washington Boulevard, Baltimore, MD 21230, using an appropriate method listed in COMAR 26.12.01.01A.12, the licensee's name and license number and the package identification number specified in the package approval.

(d) This general license applies only when the package approval authorizes use of the package under this general license.

(e) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR Sec. 71.19.

Secs. T.18 – T.20 Reserved.

Sec. T.21 General License: Use of Foreign Approved Package.

(a) A general license is issued to any licensee of the Agency 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, that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

(b) Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the applicable provisions of T.101 through T.137.

(c) This general license applies only to shipments made to or from locations outside the United States.

(d) Each licensee issued a general license under paragraph (a) of this section shall--

(1) Maintain 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 before shipment; and

(2) Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of T.1 through T.5, T.81 through T.97, and T.101 through T.137.

Sec. T.22 General License: Fissile Material.

(a) A general license is issued to any licensee of the Agency to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of T.47 and 10 CFR Part 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).

(b) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of 10 CFR Part 71 Subpart H.

(c) The general license applies only when a package's contents:

(1) Contain no more than a Type A quantity of radioactive material; and

(2) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(d) The general license applies only to packages containing fissile material that are labeled with a CSI which:

(1) Has been determined in accordance with paragraph (e) of this section;

(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).

(e) (1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{235}U}{X} + \frac{\text{grams of } {}^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right];$$

(2) The calculated CSI must be rounded up to the first decimal place;

(3) The values of X, Y, and Z used in the CSI equation must be taken from Tables T-1 or T-2, as appropriate;

(4) If Table T-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

(5) Table T-1 values for X, Y, and Z must be used to determine the CSI if:

(i) Uranium-233 is present in the package;

(ii) The mass of plutonium exceeds 1 percent of the mass of uranium-235;

(iii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(iv) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table T.1 – Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per T.22(e)

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) ^{233}U (Y) ^{239}Pu or ^{241}Pu (Z)	60 43 37	38 27 24

[a] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O.

Table T.2 – Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per T.22(e)

Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{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

Sec. T.23 General License: Plutonium-Beryllium Special Form Material.

(a) A general license is issued to any licensee of the Agency to transport 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 section. This material need not be contained in a package which meets the standards of T.47 and 10 CFR Part 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).

(b) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of 10 CFR Part 71 Subpart H.

(c) The general license applies only when a package's contents:

(1) Contain 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.

(d) The general license applies only to packages labeled with a CSI which:

(1) Has been determined in accordance with paragraph (e) of this section;

(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).

(e) (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.

Secs. T.24 – T.46 Reserved.

Sec. T.47 External Radiation Standards for All Packages.

(a) Except as provided in paragraph (b) of this section, each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.

(b) A package that exceeds the radiation level limits specified in paragraph (a) of this section must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):

(i) The shipment is made in a closed transport vehicle;

(ii) The package is secured within the vehicle so that its position remains fixed during transportation; and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, 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; and

(3) 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in.) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(4) 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with Sec. D.502.

(c) For shipments made under the provisions of paragraph (b) of this section, the shipper shall 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.

(d) 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 increased radiation levels or radiation exposures to transport workers or members of the general public.

Secs. T.48 – T.80 Reserved.

OPERATING CONTROLS AND PROCEDURES

Sec. T.81 Applicability of Operating Controls and Procedures.

A licensee subject to this Part, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of T.81 – T.97, with the quality assurance requirements of T.101 - T.137, and with the general provisions of T.1 - T.5.

Sec. T.82 Reserved.

Sec. T.83 Assumptions as to Unknown Properties.

When the isotropic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

Sec. T.84 Reserved.

Sec. T.85 Preliminary Determinations.

Before the first use of any packaging for the shipment of licensed material, the licensee shall ascertain that the determinations in 10 CFR 71.85(a) through (c) have been made.

Sec. T.86 Reserved.

Sec. T.87 Routine Determinations.

Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this Part and of the license. The licensee shall determine that--

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(h) Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of 10 CFR 71.45;

(i) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is As Low As Reasonably Achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in T.47 at any time during transportation; and

(k) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

Sec. T.88 Air Transport of Plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Part or included indirectly by citation of 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, 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 A, Table A-2, of this Part, and 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 T.5; 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.

(b) Nothing in paragraph (a) of this section is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

(c) For a shipment of plutonium by air which is subject to paragraph (a)(4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, DOT regulations applicable to the air transport of plutonium.

Sec. T.89 Opening Instructions.

Before delivery of a package to a carrier for transport, the licensee shall 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 Sec. D.906(e).

Sec. T.90 Reserved.

Sec. T.91 Records.

(a) Each licensee shall maintain, for a period of 3 years after shipment, a record of each shipment of licensed material not exempt under T.14, showing where applicable --

(1) Identification of the packaging by model number and serial number;

(2) Verification that there are no significant defects in the packaging, as shipped;

(3) Volume and identification of coolant;

(4) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(5) For each item of irradiated fissile material –

(i) Identification by model number and serial number;

(ii) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(iii) Any abnormal or unusual condition relevant to radiation safety;

(6) Date of the shipment;

(7) For fissile packages and for Type B packages, any special controls exercised;

(8) Name and address of the transferee;

(9) Address to which the shipment was made; and

(10) Results of the determinations required by T.87 and by the conditions of the package approval.

(b) Reserved.

(c) The licensee shall make available to the Agency for inspection, upon reasonable notice, of all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(d) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by T.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.

T.92 – T.96 Reserved,

Sec. T.97 Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste.

(a) (1) As specified in paragraphs (b), (c) and (d) of this section, each licensee shall 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) As specified in paragraphs (b), (c), and (d) of this section, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (c)(3)(iii) of this section, 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.

(b) Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

(1) The licensed material is required by this Part to be in Type B packaging for transportation;

(2) The licensed material is being transported to or across a State boundary en route 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 the least of the following:

(i) 3000 times the A1 value of the radionuclides as specified in Appendix A, Table A-1 for special form radioactive material;

(ii) 3000 times the A2 value of the radionuclides as specified in Appendix A, Table A-1 for normal form radioactive material; or

(iii) 1000 TBq (27,000 Ci).

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(c) Procedures for submitting advance notification.

(1) The notification must be made in writing to:

(i) The office of each appropriate governor or governor's designee;

(ii) The office of each appropriate Tribal official or Tribal official's designee; and

(iii) The Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-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 of the governor's designee or the Tribal official or Tribal official's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(i) A list of the 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).

(ii) Contact information for each State, including telephone and mailing addresses of governors and governor's designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC Web site at: https://scp.nrc.gov/special/designee.pdf.

(iii) 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 Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for 3 years.

(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) The 7-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 7-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.

(c) Revision notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee or to a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall 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 shall maintain a record of the name of the individual contacted for 3 years.

(d) Cancellation notice.

(1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall 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, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for 3 years.

Secs. T.98 – T.100 Reserved.

QUALITY ASSURANCE

Sec. T.101 Quality Assurance Requirements.

(a) Purpose. Secs. T.101 through T.137 describe quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this these sections, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to these sections.

(b) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Secs. T.101 through T.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(c) Approval of program. Before the use of any package for the shipment of licensed material subject to Secs. T.101 through T.137, each licensee shall obtain Agency approval of its quality assurance program. Using an appropriate method of communication listed in COMAR 26.12.01.01A.12, each licensee shall file a description of its quality assurance program, including a discussion of which requirements of Secs. T.101 through T.137 are applicable and how they will be satisfied, by submitting the description to: Maryland Department of the Environment, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230.

(d) Radiography containers. 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 Sec. E.31(b) of this regulation or equivalent NRC or Agreement State requirement, is deemed to satisfy the requirements of T.17(b) and T.101(b).

Sec. T.102 Reserved.

Sec. T.103 Quality Assurance Organization.

(a) The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are --

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

(c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to --

(1) Identify quality problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

Sec. T.104 Reserved.

Sec. T.105 Quality Assurance Program.

(a) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of Secs. T.101 through T.137. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(c) The licensee shall 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.

(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program which they are executing.

Sec. T.106 Changes to Quality Assurance Program.

(a) Each quality assurance program approval holder shall submit in accordance with COMAR 26.12.01.01A.12, a description of a proposed change to its Agency-approved quality assurance program that will reduce commitments in the program description as approved by the Agency. The quality assurance program approval holder shall not implement the change before receiving Agency approval.

(1) The description of a proposed change to the Agency-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of T.101 through T.137.

(2) [Reserved.]

(b) Each quality assurance program approval holder may change a previously approved quality assurance program without prior Agency approval, if the change does not reduce the commitments in the quality assurance program previously approved by the Agency. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Agency every 24 months, in accordance with COMAR 26.12.01.01A.12. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment.

(1) The use of a quality assurance standard approved by the Agency that is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(c) Each quality assurance program approval holder shall maintain records of quality assurance program changes.

Secs. T.107 – T.126 Reserved.

Sec. T.127 Handling, Storage, and Shipping Control. The licensee shall 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.

Sec. T.128 Reserved.

Sec. T.129 Inspection, Test, and Operating Status.

(a) The licensee shall 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.

(b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

Sec. T.130 Reserved.

Sec. T.131 Nonconforming Materials, Parts, or Components. The licensee shall 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 organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

Sec. T.132 Reserved.

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Sec. T.133 Corrective Action. The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a 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.

Sec. T.134 Reserved.

Sec. T.135 Quality Assurance Records. The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by T.106; the documented instructions, procedures, or drawings of a type appropriate to the circumstances to prescribe quality assurance activities including appropriate quantitative and qualitative acceptance criteria for determining that activities important to quality have been satisfactorily accomplished; and closely related specifications such as required qualifications 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 shall retain these records for 3 years beyond the date when the licensee last engages in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded.

Sec. T.136 Reserved.

Sec. T.137 Audits. The licensee shall 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. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

Part T
Appendix A
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 Terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. 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 shall obtain prior Agency 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 shall obtain prior Agency 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 shall submit requests for prior approval, described under paragraphs II.a. and II.b. of this Appendix, to the Agency, in accordance with T.1.

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, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied, shall be those corresponding to the parent radionuclide 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 shall be considered as mixtures of different radionuclides.

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 in special form, 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 as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i in normal form, and $A_2(i)$ is the A_2 value for radionuclide i.

c. If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

where B(i) is the activity of radionuclide i as special form radioactive material, $A_1(i)$ is the A_1 value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and $A_2(j)$ is the A_2 value for radionuclide j.

d. 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 $A_1(i)$ is the appropriate A_1 value for radionuclide i.

e. 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 for radionuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for radionuclide i.

f. 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](i) is the activity concentration for exempt material containing radionuclide i.

g. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and A(i) is the activity limit for exempt consignments for radionuclide i.

V. (a) 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.

(b) 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] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV of this appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

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)	(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		$1.0X10^{1}$	$2.7X10^{2}$	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		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$

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)	(Ci/g)
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	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
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		1.0 X 10^{-1}	2.7	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$

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)	(Ci/g)
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)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$

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)	(Ci/g)
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		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
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)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
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	$1.3X10^{5}$	$3.6X10^{6}$

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)	(Ci/g)
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)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
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	[c]$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$

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)	(Ci/g)
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-79	Krypton (36)	4.0	1.1 X 10^{2}	2.0	5.4 X 10^{1}	4.2 X 10^{4}	1.1 X 10^{6}
Kr-81		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
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) (h)		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	$3.0X10^{-3}$	$8.0X10^{-2}$

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)	(Ci/g)
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	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
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	$1.4X10^{2}$

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)	(Ci/g)
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	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$

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)	(Ci/g)
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
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	$5.5X10^{4}$	$1.5X10^{6}$

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)	(Ci/g)
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		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
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	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$

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)	(Ci/g)
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	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$

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)	(Ci/g)
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	$1.0X10^{3}$	$2.7X10^{4}$
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)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$

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)	(Ci/g)
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	See Table A-4	See Table A-4
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	(See Table A-3)
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	$3.7X10^{2}$	$1.0X10^{4}$
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		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$

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)	(Ci/g)
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 (70)	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)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days, as listed in the following:

Mg-28	Al-28
Ca-47	Sc-47
Ti-44	Sc-44
Fe-52	Mn-52m
Fe-60	Co-60m
Zn-69m	Zn-69
Ge-68	Ga-68
Rb-83	Kr-83m
Ru-103	Rh103m
Sr-82	Rb-82
Sr-90	Y-90
Sr-91	Y-91m
Sr-92	Y-92
Y-87	Sr-87m
Zr-95	Nb-95m
Zr-97	Nb-97m, Nb-97
Mo-99	Tc-99m
Tc-95m	Tc-95

Tc-96m	Tc-96
Ru-106	Rh-106
Pd-103	Rh-103m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-115	In-115m
In-114m	In-114
Sn-113	In-113m
Sn-121m	Sn-121
Sn-126	Sb-126m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
I-135	Xe-135m
Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144
Pm-148m	Pm-148
Gd-146	Eu-146
Dy-166	Ho-166
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m
Os-194	Ir-194
Ir-189	Os-189m
Pt-188	Ir-188
Hg-194	Au-194
Hg-195m	Hg-195
Pb-210	Bi-210
Pb-212	Bi-212, Tl-208, Po-212
Bi-210m	Tl-206
Bi-212	Tl-208, Po-212
At-211	Po-211
Rn-222	Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Ra-225	Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ra-226	Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ac-227	Fr-223
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Th-234	Pa-234m, Pa-234
Pa-230	Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214
U-230	Th-226, Ra-222, Rn-218, Po-214
U-235	Th-231
Pu-241	U-237
Pu-244	U-240, Np-240m
Am-242m	Am-242, Np-238
Am-243	Np-239
Cm-247	Pu-243
Bk-249	Am-245
Cf-253	Cm-249

[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq) (see Appendix A to Part 71 - Determination of A_1 and A_2, Section I.).
[c] The activity of Ir-192 in special form 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_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

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	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
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	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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
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	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)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

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)
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)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

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)
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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
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	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
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		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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

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)
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)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
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-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
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	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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

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-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	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	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	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

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)
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	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-79	Krypton (36)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Kr-81		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
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)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
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	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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

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)
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
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	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		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$

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)
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	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
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	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		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
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	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$

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-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 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
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)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

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)
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		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
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	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		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

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)
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
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		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

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-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
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	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

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 (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)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

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 (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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
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)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

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)
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)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a] [Reserved]

[b] Parent nuclides and their progeny included in secular equilibrium are listed as follows:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
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-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-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
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 radionuclides 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}
Alpha emitting nuclides, but no neutron emitters, are known to be present[a]	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}
Neutron emitting nuclides are known to be present or 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}

[a] If beta or gamma emitting nuclides are known to be present, the A_1 value of 0.1 TBq (2.7 Ci) should be used.

TABLE A-4—ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment[1] wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}

[1] The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

PART V

PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

General Provisions

Sec. V.1 Purpose. This Part 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 A to this Part. 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 this Part authorizes possession of licensed material.

Sec. V.2 [Reserved].

Sec. V.3 Scope.

a. This Part applies to any person who, under Sections V.21 through V.57, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

b. This Part applies to any person who, under Sections V.71 through V.81:

i. Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or

ii. Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

Sec. V.4 [Reserved].

Sec. V.5 Definitions. As used in this Part:

"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 Sections V.21 through V.33 and who has completed the training required by V.43(c).

"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 A to this Part. 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 A to this Part. 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 this Part 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.

"Fingerprint orders" means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by 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.

"License issuing authority" means the license agency that issues the license, i.e., 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 shall 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.

"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.

Sec. V.6 – V.10 [Reserved].

Sec. V.11 Specific Exemptions.

[a. – b. Reserved].

c. A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of Sections V.21 through V.81; except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this Part. The licensee shall implement the following requirements to secure the radioactive waste:

i. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

ii. Use a locked door or gate with monitored alarm at the access control point;

iii. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

iv. 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.

Sec. V.12 – V.20 [Reserved].

Background Investigations and Access Authorization Program

Sec. V.21 Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Material.

a. General.

i. Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of Sections V.21 – V.33.

ii. An applicant for a new license and each licensee that would become newly subject to the requirements of Sections V.21 – V.33 upon application for modification of its license shall implement the requirements of Sections V.21 – V.33, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

iii. Any licensee that has not previously implemented the Security Orders or been subject to the provisions of Sections V.21 through V.33 shall implement the provisions of Sections V.21 through V.33 before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

b. General Performance Objective. The licensee's access authorization program must ensure that the individuals specified in V.21(c)(i) are trustworthy and reliable.

c. Applicability.

i. Licensees shall subject the following individuals to an access authorization program in accordance with V.23:

(1) 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

(2) Reviewing officials.

ii. Licensees need not subject the categories of individuals listed in Subsections V.29(a)(i) – (xiii) to the investigation elements of the access authorization program.

iii. Licensees shall 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.

iv. Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under Sections V21 – V33.

Sec. V.22 [Reserved].

Sec. V.23 Access Authorization Program Requirements.

a. Granting Unescorted Access Authorization.

i. Licensees shall implement the requirements of Sections V.21 – V.33 for granting initial or reinstated unescorted access authorization.

ii. Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by V.43(c) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

b. Reviewing Officials.

i. 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.

ii. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the address listed in Section A.12. 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 shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with Section V.25(c).

iii. 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.

iv. Reviewing officials cannot approve other individuals to act as reviewing officials.

v. 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 Section V.29(a).

c. Informed Consent.

i. 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 shall 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 Section V.25(b). A signed consent must be obtained prior to any reinvestigation.

ii. The subject individual may withdraw his or her consent at any time. Licensees shall 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 or her consent; and

(2) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

d. Personal History Disclosure. Any individual who is applying for unescorted access authorization shall 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 this Part is sufficient cause for denial or termination of unescorted access.

e. Determination Basis.

i. The reviewing official shall 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 this Part.

ii. 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 this Part 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.

iii. The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

iv. 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.

v. Licensees shall 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 shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. Procedures. Licensees shall 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.

g. Right to Correct and Complete Information.

i. Prior to any final adverse determination, licensees shall provide each individual subject to this Part 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 1 year from the date of the notification.

ii. 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 10 days 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 or 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.

h. Records.

i. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

ii. The licensee shall retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

iii. The licensee shall retain the list of persons approved for unescorted access authorization for 3 years after the list is superseded or replaced.

Sec. V.24 [Reserved].

Sec. V.25 Background Investigations.

a. 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 shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the 7 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:

i. Fingerprinting and an FBI identification and criminal history records check in accordance with Section V.27;

ii. Verification of True Identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall 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 shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with Section V.31. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

iii. Employment History Verification. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent 7 years before the date of application;

iv. Verification of Education. Licensees shall verify that the individual Participated in the education process during the claimed period;

v. Character and Reputation Determination. Licensees shall 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 this Part must be limited to whether the individual has been and continues to be trustworthy and reliable;

vi. The licensee shall 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

vii. 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 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

b. Grandfathering.

i. 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 shall be subject to the reinvestigation requirement.

ii. Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 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 shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC 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 shall be subject to the reinvestigation requirement.

c. Reinvestigations. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with Section V.27. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

V.26 [Reserved].

Sec. V.27 Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material.

a. General Performance Objective and Requirements.

i. Except for those individuals listed in Section V.29 and those individuals grandfathered under Section V.25(b), each licensee subject to the provisions of this Part shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall 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.

ii. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

iii. 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:

(1) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(2) The previous access was terminated under favorable conditions.

iv. 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 this Part, the Fingerprint Orders, or 10 CFR Part 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 V.31(c).

v. Licensees shall 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.

b. Prohibitions.

i. 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:

(1) An arrest more than 1 year old for which there is no information of the disposition of the case; or

(2) An arrest that resulted in dismissal of the charge or an acquittal.

ii. Licensees may not use information received from a criminal history records check obtained under this Part in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for Processing of Fingerprint Checks.

i. For the purpose of complying with this Part, licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-07D04M, 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 emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html.

ii. Fees for the processing of fingerprint checks are due upon application. Licensees shall 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 Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov). 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 Web site. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check information page at http://www.nrc.gov/security/chp.html and see the link for How do I determine how much to pay for the request?)

iii. The NRC 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.

Sec. V.28 [Reserved].

Sec. V.29 Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials.

a. 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:

i. An employee of the NRC or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

ii. A Member of Congress;

iii. An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

iv. The Governor of a State or his or her designated State employee representative;

v. Federal, State, or local law enforcement personnel;

vi. State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

vii. Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under Section 274.i. of the Atomic Energy Act;

viii. 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 NRC;

ix. Emergency response personnel who are responding to an emergency;

x. Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

xi. Package handlers at transportation facilities such as freight terminals and railroad yards;

xii. Any individual who has an active Federal security clearance, provided that he or she 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 shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

xiii. 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 shall retain the documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

b. 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 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she 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 shall retain this documentation for a period of 3 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:

i. National Agency Check;

ii. Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;

iii. Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;

iv. Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;

v. Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR part 1572; and

vi. Customs and Border Protection's Free and Secure Trade (FAST) Program.

Sec. V30 [Reserved].

Sec. V.31 Protection of Information.

a. Each licensee who obtains background information on an individual under this Part shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or 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.

c. The personal information obtained on an individual from a background investigation may be provided to another licensee:

i. Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

ii. The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

d. The licensee shall make background investigation records obtained under this Part available for examination by an authorized representative of the Agency to determine compliance with the regulations and laws.

e. The licensee shall 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 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

Sec. V.32 [Reserved].

Sec. V.33 Access Authorization Program Review.

a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this Part and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.

b. 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 shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. Review records must be maintained for 3 years.

Sec. V.34 – V.40 [Reserved].

Physical Protection Requirements During Use

Sec. V.41 Security Program.

a. Applicability.

i. Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this Part.

ii. An applicant for a new license and each licensee that would become newly subject to the requirements of this Part upon application for modification of its license shall implement the requirements of this Part, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

iii. Any licensee that has not previously implemented the Security Orders or been subject to the provisions of Sections V.41 through V.57 shall provide written notification to the Agency as specified in Section A.12 at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

b. General Performance Objective. Each licensee shall 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.

c. Program Features. Each licensee's security program must include the program features, as appropriate, described in Sections V.43 through V.55.

Sec.V.42 [Reserved].

Sec. V.43 General Security Program Requirements.

a. Security Plan.

i. Each licensee identified in Section V.41(a) shall 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 this Part. The security plan must, at a minimum:

(1) Describe the measures and strategies used to implement the requirements of this Part; and

(2) Identify the security resources, equipment, and technology used to satisfy the requirements of this Part.

ii. The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

iii. A licensee shall revise its security plan as necessary to ensure the effective implementation of Agency requirements. The licensee shall ensure that:

(1) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(2) The affected individuals are instructed on the revised plan before the changes are implemented.

iv. The licensee shall retain a copy of the current security plan as a record for 3 years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

b. Implementing Procedures.

i. The licensee shall develop and maintain written procedures that document how the requirements of this Part and the security plan will be met.

ii. The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

iii. The licensee shall retain a copy of the current procedure as a record for 3 years after the procedure is no longer needed. Superseded portions of the procedure must be retained for 3 years after the record is superseded.

c. Training.

i. Each licensee shall 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:

(1) 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;

(2) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Agency requirements;

(3) 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

(4) The appropriate response to security alarms.

ii. In determining those individuals who shall be trained on the security program, the licensee shall 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.

iii. 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:

(1) Review of the training requirements of paragraph (c) of this section and any changes made to the security program since the last training;

(2) Reports on any relevant security issues, problems, and lessons learned;

(3) Relevant results of Agency inspections; and

(4) Relevant results of the licensee's program review and testing and maintenance.

iv. The licensee shall maintain records of the initial and refresher training for 3 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.

d. Protection of Information.

i. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

ii. Efforts to limit access shall 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, implementing procedures, and the list of individuals who have been approved for unescorted access.

iii. Before granting an individual access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access, licensees shall:

(1) Evaluate an individual's need to know the security plan or implementing procedures, or the list of individuals that have been approved for unescorted access; and

(2) 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 shall be conducted by the reviewing official and shall include the background investigation elements contained in V.25(a)(ii) through (a)(vii).

iv. Licensees need not subject the following individuals to the background investigation elements for protection of information:

(1) The categories of individuals listed in V.29(a)(i) through (a)(xiii); or

(2) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in V.25(a)(ii) though (a)(vii), has been provided by the security service provider.

v. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access.

vi. Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access.

vii. When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals who have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

viii. The licensee shall retain as a record for 3 years after the document is no longer needed:

(1) A copy of the information protection procedures; and

(2) The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access.

(3) The list of individuals approved for access to the security plan or implementing procedures.

Sec. V.44 [Reserved].

Sec. V.45 LLEA Coordination.

a. A licensee subject to this Part shall 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:

i. 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 this Part; and

ii. 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.

b. The licensee shall notify the Agency listed in § A.12 within 3 business days if:

i. The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

ii. The LLEA notifies the licensee that the LLEA does not plan to Participate in coordination activities.

c. The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for 3 years.

d. The licensee shall 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.

Sec. V.46 [Reserved].

Sec. V.47 Security Zones.

a. Licensees shall 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.

b. 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.

c. Security zones must, at a minimum, allow unescorted access only to approved individuals through:

i. 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

ii. Direct control of the security zone by approved individuals at all times; or

iii. A combination of continuous physical barriers and direct control.

d. For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, 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.

e. 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.

Sec. V.48 [Reserved].

Sec V.49 Monitoring, Detection, and Assessment.

a. Monitoring and Detection.

i. Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall 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.

ii. Monitoring and detection must be performed by:

(1) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(2) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(3) A monitored video surveillance system; or

(4) Direct visual surveillance by approved individuals located within the security zone; or

(5) Direct visual surveillance by a licensee designated individual located outside the security zone.

iii. A licensee subject to this Part shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(1) 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:

(a) Electronic sensors linked to an alarm; or

(b) Continuous monitored video surveillance; or

(c) Direct visual surveillance.

(2) 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.

b. Assessment. Licensees shall 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.

c. Personnel Communications and Data Transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

i. Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

ii. 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.

d. Response. Licensees shall 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 shall include requesting, without delay, an armed response from the LLEA.

Sec. V.50 [Reserved].

Sec. V.51 Maintenance and Testing.

a. Each licensee subject to this Part shall 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 this Part must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no manufacturer's suggested frequency, the testing must be performed at intervals not to exceed 12 months.

b. The licensee shall maintain records on the maintenance and testing activities for 3 years.

Sec. V.52 [Reserved].

Sec. V.53 Requirements for Mobile Devices. Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

a. 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

b. 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 shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

Sec. V.54 [Reserved].

Sec. V.55 Security Program Review.

a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this Part 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 shall periodically (at least every 12 months) review the security program content and implementation.

b. 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 describe corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. The licensee shall retain the review documentation for 3 years.

Sec. V.56 [Reserved].

Sec. V.57 Reporting of Events.

a. The licensee shall 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 shall notify the Agency by telephone. In no case shall the notification to the Agency be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

b. The licensee shall 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 4 hours after notifying the LLEA, the licensee shall notify the Agency by telephone.

c. The initial telephonic notification required by V.57(a) must be followed within a period of 30 days by a written report submitted to the Agency at the address specified in Section A.12 of this regulation. The report must include sufficient information for Agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

V.58 – V.70 [Reserved].

Physical Protection in Transit

Sec. V.71 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 Agency, NRC, or an Agreement State shall meet the license verification provisions listed below instead of those listed in Section C.40(d) of these regulations:

a. Any licensee transferring category 1 quantities of radioactive material to a licensee of the Agency, NRC, or an Agreement State, prior to conducting such transfer, shall verify with the NRC'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 shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

b. Any licensee transferring category 2 quantities of radioactive material to a licensee of the Agency, NRC, or an Agreement State, prior to conducting such transfer, shall verify with the NRC'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 shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

c. 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 shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

d. The transferor shall keep a copy of the verification documentation as a record for 3 years.

Sec. V.72 [Reserved].

Sec. V.73 Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit.

a. For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in V.75(a) and (e); V.77; V.79(a)(i), (b)(i) and (c); and V.81(a), (c), (e), (g), and (h).

b. For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in V.75(b) through (e); V.79(a)(ii), (a)(iii), (b)(ii), and (c); and V.81(b), (d), (f), (g), and (h). For those shipments of category 2 quantities of radioactive material that meet the criteria of T.97(b), the shipping licensee shall also comply with the advance notification provisions of T.97.

c. The shipping licensee shall be responsible for meeting the requirements of Sections V.71, V.73, V.75, V.77, V.79 and V.81 unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under Sections V.71, V.73, V.75, V.77, V.79 and V.81.

d. Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in V.75(a)(ii) and (e); V.77; V.79(a)(i), (b)(i), and (c); and V.81(a), (c), (e), (g), and (h) for the domestic portion of the shipment.

e. Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in V.79(a)(ii), (a)(iii), and (b)(ii); and V.81(b), (d), (f), (g), and (h) for the domestic portion of the shipment.

Sec. V.74 [Reserved].

Sec. V.75 Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material.

a. 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 shall:

i. Preplan and coordinate shipment arrival and departure times with the receiving licensee;

ii. Preplan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

(1) Discuss the State's intention to provide law enforcement escorts; and

(2) Identify safe havens; and

iii. Document the preplanning and coordination activities.

b. 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 shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

c. Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

d. 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 V.75(b), shall promptly notify the receiving licensee of the new no-later-than arrival time.

e. The licensee shall retain for 3 years a copy of the documentation for preplanning and coordination and any revision thereof.

Sec. V.76 [Reserved].

Sec. V.77 Advance Notification of Shipment of Category 1 Quantities of Radioactive Material. As specified in paragraphs (a) and (b) of this section, each licensee shall provide advance notification to the Agency and to 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.

a. Procedures for Submitting Advance Notification.

i. The notification must be made to the Agency and to the office of the Governor's designee. Notification to the Agency must be made in accordance with Section A.12 of this regulation. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at https://scp.nrc.gov/special/designee.pdf.

ii. A notification delivered by mail must be postmarked at least 7 days before transport of the shipment commences at the shipping facility.

iii. A notification delivered by any means other than mail must reach the Agency 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.

b. 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:

i. The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

ii. The license numbers of the shipper and receiver;

iii. A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

iv. The point of origin of the shipment and the estimated time and date that shipment will commence;

v. The estimated time and date that the shipment is expected to enter each State along the route;

vi. The estimated time and date of arrival of the shipment at the destination; and

vii. A point of contact, with a telephone number, for current shipment information.

c. Revision Notice.

i. The licensee shall 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 governor of the State or the governor's designee and to the Agency.

ii. A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs (b) and (c)(1) of this section. The licensee shall also immediately notify the Agency of any such changes.

d. Cancellation Notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Agency. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

e. Records. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for 3 years.

f. Protection of Information. State officials, State employees, and other individuals, who receive schedule information of the kind specified in V.77(b) shall protect that information against unauthorized disclosure as specified in V.43(d).

Sec. V.78 [Reserved].

Sec. V.79 Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment.

a. Shipments by Road.

i. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(1) 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, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(2) 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.

(3) 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.

(4) 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.

(5) Develop written normal and contingency procedures to address:

(a) Notifications to the communication center and law enforcement agencies;

(b) 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;

(c) Loss of communications; and

(d) Responses to an actual or attempted theft or diversion of a shipment.

(6) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

ii. Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

iii. Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(1) 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.

(2) 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

(3) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

b. Shipments by Rail.

i. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(1) 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 shall provide positive confirmation of the location of the shipment and its status. The communications center shall 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.

(2) Ensure that periodic reports to the communications center are made at preset intervals.

ii. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(1) 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.

(2) 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

(3) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. Investigations. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall 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 shall 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.

Sec. V.80 [Reserved].

Sec. V.81 Reporting of Events.

a. The shipping licensee shall notify the appropriate LLEA and the Agency within 1 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 V.79(c), the shipping licensee will provide agreed upon updates to the Agency on the status of the investigation.

b. The shipping licensee shall notify the Agency within 4 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 shall immediately notify the Agency.

c. The shipping licensee shall 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 shall notify the Agency 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.

d. The shipping licensee shall notify the Agency 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.

e. The shipping licensee shall notify the Agency and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

f. The shipping licensee shall notify the Agency as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

g. The initial telephonic notification required by V.81(a) through (d) must be followed within a period of 30 days by a written report submitted to the Agency at the address specified in Section
A.12 of this regulation. A written report is not required for notifications on suspicious activities required by V.81(c). The report must set forth the following information:

i. A description of the licensed material involved, including kind, quantity, and chemical and physical form;

ii. A description of the circumstances under which the loss or theft occurred;

iii. A statement of the disposition, or probable disposition, of the licensed material involved;

iv. Actions that have been taken, or will be taken, to recover the material; and

v. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

h. Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

Sec. V.82 – V.100 [Reserved].

Records

Sec. V.101 Form of Records. Each record required by this Part must be legible throughout the retention period specified by each Agency 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 shall maintain adequate safeguards against tampering with and loss of records.

Sec. V.102 [Reserved].

Sec. V.103 Record Retention. Licensees shall maintain the records that are required by the regulations in this Part for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Agency terminates the facility's license. All records related to this Part may be destroyed upon Agency termination of the facility license.

Sec. V.104 [Reserved].

Enforcement

Sec. V.105 Inspections.

a. Each licensee shall afford to the Agency at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein the nuclear material is used, produced, or stored.

b. Each licensee shall make available to the Agency for inspection, upon reasonable notice, records kept by the licensee pertaining to its receipt, possession, use, acquisition, import, export, or transfer of category 1 or category 2 quantities of radioactive material.

Appendix A - Category 1 and Category 2 Radioactive Materials

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. 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 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

$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right]\geq 1.0$$

PART W

RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

Sec. W.1 Purpose. The regulations in this part establish radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this part are in addition to, and not in substitution for, the requirements of Parts A, B, C, D, and J of these regulations.

Sec. W.2 Scope. The regulations in this part apply to all licensees or registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive markers, or subsurface tracer studies.

Sec. W.3 Definitions. As used in this part, 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.

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"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 W.401.

"Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at the well site.

"Logging tool" means a device used subsurface to perform well logging.

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

“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 down toward the bottom of a well.

"Well-bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

"Well-logging" means all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

Prohibition

Sec. W.4 Prohibition. No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well-operator, well-owner, drilling contractor, or land owner that:

(a) in the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

(b) in the event a decision is made to abandon the sealed source downhole, the requirements of W.501(c) shall be met.

Equipment Control

Sec. W.101 Limits on Levels of Radiation. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Part T and the dose limitation requirements of Part D of these regulations are met.

Sec. W.102 Storage Precautions.

(a) Each source of radiation shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

(b) Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.

Sec. W.103 Transport Precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

Sec. W.104 Radiation Survey Instruments.

(a) The licensee or registrant shall maintain two calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this part and by D.501 of these regulations. Instrumentation shall be capable of measuring 0.1 milliroentgen (0.001 mSv) per hour through at least 50 milliroentgens (0.5 mSv) per hour.

(b) Each radiation survey instrument shall be calibrated:

(1) at intervals not to exceed 6 months and after each 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 appropriate points; and

(3) so that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained for a period of 2 years for inspection by the Agency.

Sec. W.105 Leak Testing of Sealed Sources.

(a) Testing and Recordkeeping Requirements. Each licensee who uses a sealed source shall have the source tested for leakage periodically. The licensee shall keep a record of leak test results in units of microcuries and retain the record for inspection by the Agency for 3 years after the leak test is performed.

(b) Method of Testing. The wipe of a sealed source must be performed using a leak test kit or method approved by the Commission or an 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 Commission or an Agreement State to perform the analysis.

(c) Test Frequency.

(1) Each sealed source (except an energy compensation source (ECS)) must be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 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 paragraph (e) of this section must be tested at intervals not to exceed 3 years. In the absence of a certificate from a transferor that a test has been made within the 3 years before the transfer, the ECS may not be used until tested.

(d) Removal of Leaking Source from Service.

(1) If the test conducted pursuant to paragraphs (a) and (b) of this section reveals the presence of 185 Bq [0.005 microcuries] or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions.

(2) The licensee shall submit a report to the Agency within 5 days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination that resulted from the leaking source, and the corrective actions taken up to the time the report is made.

(e) Exemptions. The following sources are exempted from the periodic leak test requirements of W.105(a) through (d):

(1) hydrogen-3 (tritium) sources;

(2) sources of radioactive material with a half-life of 30 days or less;

(3) sealed sources of radioactive material in gaseous form;

(4) sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

(5) sources of alpha or neutron-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

Sec. W.106 Quarterly Inventory. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 2 years from the date of the inventory for inspection by the Agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

Sec. W.107 Utilization Records. Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the Agency for 2 years from the date of the recorded event, showing the following information for each source of radiation:

(a) make, model number, and a serial number or a description of each source of radiation used;

(b) the identity of the well-logging supervisor or field unit to whom assigned;

(c) locations where used and dates of use; and

(d) in the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

Sec. W.108 Design and Performance Criteria for Sources.

(a) 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 licensed material whose chemical and physical forms are as insoluble and non-dispersible as practical; and

(3) meets the requirements of paragraph (b), (c), or (d) of this section.

(b) 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 paragraph (c) or (d) of this section.

(c) 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."

(d) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if the sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(1) Temperature. The test source must be held at -40º C for 20 minutes, 600º C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600º C to 20º C within 15 seconds.

(2) 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.

(3) Vibration test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.

(4) 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.

(5) Pressure test. The test source must be subject to an external pressure of 1.695×10^7 pascals [24,600 pounds per square inch absolute].

(e) The requirements in paragraph (a), (b), (c), and (d) of this section do not apply to sealed sources that contain licensed material in gaseous form.

(f) The requirements in paragraphs (a), (b), (c), and (d) of this section do not apply to energy compensation sources (ECS). ECSs must be registered with the NRC under §32.210 or with an Agreement State.

Sec.W.109 Labeling.

(a) Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER[1]
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

(b) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER[1]
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES [OR NAME OF COMPANY]

[1] or CAUTION

Sec. W.110 Inspection and Maintenance.

(a) Each licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of 2 years for inspection by the Agency.

(b) If any inspection conducted pursuant to W.110(a) reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

(c) If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Agency.

(d) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Requirements for Personnel Safety

Sec. W.201 Training Requirements.

(a) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this part until such individual has:

(1) received, in a course recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, instruction in the subjects outlined in Appendix A of this part and demonstrated an understanding thereof;

(2) read and received instruction in the regulations contained in this part and the applicable sections of Parts A, D, and J of these regulations or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

(3) demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(b) No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(1) read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

(2) demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(c) The licensee or registrant shall maintain employee training records for inspection by the Agency for 2 years following termination of the individual's employment.

Sec. W.202 Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Part D of these regulations;

(b) methods and occasions for conducting radiation surveys;

(c) methods and occasions for locking and securing sources of radiation;

(d) personnel monitoring and the use of personnel monitoring equipment;

(e) transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

(f) minimizing exposure of individuals in the event of an accident;

(g) maintenance of records;

(h) use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(i) procedure to be followed in the event a sealed source is lodged downhole;

(j) procedures to be used for picking up, receiving, and opening packages containing radioactive material;

(k) for the use of tracers, decontamination of the environment, equipment, and personnel;

(l) maintenance of records generated by logging personnel at temporary jobsites;

(m) notifying proper persons in the event of an accident; and

(n) actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by W.104.

Sec. W.203 Personnel Monitoring.

(a) No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears a personnel dosimeter at all times during the handling of licensed radioactive materials. Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

(b) The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

(c) The licensee shall retain records of personnel dosimeters required by Sec. W.203(a) and bioassay results for inspection until the Agency authorizes disposition of the records.

Precautionary Procedures in Logging and Subsurface Tracer Studies

Sec. W.301 Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in Part A of these regulations.

Sec. W.302 Handling Tools. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

Sec. W.303 Subsurface Tracer Studies.

(a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

(b) No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the Agency.

Sec. W.304 Particle Accelerators. No licensee or registrant shall 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 so controlled or shielded that the requirements of D.201 and D.301 of these regulations, as applicable, are met.

Sec. W.305 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."

Sec. W.306 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].

(a) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of Sections W.105, W.106 and W.107.

(b) For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of Sections C.26(d), W.105, W.106, W.107, and W.501.

Sec. W.307 Tritium Neutron Generator Target Source.

(a) 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 this part except Sections C.26(d), W.108, and W.501.

(b) 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 this part except Section W.108.

Radiation Surveys and Records

Sec. W.401 Radiation Surveys.

(a) Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

(b) Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

(c) If the sealed source assembly is removed from the logging tool before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(d) Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

(e) Records required pursuant to W.401(a) through (d) shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the Agency for 2 years after completion of the survey.

Sec. W.402 Documents and Records Required at Field Stations. Each licensee or registrant shall maintain, for inspection by the Agency, the following documents and records for the specific devices and sources used at the field station:

(a) appropriate license, certificate of registration, or equivalent document(s);

(b) operating and emergency procedures;

(c) applicable regulations;

(d) records of the latest survey instrument calibrations pursuant to W.104;

(e) records of the latest leak test results pursuant to W.105;

(f) records of quarterly inventories required pursuant to W.106;

(g) utilization records required pursuant to W.107;

(h) records of inspection and maintenance required pursuant to W.110;

(i) survey records required pursuant to W.401; and

(j) training records required pursuant to W.201.

Sec. W.403 Documents and Records Required at Temporary Jobsites. Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the Agency:

(a) operating and emergency procedures;

(b) survey records required pursuant to W.401 for the period of operation at the site;

(c) evidence of current calibration for the radiation survey instruments in use at the site;

(d) when operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s);

(e) shipping papers for the transportation of radioactive material; and

(f) other information as required by Section C.90.

Notification

Sec. W.501 Notification of Incidents, Abandonment, and Lost Sources.

(a) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Part D of these regulations.

(b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations;

(2) notify the Agency immediately by telephone and subsequently, within 30 days, by confirmatory letter; and

(3) if the licensee knows or has reason to believe that a sealed source has been ruptured, the notification in W.501(b)(1) shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

(c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(1) advise the well-operator of COMAR 26.04.04 and an appropriate method of abandonment, which shall include:

(i) the immobilization and sealing in place of the radioactive source with a cement plug;

(ii) the setting of a whipstock or other deflection device; and

(iii) the mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by W.501(d); and

(2) 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 shall notify the Agency by telephone of the circumstances that resulted in the inability to retrieve the source and:

(i) obtain Agency approval to implement abandonment procedures; or

(ii) that the licensee implemented abandonment before receiving Agency approval because the licensee believed there was an immediate threat to public health and safety; and

(3) file a written report with the Agency within 30 days of the abandonment. The licensee shall send a copy of the report to the appointing authority as defined in COMAR 26.04.04 that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:

(i) date of occurrence;

(ii) a description of the well logging source involved, including the radionuclide and its quantity, chemical, and physical form;

(iii) surface location and identification of the well;

(iv) results of efforts to immobilize and seal the source in place;

(v) a brief description of the attempted recovery effort:

(vi) depth of the source;

(vii) depth of the top of the cement plug;

(viii) depth of the well;

(ix) the immediate threat to public health and safety justification for implementing abandonment if prior Agency approval was not obtained in accordance with Section W.501(c)(2);

(x) any other information, such as a warning statement, contained on the permanent identification plaque; and

(xi) the names of state agencies receiving a copy of this report.

(d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque[2] for posting the well or well-bore. This plaque shall:

(1) be constructed of long-lasting material, such as stainless steel or monel; and

(2) contain the following information engraved on its face:

(i) the word "CAUTION";

(ii) the radiation symbol without the conventional color requirement;

(iii) the date of abandonment;

(iv) the name of the well-operator or well-owner;

(v) the well name and well identification number(s) or other designation;

(vi) the sealed source(s) by radionuclide and activity;

(vii) the source depth and the depth to the top of the plug; and

(viii) an appropriate warning, depending on the specific circumstances of each abandonment.[3]

(e) The licensee shall immediately notify the Agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

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[2] An example of a suggested plaque is shown in Appendix B of this part.

[3] Appropriate warnings may include: (a) "Do not drill below plug-back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Maryland Department of the Environment".

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Part W

APPENDIX A

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

I. Fundamentals of Radiation Safety

- A. Characteristics of radiation
- B. Units of radiation dose and quantity of radioactivity
- C. Significance of radiation dose
  - 1. Radiation protection standards
  - 2. Biological effects of radiation dose
- D. Levels of radiation from sources of radiation
- E. Methods of minimizing radiation dose
  - 1. Working time
  - 2. Working distances
  - 3. Shielding
- F. Radiation safety practices including prevention of contamination and methods of decontamination

II. Radiation Detection Instrumentation To Be Used

- A. Use of radiation survey instruments
  - 1. Operation
  - 2. Calibration
  - 3. Limitations
- B. Survey techniques
- C. Use of personnel monitoring equipment

III. Equipment to be Used

- A. Handling equipment
- B. Sources of radiation
- C. Storage and control of equipment
- D. Operation and control of equipment

IV. The Requirements of Pertinent Federal and State Regulations

V. The Licensee's or Registrant's Written Operating and Emergency Procedures

VI. The Licensee's or Registrant's Record Keeping Procedures

APPENDIX B

Example of Plaque for Identifying Wells Containing Sealed Sources
Containing Radioactive Material Abandoned Downhole

[COMPANY NAME]
[WELL IDENTIFICATION]

CAUTION

ONE 2 CURIE CS-137
RADIOACTIVE SOURCE
ABANDONED 3-3-75 AT 8400 FT.
PLUG BACK DEPTH 8200 FT. DO
NOT RE-ENTER THIS WELL
BEFORE CONTACTING:

[RADIATION CONTROL AGENCY]

The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., 1/2-inch and 1/4-inch letter size, respectively.

Part X

Use of Radioactive Materials in Irradiators

General Provisions

Sec. X.1 Purpose and Scope.

(a) This part establishes requirements and provisions for the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements in these regulations. Nothing in this part 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.

(b) The regulations in this part apply 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, are covered by this part.

(c) The regulations in this part do 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.

Sec. X.2 Definitions.

“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 and are not accessible to personnel.

"Irradiator operator" means an individual who has successfully completed the training and testing described in Section X.51 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.

"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 percent, 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.

Design and Performance Requirements for Irradiators

Sec X.21 Performance Criteria for Sealed Sources.

(a) Sealed sources installed after [the effective date of these regulations]:

(1) Must have a certificate of registration issued under 10 CFR 32.210;

(2) Must be doubly encapsulated;

(3) Must use radioactive material that is as non-dispersible 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 paragraphs (b) through (g) of this section.

(b) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(c) Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.

(d) Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(e) Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations

sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(f) Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(g) 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 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

Sec. X.23 Access Control.

(a) 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 fully shielded position. Product conveyor systems may serve as barriers as long as they prevent inadvertent entry of personnel if the sources are not in the fully shielded position. 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 not in the fully shielded position must cause the sources to return promptly to their fully 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.

(b) 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 shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(c) 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 high radiation levels exist. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in paragraph (b) of this section. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam. The monitor must also activate a conspicuously visible warning light for personnel entry points.

(d) Before the sources move from their fully 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 fully shielded position.

(e) 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.

(f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the fully 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.

(g) 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 (or danger) radioactive material." 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.

(h) 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.

(i) 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.

Sec. X.25 Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisieverts (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 an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas that are not normally occupied where the radiation dose rate exceeds 0.02 millisieverts (2 millirems) per hour must be locked, roped off, or posted.

(b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisieverts (2 millirems) per hour when the sources are in the fully shielded position.

(c) 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 millisieverts (2 millirems) per hour and at 5 centimeters from the shield must not exceed 0.2 millisieverts (20 millirems) per hour.

Sec. X.27 Fire Protection.

(a) 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.

(b) 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.

Sec X.29 Radiation Monitors.

(a) 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 paragraph.

(b) 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.

Sec. X.31 Control of Source Movement.

(a) 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 fully 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 not in the fully shielded position. The door to the radiation room must require the same key.

(b) 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.

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the fully shielded position.

(d) Each control for a panoramic irradiator must be clearly marked as to its function.

Sec. X.33 Irradiator Pools.

(a) For licenses initially issued after [the effective date of these regulations], irradiator pools must:

(1) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool. This liner must be constructed such that a system is provided for the detection of leaks through the use of a pressurized gas channel located at each weld in the liner surface.

(2) the licensee shall have a method to safely store the sources during repairs of the pool.

(b) For licenses initially issued after [the effective date of these regulations], 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.

(c) A means must be provided to replenish water losses from the pool.

(d) 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.

(e) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 10 microsiemens per centimeter or

less and with a clarity so that the sources can be seen clearly.

(f) 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.

(g) 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 0.00002 sievert (2 millirems) per hour.

Sec. X.35 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.

Sec. X.37 Power Failures.

(a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the fully shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

(c) 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.

Sec. X.39 Design Requirements. Irradiators whose construction begins after [the effective date of these regulations], must meet the design requirements of this section. Construction shall not begin until the Agency has reviewed and approved plans submitted by the Applicant.

(a) Shielding. For panoramic irradiators, the licensee shall 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 Section X.25. If the irradiator will use more than 2×10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(b) Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(c) Pool Integrity. For pool irradiators, the licensee shall design the pool to assure that it meets the requirements of X.33(a)(1), 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 Section X.33(b), and that metal components are metallurgically compatible with other components in the pool.

(d) Water Handling System. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of Section X.33(e). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(e) Radiation Monitors. For all irradiators, the licensee shall evaluate the location and sensitivity

of the monitor to detect sources carried by the product conveyor system as required by Section X.29(a). The licensee shall 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 Section X.59(b), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(f) Source Rack. For pool irradiators, the licensee shall 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 shall 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 shall 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.

(g) Access Control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of Section X.23.

(h) Fire Protection. For panoramic irradiators, the licensee shall 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 shall 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.

(i) Source Return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

(j) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall 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.

(k) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

Sec. X.41 Construction Monitoring and Acceptance Testing. The requirements of this section must be met for irradiators whose construction begins after [the effective date of these regulations]. The requirements must be met prior to loading sources.

(a) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(b) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(c) Pool Integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and meets the requirements of X.33(a)(1). The licensee shall verify that outlets and pipes meet the requirements of Section X.33(b).

(d) Water Handling System. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(e) Radiation Monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by Section X.29(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet Section X.59(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by SectionX.29(b).

(f) Source Rack. For panoramic irradiators, the licensee shall 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 shall observe and test the operation of the conveyor system to assure that the requirements in Section X.35 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.

(g) Access Control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(h) Fire Protection. For panoramic irradiators, the licensee shall 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 shall test the operability of the fire extinguishing system.

(i) Source Return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

(j) Computer Systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall 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.

(k) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

Operation of Irradiators

Sec. X.51 Training.

(a) 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, dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large

doses, how an 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 Parts J and X of these regulations that are relevant to the irradiator;

(3) The operation of the irradiator;

(4) Those operating and emergency procedures listed in Section X.53 that the individual is responsible for performing; and

(5) Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) 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 shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a 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.

(e) The licensee shall 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 shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who 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, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in Section X.53 that they are expected to perform or comply with, and their proper response to alarms required in this

Part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by Sections X.23(b), X.23(i), X.27(a), X.29(a), X.29(b), and X.59(b) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

Sec. X.53 Operating and Emergency Procedures.

(a) The licensee shall 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 Section X.61;

(7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(8) Inspection of movable shielding required by Section X.23(h), if applicable.

(b) The licensee shall 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.

Sec. X.55 Personnel Monitoring.

(a) Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter must be capable of detecting high energy photons in the normal and accident dose ranges. 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 that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, all persons who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

Sec. X.57 Radiation Surveys.

(a) 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 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in Section X.25 are exceeded, the facility must be modified to comply with the requirements in Section X.25.

(c) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20 percent 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.

(d) 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 Part D, Table 2, Column 2 or Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(e) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.0005 millisievert (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 0.0005 millisievert (0.05 millirem) per hour.

Sec. X.59 Detection of Leaking Sources.

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Agency, Agreement State or NRC. In the absence of a certificate from a transferor that a test has been made within the 6 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 Agency, Agreement State or NRC to perform the test.

(b) 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 6 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 possible, 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.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an Agreement State or NRC licensee that is authorized to perform these functions. The licensee shall 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 shall 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 products are found, the licensee shall arrange to have them decontaminated or disposed of by an Agreement State or NRC licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B of Part D.

Sec. X.61 Inspection and Maintenance.

(a) The licensee shall 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 Section X.23;

(2) Functioning of the source position indicator required by Section X.31(b);

(3) Operability of the radiation monitor for radioactive contamination in pool water required by Section X.59(b) using a radiation check source, if applicable;

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by Section X.29(b);

(5) Operability of the product exit monitor required by Section X.29(a);

(6) Operability of the emergency source return control required by Section X.31(c);

(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 Section X.27 (but without turning extinguishers on);

(9) Operability of the means of pool water replenishment required by Section X.33(c);

(10) Operability of the indicators of high and low pool water levels required by Section X.33(d);

(11) Operability of the intrusion alarm required by Section X.23(i), if applicable;

(12) Functioning and wear of the system, 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 Section X.35;

(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 Section X.63(b); and

(17) Leak tightness as required in Section X.33(a)(1).

(b) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

Sec. X.63 Pool Water Purity.

(a) The pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 10 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 10 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 10 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

Section X.65 Attendance During Operation.

(a) 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, shall 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.

(b) 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 Section X.51(g) must be onsite.

(c) 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 Sections X.51(f) and (g). Static irradiations may be performed without a person present at the facility.

Sec X.67 Entering and Leaving the Radiation Room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(1) Visually inspect the entire radiation room to verify that it is unoccupied; 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.

(c) 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 Section X.29(b) is operating with backup power.

Sec. X.69 Irradiation of Explosive or Flammable Materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Agency. 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.

(b) 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 Agency. 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

Sec. X.81 Records and Retention Periods. The licensee shall maintain the following records at the irradiator for the periods specified.

(a) 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 Agency terminates the

license for documents not superseded.

(b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of Sections X.51(a), (b), (c), (d), (f), and (g) until 3 years after the individual terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by Section X.51(e) for 3 years after the evaluation.

(d) A copy of the current operating and emergency procedures required by Section X.53 until superseded or the Agency terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by Section X.53(c)(3) retained for 3 years from the date of the change.

(e) Personnel dosimetry results required by Section X.55 until the Agency terminates the license.

(f) Records of radiation surveys required by Section X.57 for 3 years from the date of the survey.

(g) Records of radiation survey meter calibrations required by Section X.57 and pool water conductivity meter calibrations required by Section X.63(b) until 3 years from the date of calibration.

(h) Records of the results of leak tests required by Section X.59(a) and the results of contamination checks required by Section X.59(b) for 3 years from the date of each test.

(i) Records of inspection and maintenance checks required by Section X.61 for 3 years.

(j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

(k) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by Section A.4.

(l) Records on the design checks required by Section X.39 and the construction control checks as required by Section X.41 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(m) Records related to decommissioning of the irradiator as required by Section C.29.

Sec.X.83 Reports.

(a) The licensee shall immediately report the following events if not reported under other parts of these regulations:

(1) Source stuck in a not fully shielded 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 a 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; and

(10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report must include a telephone report within 24 hours as described in Section D.1202, and a written report within 30 days as described in Section D.1203.