105 CMR 120.000: THE CONTROL OF RADIATION

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120.001: GENERAL PROVISIONS

120.002: Purpose and Scope

Except as otherwise specifically provided, 105 CMR 120.000 apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in 105 CMR 120.000 shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission (NRC). Regulation by the Commonwealth 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 NRC and to 10 CFR Part 150 of the NRC's regulations.

120.003: Regulatory Authority

The authority for the Department of Public Health to promulgate 105 CMR 120.000 is found in: M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P.

120.004: Citation

105 CMR 120.000 shall be known and may be cited as the Massachusetts Regulations for the Control of Radiation (MRCR).

120.005: Definitions

As used in 105 CMR 120.000, these terms have the definitions set forth in 105 CMR 120.005. Additional definitions used only in a certain Section will be found in that Section.

105 CMR 120.000 means all Sections of the Massachusetts Regulations for the Control of Radiation.

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.

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. For purposes of Accelerator, "particle accelerator" is an equivalent term.

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

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 years of age or older.

Agency means the Radiation Control Program of the Massachusetts Department of Public Health.

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 § 274b of the Atomic Energy Act of 1954, as amended (St. 1973, c. 689).

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

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Airborne Radioactivity Area means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in 105 CMR 120.200: *Appendix B*, Table I; or

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

Airline Respirator (*see* Supplied-air Respirator (SAR)).

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.

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

As Low as is Reasonably Achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in 105 CMR 120.000 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 ionizing radiation and licensed or registered sources of radiation in the public interest.

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 trained and fitted 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 (SAR's) and self-contained breathing apparatus (SCBA) units.

Background Radiation means radiation from cosmic sources; non-technologically enhanced naturally occurring radioactive material, 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 or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency.

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

Bioassay means the determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (*in vivo* counting), or by analysis and evaluation of materials excreted or removed from the human body. For purposes of 105 CMR 120.000, Radiobioassay is an equivalent term.

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

Byproduct Material means:

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

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(2) (a) 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

(b) Any material that:

1. Has been made radioactive by use of a particle accelerator; and

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

(3) Any discrete source of naturally occurring radioactive material, other than source material, that:

(a) The Commission, 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

(b) 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. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

Calibration means the determination of:

(1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(2) the strength of a source of radiation relative to a standard.

CFR means Code of Federal Regulations.

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

CMR means Code of Massachusetts Regulations.

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.

Commissioner means the Commissioner, Massachusetts Department of Public Health.

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.

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

Confirmatory Action Letters means letters, confirming a licensee's, registrant's, or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

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.

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

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

Curie means a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} "disintegrations or transformations per second (dps or tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 1×10^{-3} curie = 3.7×10^{7} tps. One microcurie (μCi) = 1×10^{-6} curie = 3.7×10^{4} tps. One nanocurie (nCi) = 1×10^{-9} curie = 3.7×10^{1} tps. One picocurie (pCi) = 1×10^{-12} curie = 10^{-2} tps.

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of ten megaelectron volts and is commonly used for production of short half-life radionuclides for medical use. (*See* 105 CMR 120.005: Accelerator).

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

Deep Dose Equivalent (H_d) means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm^2) and applies to external whole body exposure.

Demand Respirator means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the facepiece by inhalation.

Department means the Department of Public Health.

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, industrial, or research activities.

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).

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, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of 105 CMR 120.000, Radiation Dose is an equivalent term.

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

Dose Limits means the permissible upper bounds of radiation doses established in accordance with 105 CMR 120.000. For purposes of 105 CMR 120.000, Limits is an equivalent term.

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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 ($H_E = \sum w_T H_T$).

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

Entrance or Access Point means any location through which 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 SI unit of exposure is the coulomb per kilogram (C/kg). *See* 105 CMR 120.014: *Units of Exposure and Dose* for the special unit.

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

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

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

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 evaluate the fit of a respirator on an individual.

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

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

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

Half-value layer (HVL) means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent that the air kerma rate, exposure rate, or absorbed dose rate is reduced to ½ of the value measured without the material at the same point.

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

Healing Arts means any discipline which involves the diagnosis or treatment of persons by a practitioner or animals by a veterinarian, and who is licensed for that purpose by the Commonwealth of Massachusetts, and which discipline includes the intentional exposure of persons and animals to sources of radiation for diagnosis or treatment.

Healing Arts Radiologic Screening means the completion of a procedure that irradiates an individual, with no symptoms or other potential indicators of disease, to ionizing radiation for the purpose of diagnosing the presence or absence of disease within the individual.

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

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

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

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* the definition of DAC-hours in 105 CMR 120.200).

Individual Monitoring Devices means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of 105 CMR 120.000, Personnel Dosimeter and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters, and personal (lapel) air sampling devices.

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.

Instrument Traceability means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at laboratory accredited by a program which requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

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.

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Ionizing Radiation (*See* Radiation).

Irradiation means the exposure of a living being or matter to ionizing radiation.

Kilovolt (kV) [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 1,000 volts in a vacuum. [*Note*: current convention is to use kV for photons and keV for electrons.]

Lead Equivalent means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

Leakage Radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

(1) The useful beam; and,
(2) Radiation produced when the exposure switch or timer is not activated.

Lens Dose Equivalent (LDE) means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

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

Licensed (or Registered) Material means radioactive material received, possessed, used, transferred or disposed of under a general or specific license [or registration] issued by the Agency.

Licensee means any person who is licensed by the Agency in accordance with 105 CMR 120.000 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P.

Licensing State means any State which has been finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviews state regulations to establish equivalency with the Suggested State Regulations and ascertains whether a State has an effective program for control of natural occurring or accelerator produced radioactive material (NARM). The Conference will designate as Licensing States those states with regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM.

Limits (*See* Dose limits).

Loose-fitting Facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lost or Missing Source of Radiation means licensed (or registered) source of radiation whose location is unknown. This definition includes, but is not limited to, licensed (or registered) 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 four 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 105 CMR 120.772.

Manifest means a detailed record of the characteristics and quantities of packaged waste as presented for transportation, treatment, storage, or disposal which usually accompanies waste transfers for these purposes.

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

Minor means an individual less than 18 years of age.

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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 105 CMR 120.000, Radiation Monitoring and Radiation Protection Monitoring are equivalent terms.

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

Nationally Tracked Source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 105 CMR 120.298: *Appendix D*. 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.

Natural Radioactivity means radioactivity of naturally occurring nuclides.

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.

Non-ionizing Radiation (*See* Radiation).

NORM means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear 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 for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 105 CMR 120.527, or from voluntary participation in medical research program, or as a member of the public.

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

Particle Accelerator (*See* Accelerator).

Patient means an individual subjected to healing arts examination, diagnosis, or treatment

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of the commonwealth other than the Department, any political subdivision of the commonwealth, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but not including federal government agencies.

Personnel Monitoring Equipment (*See* Individual Monitoring Devices).

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

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Pharmacist means an individual certified as such under M.G.L. c. 112, § 24 to compound and dispense drugs, prescriptions, and poisons.

Physician means an individual certified as a physician under M.G.L. c. 112, § 2 or corresponding citation of earlier laws.

Positive Pressure Respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

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

Powered Air-purifying Respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure Demand Respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

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

Protective Apron means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

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.

(2) Secondary protective barrier means the material which attenuates stray radiation.

Public Dose means the dose received by a member of the public from exposure to sources of radiation released by the 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 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 105 CMR 120.540, or from voluntary participation in medical research programs.

Pyrophoric Material means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C) or 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.

Qualified Expert means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

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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.

Quality Factor (Q) means the modifying factor, listed in 105 CMR 120.014: *Tables I* and *II*, that is used to derive dose equivalent from absorbed dose.

Quantitative Fit Test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

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

Radiation means 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 105 CMR 120.000, ionizing radiation is an equivalent term. Radiation, as used in 105 CMR 120.000, 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 one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation Dose (*See* Dose).

Radiation Detector means a device which, in the presence of radiation, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation Machine means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

Radiation Safety Officer means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and programs and has been assigned such responsibility by the licensee or registrant.

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

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

Radiobioassay (*See* Bioassay).

Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to 105 CMR 120.000 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P.

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

Regulations of the U.S. Department of Transportation (U.S. DOT) means the regulations in 49 CFR Parts 100 through 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 (one rem = 0.01 Sv).

Research and Development means:

(1) theoretical analysis, exploration, or experimentation; or

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(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 materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 105 CMR 120.200.

Restricted Area means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (*see* Exposure).

Scattered Primary Radiation means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.

Scattered Radiation means ionizing radiation emitted by the interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

Sealed Source means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Sealed Source and Device Registry means the national registry that contains the registration certificates, generated by both the Nuclear Regulatory Commission (NRC) and the Agreement States, that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions approved for the product.

Self-contained Breathing Apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow Dose Equivalent (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

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.

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 (one Sv = 100 rem).

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

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

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(2) ores which contain by weight $^{1}/_{20}$ of one percent (0.05%) or more of:
(a) uranium;
(b) thorium; or
(c) any combination thereof.
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 105 CMR 120.005: Byproduct Material(2).

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

Source Traceability means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology (NIST), or by a laboratory which participates in a continuing measurement quality assurance program with NIST or other equivalent national or international program.

Special Form Radioactive Material means radioactive material which 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 five millimeters (0.2 inch); and
(3) It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission 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 prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission 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 prior to April 1, 1998, may continue to be used. Special form material that was successfully tested before September 10, 2015 in accordance with the Nuclear Regulatory Commission 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 Special Form Radioactive Material.

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 § 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 one. For example, the following quantities in combination would not exceed the limitation and are within the formula:

NON-TEXT PAGE

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

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.

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

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

Tight-fitting Facepiece means a respiratory inlet covering that forms a complete seal with the face.

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

Total Organ Dose Equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 105 CMR 120.267(A)(6).

Traceable to National Standard (*See* Instrument Traceability or Source Traceability)

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 at 1237, 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 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

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

Unrestricted Area (Uncontrolled Area) means area access to which is neither limited nor controlled by the licensee or registrant. For purposes of 105 CMR 120.000, Uncontrolled Area is an equivalent term.

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.

Vendor means a supplier of products or services to be used by a licensee or registrant or a licensed or registered facility or activity.

Very High Radiation Area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates. [*Note*: At very high doses rates, units of adsorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem].

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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 105 CMR 120.005: Byproduct Material(2) and (3).

Waste Handling Licensees means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

Week means seven consecutive days starting on Sunday.

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

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

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

Working Level Month (WLM) means an exposure to one 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.

Year means the period of time beginning in January used to determine compliance with the provisions of 105 CMR 120.000. 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.

120.006: Exemptions

(A) General Provision. The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of 105 CMR 120.000 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 Commonwealth is exempt from 105 CMR 120.000 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 Government-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:

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

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

120.007: Prohibited Uses

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

(B) A Shoe-fitting fluoroscopic device shall not be used.

120.008: Impounding

Sources of radiation shall be subject to impounding pursuant to M.G.L. c. 111, §§ 5O and 5P.

120.009: Records

(A) Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in 105 CMR 120.000.

(B) 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 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254,120.255; and,

(2) Records required by 105 CMR 120.263(B)(4).

(C) If licensed activities are transferred or assigned in accordance with 105 CMR 120.131(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 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254,120.255; and,

(2) Records required by 105 CMR 120.263(B)(4).

(D) Prior to license termination, each licensee shall forward the records required by 105 CMR 120.125(C)(1)(g) to the Agency.

120.010: Inspections

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

(B) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to 105 CMR 120.000.

120.011: 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;

120.011: continued

(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.

120.012: Additional Requirements

(A) The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in 105 CMR 120.000 as it deems appropriate or necessary to minimize danger to public health and safety or property.

(B) Any person who finds or detects any source of radiation that is not under the physical or administrative control of a licensee or registrant, and that is not excluded, exempted or otherwise authorized under the provisions of 105 CMR 120.000, shall immediately report such source to the Radiation Control Program.

120.013: Communications

All correspondence in compliance with 105 CMR 120.000 shall be sent to the Department of Public Health, Radiation Control Program, at the programs's current mailing address, as stated in the website https://www.mass.gov/orgs/radiation-control-program.

120.014: Units of Exposure and Dose

(A) As used in 105 CMR 120.000, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.

(B) As used in 105 CMR 120.000, the units of dose are:

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

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

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 sievert).

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 sievert = 100 rems).

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(C) As used in 105 CMR 120.000, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

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

(D) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 105 CMR 120.014(C), 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of 105 CMR 120.000, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

120.014: continued

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

Neutron Energy (MeV)	Quality Factor* (Q)	Fluence per Unit Dose Equivalent** (neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent** (neutrons cm^{-2} Sv^{-1})
1.0×10^{-7}	2	980×10^{6}	980×10^{8}
1.0×10^{-6}	2	810×10^{6}	810×10^{8}
1.0×10^{-5}	2	810×10^{6}	810×10^{8}
1.0×10^{-4}	2	840×10^{6}	840×10^{8}
1.0×10^{-3}	2	980×10^{6}	980×10^{8}
1.0×10^{-2}	2.5	1010×10^{6}	1010×10^{8}
1.0×10^{-1}	7.5	170×10^{6}	170×10^{8}
5.0×10^{-1}	11	39×10^{6}	39×10^{8}
1	11	27×10^{6}	27×10^{8}
2.5	9	29×10^{6}	29×10^{8}
5	8	23×10^{6}	23×10^{8}
7	7	24×10^{6}	24×10^{8}
10	6.5	24×10^{6}	24×10^{8}
14	7.5	17×10^{6}	17×10^{8}
20	8	16×10^{6}	16×10^{8}
40	7	14×10^{6}	14×10^{8}
60	5.5	16×10^{6}	16×10^{8}
1.0×10^{2}	4	20×10^{6}	20×10^{8}
2.0×10^{2}	3.5	19×10^{6}	19×10^{8}
3.0×10^{2}	3.5	16×10^{6}	16×10^{8}
4.0×10^{2}	3.5	14×10^{6}	14×10^{8}

120.015: Units of Activity

For purposes of 105 CMR 120.000, 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 (dps or tps).

(B) One curie (Ci) = 3.7×10^{10} disintegrations or transformations per second (dps or tps) = 3.7×10^{10} becquerel (Bq) = 2.22×10^{12} disintegrations or transformations per minute (dpm or tpm).

ENFORCEMENT

120.016: Enforcement Policy and Procedures

(A) Purpose. The purpose of the enforcement program of the Agency is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

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

** Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

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(1) Ensuring compliance with regulations and conditions of license;
(2) Obtaining prompt correction of violations that may affect safety;
(3) Deterring future violations; and
(4) Encouraging improvement of licensee, registrant and vendor performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with all persons who do not comply with regulations. In no case will licensees who do not achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

(B) Grounds for Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease Activity. In accordance with M.G.L. c. 111, § 5O, the Commissioner may summarily suspend a license or certificate of registration or order immediate cessation of an activity, without a prior hearing, whenever the Department finds that public health, safety or the environment would be threatened by delay in issuance of an order. A facility or person may not operate during the period of a suspension of his/its license or certificate of registration and may not conduct a prohibited activity after notification of an order requiring the immediate cessation of an activity. However, upon request by the licensee or registrant, a hearing shall be provided promptly after the issuance of such suspension or order.

(C) Grounds for Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration.

(1) Specific Grounds. The Department may issue an order denying, revoking, modifying, limiting, or refusing to renew a license or certificate of registration sought or issued under 105 CMR 120.000, or issue an order to cease an activity, for any one of the following reasons:

(a) The applicant, licensee or registrant has failed to submit the information required for licensure or registration under 105 CMR 120.000.

(b) The applicant failed to meet the requirements for licensure or registration as specified in 105 CMR 120.000.

(c) The applicant, licensee or registrant is not suitable and responsible to operate a facility as required or provide the service as licensed or registered.

(d) The applicant, licensee or registrant has obtained or attempted to obtain or maintain a certificate of registration or license by fraud, misrepresentation, or by the submission of incorrect, false or misleading information.

(e) The applicant, licensee or registrant has failed to pay licensure and/or registration fees.

(f) The applicant, licensee or registrant has failed to pay civil penalties or criminal fines levied in accordance with of M.G.L. c. 111, § 5O or 5P and/or 105 CMR 120.000.

(g) The applicant, licensee or registrant has:

1. failed to allow duly authorized agents of the Agency to conduct inspections; or
2. attempted to impede the work of duly authorized representatives of the Agency or the enforcement of any provisions of M.G.L. c. 111 §§ 5N through 5P or 105 CMR 120.000.

(h) The applicant, licensee or registrant has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he/she is guilty of, any criminal violation relating directly or indirectly to his/her fitness to be licensed or registered under 105 CMR 120.000.

(i) The applicant, licensee or registrant has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of a similar license or certificate of registration or refusal of renewal of a similar license.

(j) The applicant, licensee or registrant has violated 105 CMR 120.000 or a license condition and has a history of non-compliance with the same or similar violation or has received a warning letter from the Department within the last five years for the same or similar violation.

(k) The applicant, licensee or registrant has been disciplined in another jurisdiction in any way by a licensing authority for reasons substantially the same as those set forth in 105 CMR 120.016(C).

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(l) The applicant or licensee operated a facility after the expiration of the license.

(m) The applicant, licensee or registrant has failed to remedy or correct a cited violation by the date specified in the written notice from the Department under M.G.L. c. 111, § 5O or by the date specified in the plan of correction accepted or modified by the Department, unless the applicant, licensee or registrant demonstrates to the satisfaction of the Department that such failure was not due to neglect of duty and occurred despite his/her good faith attempt to make corrections by the specified time.

(n) The applicant or licensee has engaged in or aided in the falsification of test results or any other records required to be maintained in accordance with 105 CMR 120.000.

(o) The applicant, licensee or registrant receives, possesses, uses, transfers, owns or operates or uses radioactive materials or machines which emit ionizing radiation in a manner which endangers public health, safety, or the environment.

(2) Other Grounds. The Department reserves the right to deny, modify, limit revoke or refuse to renew a license or certificate of registration for any other sufficient reason not listed in 105 CMR 120.016(C)(1) if it reasonably considers such action necessary to protect the public health, safety or the environment. In addition, nothing in 105 CMR 120.000 shall be deemed to limit the Department's authority to establish or recognize further general or specific grounds for discipline through rulemaking, adjudication, the issuance of polices or advisories or other similar means.

(D) Severity of Violations.

(1) Violations of 105 CMR 120.000 are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

(a) Health Physics;

(b) Transportation;

(c) Materials Operations;

(d) Miscellaneous Matters; and,

(e) Emergency Preparedness.

(2) Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V to those that are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; *i.e.* if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

(3) Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Health Physics is not directly comparable to that associated with Severity Level I violations in Emergency Preparedness.

(4) While examples are provided in 105 CMR 120.019: *Appendix A* for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each of the examples is predicated on a violation of an existing regulatory requirement. Each is designed to illustrate the significance which the Department places on a particular type of violation of regulatory requirements.

(5) In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

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(6) The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication of willfulness. The term "willfulness" includes, but is not limited to, the deliberate violation of any provision of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P or careless disregard of the requirements of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P. Willfulness does not include acts which do not rise to the level of careless disregard, *e.g.* inadvertent clerical errors in a document submitted to the Agency. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (*e.g.*, first-line supervisor or senior manager), the significance or any underlying violation, the intent of the violator (*i.e.* negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

(7) The Agency expects licensees to provide complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in 105 CMR 120.019: *Appendix A* the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event which it failed to report or should have been aware of the condition or event. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

(E) Enforcement Conference. Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the Agency may schedule an enforcement conference with the licensee or vendor prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, *e.*g. Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to:

(a) Discuss the violations or nonconformance, their significance and causes, and the licensee's or vendor's corrective actions;

(b) Determine whether there are any aggravating or mitigating circumstances;

(c) Obtain other information which will help determine the appropriate enforcement action; and

(d) Provide an opportunity for the licensee to explain what corrective actions have been taken or will be taken in response to the Notice of Violation. (*See* 105 CMR 120.016(F).

(F) Enforcement Procedures.

(1)(a) Notice of Violation. Whenever the Agency finds upon inspection, investigation of a complaint or through information in its possession that an applicant, licensee or registrant is not in compliance with provisions of M.G.L. c. 111, §§ 5N through 5P or a regulation promulgated thereunder, the Agency shall notify the applicant, licensee or registrant of such violation or deficiency. The notice shall include a statement of the violations or deficiencies found, the provision of the law relied upon, and a reasonable period of time for correction. A violation or deficiency may result in denial, suspension, revocation or refusal to renew a license or certificate of registration; a modification or limitation of a license or certificate of registration; a cease and desist order; and/or the imposition of a civil penalty and/or criminal sanctions.

(b) Confirmatory Action Letters. The Agency may issue Confirmatory Action Letters confirming a licensee's, registrant's, or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(2) Plan of Correction.

(a) The applicant, licensee or registrant shall within ten days of receipt of the notice, file with the Agency a written plan of correction. The plan shall clearly identify the licensee or registrant, state the date, reference the violation(s) cited, state specific corrective action(s) and timetable(s) and date(s) for completion for each violation cited, and shall be signed by either the applicant, licensee or registrant or his/her designee.

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(b) The Agency may re-inspect a facility in order to determine whether the corrections have been made. If upon review of plan of correction and/or reinspection the Agency finds that the applicant, licensee or registrant is in compliance with 105 CMR 120.000 and that the applicant, licensee or registrant has submitted an acceptable plan of correction, the Agency shall notify the applicant, licensee or registrant of its findings of compliance and/or its acceptance or modification of the plan of correction.

(c) If upon review of plan of correction and/or reinspection the Agency finds the plan of correction is unacceptable, the Agency may request that the applicant, licensee or registrant amend and resubmit the plan of correction within five days of the date of notice of the required amendment to the plan of correction or such other time as the Agency may specify for resubmission.

(d) If upon review of the plan of correction and/or reinspection the Agency determines that an applicant, licensee or registrant remains non-compliant with applicable laws and regulations regarding licensure, or the Agency determines that further enforcement action is necessary to ensure compliance with regulatory requirements and deter future non-compliance the Department may initiate enforcement procedures as set forth in 105 CMR 120.016.

(3) Notice of Department's Intent to Issue an Order.

(a) Except as specified in 105 CMR 120.016(F)(4)(b), prior to the Department issuing an order to modify, limit, deny, revoke or refuse to renew a license, and/or to require a person to cease and desist any activity, and/or to impose civil penalties, the applicant, licensee or registrant shall be notified in writing of the Agency's Intent to Issue an Order. The Notice of Intent to Issue an Order shall include the grounds for the Department's action, the provision(s) of law relied upon, the amount of any civil penalty or the requirements of the proposed order, and a right to request an adjudicatory hearing.

(b) If a license or certificate of registration is to be denied, modified, limited, revoked or refused renewal or if an activity is to be ceased or a civil penalty imposed by the Department, then the aggrieved applicant, licensee or registrant may request an adjudicatory hearing within 21 days of receipt of notification of the Department's Intent to Issue an Order. Said request shall be filed in accordance with 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

(4) Administrative Hearings: Procedure.

(a) Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease an Activity:

1. The Department shall give the licensee or registrant written notice stating the reason(s) for the immediate suspension or issuance of an order to immediately cease an activity and the provisions of law relied upon. The immediate suspension or order to immediately cease an activity shall take effect immediately upon issuance of the notice.

2. The Department shall provide for a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures* promptly after the issuance of an order of immediate suspension or an order to immediately cease an activity.

3. In cases of immediate suspension of a license or certificate of registration or issuance of an order to immediately cease an activity, the Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the immediate suspension or cease and desist order, a threat to public health, safety or the environment.

4. In the event that the Department determines that the violation of state law or of 105 CMR 120.000 which posed a threat to public health, safety or the environment is corrected prior to the decision of the Hearing Officer, the Department may lift the immediate suspension by giving written notice to the licensee or registrant.

(b) Denial, Modification, Limitation, Revocation, or Refusal to Renew a License or Certificate of Registration Based on Failure to File Reports or Pay Fees or Maintain Insurance: In accordance with M.G.L. c. 30A, § 13, no Notice of Intent to Issue an Order shall be required and no hearing shall be offered where denial, modification, limitation, revocation, suspension or refusal to renew is based solely upon failure of the licensee or registrant to file timely reports, schedules or applications or to pay lawfully prescribed fees, or to maintain insurance coverage as required by any law or regulation.

120.016: continued

(c) Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration; Orders to Cease an Activity; Civil Penalties:

1. All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

2. Except for circumstances specified in 105 CMR 120.016(F)(4)(b), if the Department determines that a license or certificate of registration should be denied, modified, limited, revoked, or refused renewal, and/or that a facility should cease an activity, and/or that a civil penalty should be imposed, and if the Department notifies the applicant, licensee or registrant of its intended action, upon receipt of a Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

3. The Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that the license or certificate of registration should be denied, modified, limited, revoked or refused renewal; that an activity should be ceased; and/or that a civil penalty be imposed based on relevant facts as they existed at or prior to the time the Department initiated the hearing procedure.

4. If the Hearing Officer finds any single ground for denial, modification, limitation, revocation, suspension, or refusal to renew a license or certificate of registration; for a cessation of an activity; and/or for imposition of a civil penalty, then the Hearing Officer shall render a recommended decision affirming the issuance of the Department's Order.

(d) Final Agency Decision and Judicial Review:

1. The recommended decision of a Hearing Officer in any adjudicatory proceeding conducted under 105 CMR 120.000 shall be reviewed by the Commissioner. The Commissioner's decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

2. Any applicant, licensee or registrant that fails to exercise its right to an adjudicatory proceeding under 105 CMR 120.000 waives its right to an adjudicatory hearing, its right to administrative review by the Commissioner and its right to judicial review pursuant to M.G.L. c. 30A, § 14.

(G) Civil Penalties.

(1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a licensee, registrant or vendor has not complied with an order issued pursuant to M.G.L. c. 111, § 5O or with any provision of M.G.L. c. 111, §§ 5N through 5P or with any applicable rule, regulation, license or certificate of registration adopted or issued thereunder, the Department, in *lieu* of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license or certificate of registration, may assess civil penalties in an amount not exceeding $100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.

(2) The decision whether to issue a civil penalty and the amount of any civil penalty depends on the facts of each case. Generally, civil penalties are most likely to be imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations that occurred after the date of the last inspection or within two years, whichever period is greater for which the licensee did not take effective corrective action.

(3) Civil penalties may be assessed for known and conscious violations of the reporting requirements of 105 CMR 120.000 and for any willful violation of any Agency requirement including those at any severity level.

(4) Payment of civil penalties imposed under M.G.L. c. 111, § 5O shall be made by check, draft, or money order payable to the Commonwealth of Massachusetts, and mailed to the Radiation Control Program.

(5) Factors in Determining the Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:

(a) The willfulness of the violation;

(b) The actual and potential danger to the public health or the environment;

(c) The actual or potential costs of such danger to the public health or the environment;

120.016: continued

(d) The actual or potential damage or injury to the public health or environment;
(e) The actual and potential cost of such damage or injury;
(f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;
(g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
(h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5P;
(i) Whether imposition of a civil penalty is likely to deter future non-compliance;
(j) The financial condition of the person being assessed the civil penalty; and
(k) The public interest.

(H) Escalation of Enforcement Sanctions.
(1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. When Severity Level I, II or III violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in 105 CMR 120.016(D).
(2) The progression of enforcement actions for similar violations will usually be based on similar violations at an individual facility and not on similar violations under the same license. However, under some circumstances, *e.g.*, where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(I) Criminal Enforcement. The Department may elect to enforce any section of 105 CMR 120.000 or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or § 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, § 5N or § 5O shall be fined not less than $100 nor more than $2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than $1,000 nor more than $20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(J) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(K) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

(L) Deliberate Misconduct.
(1) Any licensee; certificate of registration holder; quality assurance program approval holder; applicant for a license or certificate of registration or quality assurance program approval; employee of a licensee, certificate of registration holder, quality assurance program approval 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, quality assurance program approval holder or applicant for a license or certificate of registration or quality assurance program approval, who knowingly provides to any licensee, applicant, certificate holder, quality assurance program approval holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's or applicant's activities in this part, may not:

120.016: continued

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

(b) Deliberately submit to the Agency, a licensee, certificate of registration holder, quality assurance program approval holder, an applicant, or a licensee's, certificate holder's, quality assurance program approval 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 Agency.

(2) A person who violates 105 CMR 120.016(L)(1)(a) or (b) may be subject to enforcement action in accordance with the procedures in 105 CMR 120.016.

(3) For the purposes of 105 CMR 120.016(L)(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate of registration holder, quality assurance program approval 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 Agency; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, quality assurance program approval holder, applicant, contractor, or subcontractor.

120.017: Severability

The provisions of 105 CMR 120.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

120.018: Public Disclosure of Enforcement Actions

In accordance with M.G.L. c. 30A, the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases may be issued for civil penalties related to violations at Severity Level I, II, or III.

120.019: Appendix A – Severity Categories

The following examples of severity levels are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

(A) Severity Level 1 – Most Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 105 CMR 120.253;

(d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 105 CMR 120.253;

(e) Exposure of a worker in restricted areas of ten times the limits of 105 CMR 120.212.

(2) Transportation.

(a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

(b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.

(3) Materials Operations.

(a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

(b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

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(4) Miscellaneous Matters.

(a) A Material False Statement (MFS)[1] in which the statement made was deliberately false;

(b) Falsification of records which the Agency requires be kept of significant information in which the records were deliberately falsified by or with the knowledge of management; or,

(c) A knowing and intentional failure to provide any notice required by 105 CMR 120.000.

(d) Possession of licensable quantities of radioactive material without a license, or loss of control of a source of radiation.

(e) Refusing authorized Agency personnel access to facilities, records and/or equipment to conduct inspections or investigations.

(5) Emergency Preparedness. In an emergency, licensee failure to promptly:

(a) correctly identify the event;

(b) make required notifications to responsible Federal, State, and local agencies; or

(c) respond to the event (*e.g.*, assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

(B) Severity Level II -- Very Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms or to any other organ or tissue;

(b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of five times the limits of 105 CMR 120.222;

(d) Failure to make an immediate notification as required by 105 CMR 120.282(A), and (B);

(e) Disposal of license material in quantities or concentrations in excess of five times the limits of 105 CMR 120.253;

(f) Exposure of a worker in restricted areas in excess of five times the limits of 105 CMR 120.212.

(g) An x-ray system having a malfunction such that inadvertent exposures could occur *e.g.*, a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

(h) A fluoroscopic x-ray system with a tabletop entrance exposure rate of greater than or equal to 25 R/min. 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 activated.

(i) A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier; or,

(j) Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, *etc*.

(k) Therapy system, with improper operator/patient communication/observation.

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[1] In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process. As can be seen in the examples, in determining the specific severity level of a violation involving material false statements or falsification of records, consideration will be given to such factors as the position of the person involved in the violation (*e.g.*, first line supervisor or senior manager), the significance of the information involved, and the intent of the violator (*i.e.*, negligence not amounting to careless disregard or deliberateness). The relative weight given to each of these factors will be dependent on the circumstances of the violation.

120.019: continued

(2) Transportation.
(a) Breach of package integrity resulting in surface contamination or external radiation levels in excess of Agency requirements;
(b) Surface contamination or external radiation levels in excess of five times Agency limits that did not result from a breach of package integrity; or,
(c) Failure to make required initial notifications associated with Severity Level I or II violations.

(3) Material Operations.
(a) Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or,
(b) A system designed to prevent or mitigate a serious safety event being inoperable.

(4) Miscellaneous Matters.
(a) A MFS, or a reporting failure, involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in the Agency seeking further information;
(b) A MFS in which the false statement was made with careless disregard.
(c) Deliberate falsification of records which the Agency requires be kept involving significant information; or,
(d) A failure to provide the notice required.
(e) Failure to register sources of radiation or services as required by 105 CMR 120.000.
(f) Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency.

(5) Emergency Preparedness. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

(C) Severity Level III --- Significant Violations.

(1) Health Physics.
(a) A radiation exposure during any year of a worker in excess of 5 rems total effective dose equivalent, 15 rems to the lens of the eye, or 50 rems to the skin of the whole body or to the feet, ankles, hands or forearms, or to any other organ or tissue;
(b) A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in a seven consecutive days;
(c) Failure to make a 24-hour notification as required by 105 CMR 120.281 or an immediate notification required by 105 CMR 120.282;
(d) Substantial potential for an exposure or release in excess of 105 CMR 120.200, whether or not such exposure or release occurs (*e.g.*, entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);
(e) Release of radioactive material to an unrestricted area in excess of the limits of 105 CMR 120.222;
(f) Improper disposal of licensed material not covered in Severity Level I or II;
(g) Exposure of worker in restricted areas in excess of the limits of 105 CMR 120.212;
(h) Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;
(i) Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;
(j) Conduct of licensee activities by a technically unqualified person;
(k) Significant failure to control licensed material;
(l) Failure to use exposure reduction devices properly (*e.g.*, collimators, filtration);
(m) For a fluoroscopic system where the maximum allowable tabletop exposure rate is 5 R/min., test values of greater than or equal to 7 R/min. (uncorrected), but less than 25 R/min. Correspondingly, for a maximum allowable rate of 10 R/min., test values of greater than or equal to 14 R/min. (uncorrected) but less than 25 R/min. are included.

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(n) A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

(o) Intraoral dental systems capable of operations in the above 50 kVp range for which the field size at the cone tip is greater than or equal to nine centimeters or which exhibit a minimum SSD less than 16 centimeters.

(p) Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.

(q) Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5% of the source to image receptor distance.

(r) Therapy systems which fail to maintain proper surveys, calibrations, spot checks or operating procedures.

(2) Transportation.

(a) Breach of package integrity;

(b) Surface contamination or external radiation levels in excess of, but less than a factor of five above Agency requirements that did not result from a breach of package integrity;

(c) Any noncompliance with labeling, placarding, shipping paper, packaging loading, or other requirements that could reasonably result in the following:

a. Improper identification of the type, quantity, or form of material;

b. Failure of the carrier or recipient to exercise adequate controls; or,

c. Substantial potential for personnel exposure or contamination, or improper transfer of material; or,

(d) Failure to make required initial notification associated with Severity Level III violations.

(3) Materials Operations.

(a) Failure to control access to licensed materials for radiation purposes as specified by Agency requirements;

(b) Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

(c) Use of radioactive material on humans where such use is not authorized;

(d) Conduct of licensed activities by a technically unqualified person;

(e) Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or,

(f) Medical therapeutic misadministrations.

(g) Failure to obtain appropriate Agency approval before moving to a new use and/or storage location.

(4) Miscellaneous Matters.

(a) An MFS not amounting to a Severity Level I or II violation; or,

(b) Deliberate falsification, or falsification by or with the knowledge of management of records which the Agency requires be kept that did not involve signification information.

(5) Emergency Preparedness. Violations of lesser severity than Severity Level II violations.

(D) Severity Level IV -- Violations.

(1) Health Physics.

(a) Exposures in excess of the limits of 105 CMR 120.211 not constituting Severity Level I, II, or III violations;

(b) A radiation level in an unrestricted area such that an individual could receive greater than two millirem in a one-hour period or 50 millirem in a year;

(c) Failure to make a 30-day notification required by 105 CMR 120.283;

(d) Failure to make a follow-up written report as required by 105 CMR 120.281, 120.287 and 120.750; or,

(e) Any other matter that has more than minor safety or environmental significance.

(f) A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.

(g) Systems equipped with positive beam limiting devices which do not allow the field size to be reduced to a size less than that of the image receptor.

120.019: continued

(h) Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.

(i) Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.

(j) Mammographic systems manufactured after October 1977 for which the edges of the x-ray field on the right or left sides extend beyond the edges of the image receptor. If manufactured prior to November 1977 and the edges of the x-ray field on either side extend beyond the edge of the image receptor by more than 5% of the SID.

(2) Transportation.

(a) Package selection of preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of Agency requirements; or,

(b) Other violations that have more than minor safety or environmental significance.

(3) Material Operations.

(a) Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

(b) Other violations that have more than minor safety or environmental significance; or,

(c) Failure to report medical diagnostic misadministrations.

(4) Miscellaneous Matters.

(a) A false statement caused by an inadvertent clerical or similar error involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or the Agency seeking additional information.

(b) Unless specified in a more severe category, changes in procedures or other conditions of a license or certificate of registration of which the Agency was not informed (*e.g.*, change of address, expiration of certificate of registration); or,

(5) Emergency Preparedness. Violations of lesser severity than Severity Level III violations.

120.020: REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES

120.021: Purpose and Scope

(A) 105 CMR 120.020 through 120.040 provides for the registration of radiation machine facilities and for the registration of persons providing radiation machine installation, servicing, and/or services to Department registrants or registrable facilities. For the purposes of 105 CMR 120.020, particle accelerators, whether used primarily for x-ray production or other purposes, shall be considered a radiation machine facility.

(B) In addition to the requirements of 105 CMR 120.020 through 120.040, all registrants are subject to the applicable provisions of other parts of 105 CMR 120.000.

120.022: Definitions

As used in 105 CMR 120.020 through 120.040, "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.

120.023: Exemptions

(A) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 105 CMR 120.020 through 120.040, providing dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem (5μ Sv) per hour at five 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 incident thereto are exempt from the requirements of 105 CMR 120.020 through 120.040.

120.023: continued

(C) Domestic television receivers are exempt from the requirements of 105 CMR 120.020 through 120.040.

120.024: Plan Review

(A) Prior to construction, the floor plans and equipment arrangements of all new installations, or modifications of existing installations, utilizing ionizing radiation for diagnostics or therapeutic purposes shall be submitted to the Agency for review and approval. The installation shall meet the requirements of 105 CMR 120.420: *Appendix A* and 105 CMR 120.422: *Appendix C* unless specifically exempted. Additional shielding and design requirements are specified elsewhere in 105 CMR 120.000.

(B) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(C) 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 105 CMR 120.211, 120.217, 120.218 and 120.221.

120.025: Application for Registration

Each person who owns or possess and administratively controls a facility, unless specifically exempted in 105 CMR 120.023 shall:

(A) Apply for registration of such facility with the Agency prior to the operation of a radiation machine facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions.

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

(C) Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 105 CMR 120.026(D) to his radiation machine facility until such person provides evidence that he has been registered with the Agency as a provider of services in accordance with 105 CMR 120.026.

120.026: Application for Registration Services

(A) Each person, prior to engaging in the business of installing or offering to install radiation machines or engaging in the business of furnishing or offering to furnish radiation machine servicing or services in this Commonwealth shall apply for and receive registration for such services with the Agency.

(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 105 CMR 120.020 through 120.040 shall specify:

(1) That he has read and understands the requirements of 105 CMR 120.020 through 120.040;

(2) The services for which he is applying for registration; and,

(3) The training and experience that qualify him to discharge the services for which he is applying for registration;

(D) For the purpose of 105 CMR 120.026, services may include but shall not be limited to:

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

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(2) Calibration of radiation machines or radiation measurement instruments or devices;
(3) Radiation protection or health physics consultations or surveys; and,
(4) Personnel dosimetry services.

120.027: Certificate of Registration

(A) No person shall maintain a facility that is required by 105 CMR 120.000 to be registered unless such a person has obtained a valid certificate of registration for such facility.

(B) A person who applies for registration and whose application meets the requirements of 105 CMR 120.000, shall, upon payment of the required fee, be issued a certificate of registration effective on the date stated on such certificate.

(C) A current certificate of registration or a legible copy thereof shall be posted conspicuously at each registered facility.

(D) The Director of the Radiation Control Program may incorporate in the certificate of registration, at the time of issuance or thereafter, any such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as said Director finds appropriate and necessary for the protection of the general public or individuals against radiation hazards.

120.028: Expiration of Notice of Registration

Each certificate of registration shall expire at the end of the specified day in the month and year stated therein.

120.029: Renewal of Notice of Registration

(A) Application for renewal of registration shall be filed in accordance with 105 CMR 120.025 or 105 CMR 120.026.

(B) In any case in which a registrant not less than 30 days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Agency.

120.030: 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. In the case of disposition of an x-ray system, such notification should specify the recipient of the system. In the case of modification involving a structural change, or the addition or relocation of an x-ray system, the Director of the Radiation Control Program may require the registrant to submit the information contained in 105 CMR 120.420: *Appendix A* and/or 105 CMR 120.421: *Appendix C*.

120.031: Approval Not Implied

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 105 CMR 120.025 or 120.026, and no person shall state or imply that any activity under such registration has been approved by the Agency.

120.032: Assembler and/or Transfer Obligation

(A) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this Commonwealth shall notify the Agency within 15 days of:
(1) The name and address of persons who have received these machines;
(2) The manufacturer, model, and serial number of each radiation machine transferred; and,
(3) The date of transfer of each radiation machine.

120.032: continued

(4) In the case of diagnostic x-ray system which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30 (d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in *lieu* of any other by the assembler.

(B) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and use shall meet the requirements of 105 CMR 120.000.

120.033: Out-of-state Radiation Machines

(A) Whenever any radiation machine is to be brought into the Commonwealth, for any temporary use, the person proposing to bring such machine into the Commonwealth shall give written notice to the Agency at least ten working days before such machine is to be used in the Commonwealth. The notice shall include:

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

(B) The person referred to in 105 CMR 120.033 shall:

(1) Comply with all applicable regulations of the Agency;
(2) Register the radiation machine(s) with the Agency; and,
(3) Submit payment of the required fee for registration.

(C) A pre-operational inspection may be required at the discretion of the Director of the Radiation Control Program.

(D) If, for a specific case, the ten working day period is not practical, notification to the Agency by telephone and hardcopy, permission to proceed sooner may be granted.

120.040: Notification to Fire Department

The user shall notify the local fire department of the presence on his premises of any radioactive material that may present special fire-fighting problems or require special precautionary measures in case of fire or other natural catastrophe, and he shall establish effective liaison with the fire department in regards to this matter.

120.050: PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

GENERAL PROVISIONS

120.051: Purpose

105 CMR 120.050 through 120.080 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 105 CMR 120.080: *Appendix A: Table 1*. 105 CMR 120.050 through 120.080 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 105 CMR 120.050 through 120.080 authorizes possession of licensed material.

120.052: Scope

(A) 105 CMR 120.056 through 120.071 applies to any person who, under the regulations in 105 CMR 120.000, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

120.052: continued

(B) 105 CMR 120.072 through 120.077 applies to any person who, under 105 CMR 120.000:
(1) Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or
(2) Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

120.053: Definitions

As used in 105 CMR 120.050 through 120.080, the following definitions apply:

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 105 CMR 120.056 through 120.062 and who has completed the training required by 105 CMR 120.064(C).

Background Investigation means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

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.

Category 1 Quantity of Radioactive Material means a quantity of radioactive material meeting or exceeding the category 1 threshold in 105 CMR 120.080: *Appendix A: Table 1*. 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 105 CMR 120.080: *Appendix A: Table 1*. 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 one, 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 105 CMR 120.050 through 120.080 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.

120.053: continued

Government Agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

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 six 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.

State means a State or Commonwealth of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Telemetric Position Monitoring System means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

Trustworthiness and Reliability are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

Unescorted Access means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

120.054: Communications

Except where otherwise specified or covered, all communications and reports concerning 105 CMR 120.050 through 120.080 may be sent as stated in 105 CMR 120.013.

120.055: Specific Exemptions

(A) The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of 105 CMR 120.050 through 120.080 as it determines are authorized by law and will not endanger life or property or the physical protection of agreement material, and are otherwise in the public interest.

(B) A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of 105 CMR 120.056 through 120.077. 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 105 CMR 120.050 through 120.080. The licensee shall implement the following requirements to secure the radioactive waste:

(1) Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(2) Use a locked door or gate with monitored alarm at the access control point;

(3) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

(4) Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

120.056: Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Materials

(A) General.

(1) 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 105 CMR 120.056 through 120.062.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of 105 CMR 120.056 through 120.062 upon application for modification of its license shall implement the requirements of 105 CMR 120.056 through 120.062, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to the provisions of 105 CMR 120.056 through 120.062 shall implement the provisions of 105 CMR 120.056 through 120.062 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 105 CMR 120.056(C)(1) are trustworthy and reliable.

(C) Applicability.

(1) Licensees shall subject the following individuals to an access authorization program:

(a) 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

(b) Reviewing officials.

(2) Licensees need not subject the categories of individuals listed in 105 CMR 120.060(A)(1) through (13) to the investigation elements of the access authorization program.

(3) 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.

120.056: continued

(4) Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under 105 CMR 120.056 through 120.062.

120.057: Access Authorization Program Requirements

(A) Granting Unescorted Access Authorization.

(1) Licensees shall implement the requirements of 105 CMR 120.056 through 120.062 for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by 105 CMR 120.064(C) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

(B) Reviewing Officials.

(1) 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.

(2) 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. Licensees shall provide oath or affirmation certifications to the Agency using an appropriate method listed in 105 CMR 120.054. 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 ten years in accordance with 105 CMR 120.058(C).

(3) 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.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) 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

(b) The individual is subject to a category listed in 105 CMR 120.060(A).

(C) Informed Consent.

(1) 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 105 CMR 120.058(B). A signed consent must be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(a) 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

(b) 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 105 CMR 120.056 through 120.062 is sufficient cause for denial or termination of unescorted access.

120.057: continued

(E) Determination Basis.

(1) 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 105 CMR 120.056 through 120.062.

(2) 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 105 CMR 120.056 through 120.062 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.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) 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.

(5) 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 seven 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.

(1) Prior to any final adverse determination, licensees shall provide each individual subject to the requirements of 105 CMR 120.056 through 120.062 with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one year from the date of the notification.

(2) 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 ten 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.

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

120.057: continued

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of persons approved for unescorted access authorization for three years after the list is superseded or replaced.

120.058: 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 seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter. The background investigation must include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with 105 CMR 120.059;

(2) 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 105 CMR 120.061. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

(3) 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 seven years before the date of application;

(4) Verification of Education. Licensees shall verify that the individual participated in the education process during the claimed period;

(5) 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 105 CMR 120.056 through 120.062 must be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) 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

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after ten business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

(B) Grandfathering.

(1) 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.

120.058: continued

(2) 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 ten 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 105 CMR 120.059. The reinvestigations must be completed within ten years of the date on which these elements were last completed.

120.059: 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.

(1) Except for those individuals listed in 105 CMR 120.060 and those individuals grandfathered under 105 CMR 120.058(B), each licensee subject to the provisions of 105 CMR 120.056 through 120.062 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 U.S. Nuclear Regulatory Commission 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.

(2) 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.

(3) 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:

(a) 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

(b) The previous access was terminated under favorable conditions.

(4) 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 105 CMR 120.056 through 120.062, 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 105 CMR 120.061(C).

(5) 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.

(1) 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:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

120.059: continued

(2) Licensees may not use information received from a criminal history records check obtained under 105 CMR 120.056 through 120.062 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.

(1) For the purpose of complying with 105 CMR 120.056 through 120.062, 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-8B20, 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.

(2) 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 website. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check Information page at https://www.nrc.gov/security/chp.html and *see* the link for How do I determine how much to pay for the request?).

(3) The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

120.060: 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:

(1) An employee of the U.S. Nuclear Regulatory Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(2) A Member of Congress;

(3) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(4) The Governor of a State or his or her designated State employee representative;

(5) Federal, State, or local law enforcement personnel;

(6) State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

(7) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;

(8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(9) Emergency response personnel who are responding to an emergency;

(10) Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

(11) Package handlers at transportation facilities such as freight terminals and railroad yards;

120.060: continued

(12) 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 three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(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 five 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 three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

(1) National Agency Check;

(2) Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;

(3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;

(4) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;

(5) Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR part 1572; and

(6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

120.061: Protection of Information

(A) Each licensee who obtains background information on an individual under 105 CMR 120.056 through 120.062 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:

(1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

(2) 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 105 CMR 120.056 through 120.062 available for examination by an authorized representative of the Agency to determine compliance with the regulations and laws.

120.061: continued

(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 three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

120.062: 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 105 CMR 120.056 through 120.062 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 three years.

PHYSICAL PROTECTION REQUIREMENTS DURING USE

120.063: Security Program

(A) Applicability.

(1) 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 105 CMR 120.063 through 120.071.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of 105 CMR 120.063 through 120.071 upon application for modification of its license shall implement the requirements of 105 CMR 120.063 through 120.071, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to 105 CMR 120.063 through 120.071 shall provide written notification to the Agency as specified in 105 CMR 120.054 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 105 CMR 120.064 through 120.070.

120.064: General Security Program Requirements

(A) Security Plan.

(1) Each licensee identified in 105 CMR 120.063(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 105 CMR 120.063 through 120.071. The security plan must, at a minimum:

120.064: continued

(a) Describe the measures and strategies used to implement the requirements of 105 CMR 120.063 through 120.071; and

(b) Identify the security resources, equipment, and technology used to satisfy the requirements of 105 CMR 120.063 through 120.071.

(2) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of Agency requirements. The licensee shall ensure that:

(a) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(b) The affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(B) Implementing Procedures.

(1) The licensee shall develop and maintain written procedures that document how the requirements of 105 CMR 120.063 through 120.071 and the security plan will be met.

(2) The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure must be retained for three years after the record is superseded.

(C) Training.

(1) 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:

(a) 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;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Agency requirements;

(c) 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

(d) The appropriate response to security alarms.

(2) 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.

(3) 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:

(a) Review of the training requirements of 105 CMR 120.064(C) and any changes made to the security program since the last training;

(b) Reports on any relevant security issues, problems, and lessons learned;

(c) Relevant results of Agency inspections; and

(d) Relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

(D) Protection of Information.

(1) 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.

120.064: continued

(2) 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 that have been approved for unescorted access.

(3) Before granting an individual access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

(a) Evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

(b) 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 105 CMR 120.058(A)(2) through (7).

(4) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(a) The categories of individuals listed in 105 CMR 120.060(A)(1) through (13); or

(b) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in 105 CMR 120.058(A)(2) through (7), has been provided by the security service provider.

(5) 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 that have been approved for unescorted access.

(6) Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that 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 that 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 seven 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 that have been approved for unescorted access.

(7) When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

(8) The licensee shall retain as a record for three years after the document is no longer needed:

(a) A copy of the information protection procedures; and

(b) The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

120.065: LLEA Coordination

(A) A licensee subject to 105 CMR 120.063 through 120.071 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:

(1) 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 105 CMR 120.063 through 120.071; and

(2) 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 within three business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) 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 three years.

120.065: continued

(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.

120.066: 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:

(1) 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

(2) Direct control of the security zone by approved individuals at all times; or

(3) 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.

120.067: Monitoring, Detection, and Assessment

(A) Monitoring and Detection.

(1) 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.

(2) Monitoring and detection must be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(c) A monitored video surveillance system; or

(d) Direct visual surveillance by approved individuals located within the security zone; or

(e) Direct visual surveillance by a licensee designated individual located outside the security zone.

(3) A licensee subject to 105 CMR 120.063 through 120.071 shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(a) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

1. Electronic sensors linked to an alarm; or
2. Continuous monitored video surveillance; or
3. Direct visual surveillance.

120.067: continued

(b) 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:

(1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(2) 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.

120.068: Maintenance and Testing

(A) Each licensee subject to 105 CMR 120.063 through 120.071 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 105 CMR 120.050 through 120.080 must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

(B) The licensee shall maintain records on the maintenance and testing activities for three years.

120.069: 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.

120.070: 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 105 CMR 120.063 through 120.071 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 annually) review the security program content and implementation.

120.070: continued

(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 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 maintain the review documentation for three years.

120.071: 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 four 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 four hours after notifying the LLEA, the licensee shall notify the Agency by telephone.

(C) The initial telephonic notification required by 105 CMR 120.071(A) must be followed within a period of 30 days by a written report submitted to the Agency by an appropriate method listed in 105 CMR 120.054. The report must include sufficient information for Agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

PHYSICAL PROTECTION IN TRANSIT

120.072: 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, U.S. Nuclear Regulatory Commission, or an Agreement State shall meet the license verification provisions of 105 CMR 120.072(A) through (D) instead of those listed in 105 CMR 120.140(D):

(A) Any licensee transferring category 1 quantities of radioactive material to a licensee of the Agency, U.S. Nuclear Regulatory Commission, 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, U.S. Nuclear Regulatory Commission, 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.

120.072: continued

(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 three years.

120.073: 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 105 CMR 120.074(A) and (E); 120.075; 120.076(A)(1), (B)(1) and (C); and 120.077(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 105 CMR 120.074(B) through (E); 120.076(A)(2) and (3) and (B)(2), and (C); and 120.077(B), (D), (F), (G), and (H). For those shipments of category 2 quantities of radioactive material that meet the criteria of 105 CMR 120.790(B), the shipping licensee shall also comply with the advance notification provisions of 105 CMR 120.790.

(C) The shipping licensee shall be responsible for meeting the requirements of 105 CMR 120.072 through 120.077 unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under 105 CMR 120.072 through 120.077.

(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 105 CMR 120.074(A)(2) and (E); 120.075; 120.076(A)(1), (B)(1), and (C); and 120.077(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 105 CMR 120.076(A)(2) and (3), and (B)(2); and 120.077(B), (D), (F), (G), and (H) for the domestic portion of the shipment.

120.074: Pre-planning 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:

(1) Pre-plan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Pre-plan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

(a) Discuss the State's intention to provide law enforcement escorts; and

(b) Identify safe havens; and

(3) Document the pre-planning 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.

120.074: continued

(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 105 CMR 120.074(B), shall promptly notify the receiving licensee of the new no-later-than arrival time.

(E) The licensee shall retain a copy of the documentation for pre-planning and coordination and any revision thereof, as a record for three years.

120.075: Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

As specified in 105 CMR 120.075(A) and (B), each licensee shall provide advanced 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.

(1) The notification must be made to the Agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon 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. Notifications to the Agency must be made in accordance with 105 CMR 120.054.

(2) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail must reach the Agency at least four days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four 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:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each State along the route;

(6) The estimated time and date of arrival of the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

(C) Revision Notice.

(1) 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 by an appropriate method listed in 105 CMR 120.054.

(2) 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 105 CMR 120.075(B) and (C)(1). The licensee shall also immediately notify the Agency of any such changes.

120.075: continued

(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 three years.

(F) Protection of Information. State officials, State employees, and other individuals, whether or not licensees of the Agency, who receive schedule information of the kind specified in 105 CMR 120.075(B) shall protect that information against unauthorized disclosure as specified in 105 CMR 120.064(D).

120.076: Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment

(A) Shipments by Road.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, seven days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(b) 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.

(c) 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 pre-planned 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.

(d) 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.

(e) Develop written normal and contingency procedures to address:

1. Notifications to the communication center and law enforcement agencies;
2. 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;
3. Loss of communications; and
4. Responses to an actual or attempted theft or diversion of a shipment.

(f) 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.

(2) 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.

(3) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

120.076: continued

(a) 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.

(b) 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

(c) 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.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(a) 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 pre-planned 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.

(b) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(a) 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.

(b) 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

(c) 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.

120.077: Reporting of Events

(A) The shipping licensee shall notify the appropriate LLEA and the Agency by telephone within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by 105 CMR 120.076(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 by telephone within four hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Agency.

120.077: continued

(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 by telephone 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 by telephone 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 by telephone 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 by telephone as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(G) The initial telephonic notification required by 105 CMR 120.077(A) through (D) must be followed within a period of 30 days by a written report submitted to the Agency by an appropriate method listed in 105 CMR 120.054. A written report is not required for notifications on suspicious activities required by 105 CMR 120.077(C) and (D). The report must set forth the following information:

(1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;
(2) A description of the circumstances under which the loss or theft occurred;
(3) A statement of disposition, or probable disposition, of the licensed material involved;
(4) Actions that have been taken, or will be taken, to recover the material; and
(5) 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, by an appropriate method listed in 105 CMR 120.054, any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

RECORDS

120.078: Form of Records

Each record required by 105 CMR 120.050 through 120.080 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.

120.079: Record Retention

Licensees shall maintain the records that are required by the regulations in 105 CMR 120.050 through 120.080 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 105 CMR 120.050 through 120.080 may be destroyed upon Agency termination of the facility license.

120.080: Apendix 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 105 CMR 120.050 through 120.080.

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 105 CMR 120.050 through 120.080 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.

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R1 = total activity for radionuclide 1
R2 = total activity for radionuclide 2
Rn = total activity for radionuclide n
AR1 = activity threshold for radionuclide 1
AR2 = activity threshold for radionuclide 2
ARn = activity threshold for radionuclide n

$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right] \geq 1.0$$

120.100: LICENSING OF RADIOACTIVE MATERIAL

120.101: Purpose and Scope

(A) 105 CMR 120.100, 120.500 and 120.770, provide for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to 105 CMR 120.100, 120.500 or 120.770, or as otherwise provided in 105 CMR 120.000.

(B) In addition to the requirements of 105 CMR 120.100, all licensees are subject to the requirements of 105 CMR 120.000, 120.200, 120.750, and 120.770. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of 105 CMR 120.300; licensees using radionuclides in the healing arts are subject to the requirements of 105 CMR 120.500, licensees engaged in land disposal of radioactive material are subject to the requirements of 105 CMR 120.801 through 120.885, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 105 CMR 120.900.

120.102: Definitions

As used in 105 CMR 120.100, the following definitions apply:

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

Commencement of Construction means taking any action defined as "construction" or any other activity at the site of a facility subject to 105 CMR 120.100 through 120.198 that has a reasonable nexus to radiological health and safety. Commencement of construction as defined in 105 CMR 120.102 may include non-construction activities if the activity has a reasonable nexus to radiological safety or security.

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 105 CMR 120.100 through 120.198 that are related to radiological safety or security. The term "construction" does not include:

(1) Changes for temporary use of the land for public recreational purposes;
(2) 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;
(3) 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;
(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to 105 CMR 120.100 through 120.198;
(5) Excavation;
(6) 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;

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(7) 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);
(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
(9) Taking any other action that has no reasonable nexus to radiological health and safety.

Decommissioning Funding Plan means a written document that contains a cost estimate for decommissioning and a description of the method for assuring for decommissioning, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

Facility means the location within one building, vehicle, or under one roof and under the same administrative control:
(1) at which the possession, use, processing or storage of radioactive material is or was authorized; or
(2) at which one or more radioactivity-inducing machines are installed or located.
Facility may also mean multiple such locations at a site or part of a site.

Financial Surety means the method of assuring that sufficient funds will be available at the time of license termination and decommissioning of the facility to cover all costs associated with the decommissioning.

Site means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

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

120.103: Source Material

(A) Any person is exempt from 105 CMR 120.100 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% (0.05%) of the mixture, compound, solution, or alloy.

(B) Any person is exempt from 105 CMR 120.100 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 105 CMR 120.100, 120.200 and 120.750 to the extent that such person receives, possesses, uses, or transfers:
(1) any quantities of thorium contained in:
(a) incandescent gas mantles;
(b) vacuum tubes;
(c) welding rods;
(d) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
(e) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;
(f) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or
(g) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
(2) source material contained in the following products:
(a) glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20% by weight source material;
(b) glassware containing not more than 2% by weight source material or, for glassware manufactured before August 27, 2013, 10% by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

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(c) glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or

(d) piezoelectric ceramic containing not more than 2% by weight source material.

(3) photographic film, negatives, and prints containing uranium or thorium;

(4) any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that 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:

(a) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM"[1];

(b) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"[1]; and

(c) this exemption 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:

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

(b) the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of ⅛ 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% by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30% by weight of thorium; and that this exemption shall not be deemed to authorize either:

(a) the shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(b) the receipt, possession, use, or transfer of thorium or uranium 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:

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

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

(D) The exemptions in 105 CMR 120.103(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 105 CMR 120.103(C), or equivalent regulations of the NRC or an Agreement State, unless authorized by a license issued by the NRC 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 under a specific license issued by the Agency, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued by NRC under 10 CFR 40.52 for distribution only and are exempt from the requirements of 10 CFR 19, 20 and 40.32(b) and (c).

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[1] The requirements specified in 105 CMR 120.103(C)(5)(a) and (b) 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 are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by 105 CMR 120.000.

120.104: Radioactive Material Other than Source Material

(A) Exempt Concentrations.

(1) Except as provided in 105 CMR 120.104(A)(3), and (4), any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing byproduct material introduced in concentrations not in excess of those listed in 105 CMR 120.195: *Appendix A*.

(2) 105 CMR 120.104(A) shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(3) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in 105 CMR 120.100 to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in 105 CMR 120.195: *Appendix A* and introduced into the product or material by a licensee holding a specific license issued by 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.

(4) 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 105 CMR 120.104(A) or equivalent regulations of the NRC, or an Agreement State except in accordance with a specific license issued pursuant to 10 CFR 32.11.

(B) Exempt Quantities.

(1) Except as provided in 105 CMR 120.104(B)(2), (3), and (5), any person is exempt from 105 CMR 120.100 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 105 CMR 120.196: *Appendix B* Table I provided they have been distributed pursuant to a license as described in 105 CMR 120.104(B)(3).

(2) 105 CMR 120.104(B) does not authorize the production, packaging or repackaging of byproduct material for purposes of commercial distribution, or the incorporation of byproduct material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in 105 CMR 120.196: *Appendix B,* Table 1, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under 105 CMR 120.104(B) or equivalent regulations of the NRC, an Agreement State except in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.18 which license states that the byproduct material may be transferred by the licensee to persons exempt under 105 CMR 120.104(B) or the equivalent regulations of the NRC, an Agreement State.[2]

(4) Any person who possesses byproduct material received or acquired prior to September 25, 1971 under the general license then provided in 10 CFR 31.4 or similar general license of a State, is exempt from the requirements for a license set forth in 105 CMR 120.100 if such person possesses, uses, transfers, or owns such byproduct material.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by the exemption in 105 CMR 120.104(B) so that the aggregate quantity exceeds the limits set forth in 105 CMR 120.196: *Appendix B Table I* , except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by 105 CMR 120.100.

(C) Exempt Items.

(1) Certain Items Containing Byproduct Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct materials, any person is exempt from 105 CMR 120.100 to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

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[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 Nuclear Regulatory Commission (NRC), Washington, D.C.

120.104: continued

(a) 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:

1. 25 millicuries (925 MBq) of tritium per timepiece.
2. five millicuries (185 MBq) of tritium per hand.
3. 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).
4. 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.
5. 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.
6. 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).
7. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
   a. For wrist watches, 0.1 millirad (1 μGy) per hour at ten centimeters from any surface.
   b. For pocket watches, 0.1 millirad (1 μGy) per hour at one centimeter from any surface.
   c. For any other timepiece, 0.2 millirad (2 μGy) per hour at ten centimeters from any surface.
8. One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(b) Precision balances containing not more than one 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.

(c) 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.

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

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

1. 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.
2. 1 microcurie (37 kBq) of cobalt-60.
3. 5 microcuries (185 kBq) of nickel-63.
4. 30 microcuries (1.11 MBq) of krypton-85.
5. 5 microcuries (185 kBq) of cesium-137.
6. 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 one millirad (ten μGy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of 105 CMR 120.104(C)(1)(e), "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.

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

1. Each source contains no more than one exempt quantity set forth in 105 CMR 120.196: *Appendix B, Table 1*; and

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2. Each instrument contains no more than ten 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 105 CMR 120.196: *Appendix B, Table 1*, provided that the sum of such fractions shall not exceed unity.

3. For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 105 CMR 120.104(C)(1)(f).

(g) 1. 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.

2. 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.

3. Such devices authorized before October 23, 2012 for use under the general license then provided in 105 CMR 120.122(A) and equivalent regulations of the U.S. Nuclear Regulatory Commission and Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission.

(h) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in 105 CMR 120.104(C)(1), or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply to the Nuclear Regulatory Commission for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to 105 CMR 120.104(C)(1) or equivalent regulations of the Nuclear Regulatory Commission, 10 CFR 30.15(a).

(2) Self-luminous Products Containing Radioactive Material.

(a) Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.22 which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under 105 CMR 120.104(C)(2), should apply to the NRC for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 105 CMR 120.128(N). The exemption in 105 CMR 120.104(C)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(b) Radium-226. Any person is exempt from 105 CMR 120.100 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 March 11, 1994.

(3) Gas and Aerosol Detectors Containing Radioactive Material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 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 provided that detectors containing byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32, § 32.26, which license authorizes the initial transfer of the product for use under 105 CMR 120.104(C)(3). 105 CMR 120.104(C)(3) also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

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(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant 105 CMR 120.104(C)(3)(a), should apply to the NRC for a license pursuant to 10 CFR 32.26 and for a certificate of registration in accordance with 105 CMR 120.128(N).

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

(a) Except as provided in 105 CMR 120.104(C)(4)(b) and (c), any person is exempt from the requirements for a license set forth in M.G.L. c. 111, § 5P and from 105 CMR 120.100 and 120.500 provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for *in vivo* diagnostic use for humans.

(b) Any persons who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 105 CMR 120.500.

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

(d) Nothing in 105 CMR 120.104(C)(4) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

(5) Certain Industrial Devices.

(a) 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 requirement of a license set forth in 105 CMR 120.100 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, produced, or initially transferred in accordance with a specific license issued by the NRC under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under 105 CMR 120.104(C)(5). This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use pursuant 105 CMR 120.104(C)(5), should apply to the NRC for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 105 CMR 120.128(N).

120.120: Types of Licenses

Licenses for radioactive materials are of two types: general and specific.

(A) The Agency issues a specific license to a named person who has filed an application for the license under the provisions of 105 CMR 120.124.

(B) A general license is provided by regulation, grants authority to a person for certain activities involving radioactive 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.

120.121: General Licenses - Source Material

(A) A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and 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:

120.121: continued

(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 105 CMR 120.121(A)(1) 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 105 CMR 120.121(A)(2) 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 105 CMR 120.121(A)(2) unless it is accounted for under the limits of 105 CMR 120.121(A)(1); 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 105 CMR 120.121(A)(3); 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 105 CMR 120.121(A)(4) 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 pursuant to the general license issued in 105 CMR 120.121(A):

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or 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:

(a) 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 105 CMR 120.121(B)(2)(a) is exempt from the requirements to obtain a license under 105 CMR 120.100 to the extent the source material is permanently disposed. 105 CMR 120.121(B)(2)(a) does not apply to any person who is in possession of source material under a specific license issued under 105 CMR 120.100; or

(b) In accordance with 105 CMR 120.251.

(3) Is subject to the provisions in 105 CMR 120.001 through 120.019, 120.101(A), 120.131(A) through (C), 120.140, 120.142, and 120.150.

(4) 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 person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Agency, using an appropriate method listed in 105 CMR 120.013, a written justification for the request;

(5) 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 105 CMR 120.121(A) 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 by an appropriate method listed in 105 CMR 120.013 about such contamination and may consult with the Agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 105 CMR 120.245.

(D) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

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(E) 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 105 CMR 120.121(E)(2) through (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 105 CMR 120.121(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 105 CMR 120.128(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) (a) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1) shall file form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License", with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on form MRCP 120.100-1 the following information and such other information as may be required by that form:

1. name and address of the general licensee;

2. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 105 CMR 120.121(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

3. 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 105 CMR 120.121(E)(3)(a)2.

(b) The general licensee possessing or using depleted uranium under the general license established by 105 CMR 120.121(E)(1) shall report in writing to the Agency any changes in information furnished by him in form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License". 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 105 CMR 120.121(E)(1):

(a) 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;

(b) shall not abandon such depleted uranium;

(c) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 105 CMR 120.140. In the case where the transferee receives the depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1. 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 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1 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 105 CMR 120.100;

120.121: continued

(d) 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

(e) 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 105 CMR 120.121(E)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to the depleted uranium covered by that general license.

(F) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 105 CMR 120.121(A) is exempt from the provisions of 105 CMR 120.200 and 120.750 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 the provisions of 105 CMR 120.245 and 120.251 to the extent necessary to meet the provisions of 105 CMR 120.121(B)(2) and 120.121(C). However, this exemption does not apply to any person who also holds a specific license issued under 105 CMR 120.100.

(G) No person may initially transfer or distribute source material to persons generally licensed under 105 CMR 120.121(A)(1) or (2), or equivalent regulations of the NRC or an Agreement State, unless authorized by a specific license issued in accordance with 105 CMR 120.128(B) or equivalent provisions of the NRC or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

120.122: General Licenses - Radioactive Material Other than Source Material

(A) Requirements for Other General Licenses (Reserved).

(B) Luminous Safety Devices for Aircraft.

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

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

(b) 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 10 CFR Part 32, § 32.53.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 105 CMR 120.122(B)(1) are exempt from the requirements of 105 CMR 120.200 through 120.299 and 120.750 through 120.760 except that they shall comply with the provisions of 105 CMR 120.281 and 120.282.

(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 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770 through 120.798.

(C) Requirements for Other General Licenses (Reserved).

120.122: continued

(D) Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to acquire, receive, possess, use or transfer in accordance with the provisions of 105 CMR 120.122(D)(2) through (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)(a) The general license in 105 CMR 120.122(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:

1. a specific license issued by the Agency pursuant to 105 CMR 120.128(D); or
2. an equivalent specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or an equivalent specific license issued by a State with provisions comparable to 105 CMR 120.128(D).

(b) The devices must have been received from one of the specific licensees described in 105 CMR 120.122(D)(2)(a) or through a transfer made under 105 CMR 120.122(D)(3)(i).

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 105 CMR 120.122(D)(1):

(a) 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;

(b) 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 six-month intervals or at such other intervals as are specified in the label, however,

1. devices containing only krypton need not be tested for leakage of radioactive material; and
2. devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma-emitting material or ten 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;

(c) shall assure that the tests required under 105 CMR 120.122(D)(3)(b) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

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

(d) shall maintain records showing compliance with the requirements of 105 CMR 120.122(D)(3)(b) and (c). 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. The licensee shall retain these records as follows:

1. each record of a test for leakage of radioactive material required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;
2. each record of a test of the "on-off" mechanism and indicator required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of; and
3. each record that is required by 105 CMR 120.122(D)(3)(c) shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;

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(e) 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 Bq (0.005 microcurie) or more removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to repair such devices. The device and any radioactive material from the device shall only be disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the Agency. 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 Agency within 30 days. Under these circumstances, the criteria set out in 105 CMR 120.243: *Vacating Premises*, may be applicable, as determined by the Agency on a case-by-case basis;

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

(g) shall not export the device containing radioactive material except in accordance with 10 CFR110;

(h) 1. shall transfer or dispose of the device containing radioactive material only by export as provided in105 CMR 120.122(D)(3)(g), by transfer to another general licensee as authorized in 105 CMR 120.122(D)(3)(i), or to a person authorized to receive the device by a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State that authorizes waste collection or as otherwise approved under 105 CMR 120.122(D)(3)(h)3.

2. shall furnish a report to the Agency within 30 days after the transfer of a device to a specific licensee or export. 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.

3. shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in 105 CMR 120.122(D)(3)(h)1.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

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

b. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by 105 CMR 120.122(D)(3)(a)) so that the device is labeled in compliance with 105 CMR 120.240; however the manufacturer, model number, and serial number must be retained;

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

d. Reports the transfer under 105 CMR 120.122(D)(3)(h)2.

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

1. the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of 105 CMR 120.122(D), a copy of 120.122, 120.009, 120.281, and 120.282, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Agency:

a. the manufacturer's (or initial transferor's) name;

b. the model number and the serial number of the device transferred;

c. the transferee's name and mailing address for the location of use; and

d. the name, title, and phone number of the responsible individual identified by the transferee in accordance with 105 CMR 120.122(D)(3)(l) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

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

120.122: continued

(j) shall comply with the provisions of 105 CMR 120.281 and 120.282 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 105 CMR 120.200 and 120.750;

(k) 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 submitting a letter to the Director, Radiation Control Program, Massachusetts Department of Public Health, and provide written justification as to why it cannot comply;

(l) 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;

(m) 1. shall register, in accordance with 105 CMR 120.122(D)(3)(m)2. and 3., devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic (*i.e.*, element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under 105 CMR 120.122(D)(3)(m)3.d. represents a separate general licensee and requires a separate registration and fee;

2. if in possession of a device meeting the criteria of 105 CMR 120.122(D)(3)(m)1., shall register these devices annually with the Agency and shall pay any prescribed fee. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Agency. The registration information must be submitted to the Agency within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of 105 CMR 120.122(D)(3)(m)1. is subject to the bankruptcy notification requirement in 105 CMR 120.131(E);

3. in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Agency:

a. name and mailing address of the general licensee;

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

c. name, title, and telephone number of the responsible person designated as a representative of the general licensee under 105 CMR 120.122(D)(3)(l);

d. address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;

e. certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;

f. certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

4. persons generally licensed by an Agreement State, or NRC with respect to devices meeting the criteria in 105 CMR 120.122(D)(3)(m)1. are not subject to registration requirements if the devices are used in areas subject to Agency jurisdiction for a period less than 180 days in any calendar year. The Agency will not request registration information from such licensees.

(n) shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director, Radiation Control Program, Massachusetts Department of Public Health, 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;

120.122: continued

(o) may not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 105 CMR 120.122(D)(3)(b) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in 105 CMR 120.122(D)(1) does not authorize the manufacture or import of devices containing radioactive material.

[*Note*: Persons possessing radioactive material in devices under a general license in 10 CFR 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR 31.5 in effect on January 14, 1975.]

(E) 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 the provisions of 105 CMR 120.122(E)(2), (3), and (4), radium-226 contained in the following products manufactured prior to November 30, 2007.

(a) Antiquities originally intended for use by the general public. For the purposes of 105 CMR 120.122(E)(1)(a), 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.

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

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

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

(e) Small radium sources containing no more than 0.037 megabecquerel (one microcurie) of radium-226. For the purposes of 105 CMR 120.122(E)(1)(e), "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 105 CMR 120 122(E)(1) are exempt from the provisions of 105 CMR 120.750, 120.200, and120.142 and 120.009, 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 105 CMR 120.100.

(3) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in 105 CMR 120.122(E)(1):

(a) 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 Director of the Agency within 30 days.

(b) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 105 CMR120.256 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

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

(d) 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 by the Agency, Nuclear Regulatory Commission, or an Agreement State, or as otherwise approved by the Agency.

120.122: continued

(e) 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 Director of the Agency, a written justification for the request.

(4) The general license in 105 CMR 120.122(E)(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

(F) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 105 CMR 120.122, 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 105 CMR 120.122(G)(4) and (5), americium-241 in the form of calibration or reference sources:

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

(b) any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes 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 105 CMR 120.122(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 105 CMR 120.122(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 105 CMR 120.122(G)(1) through (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32, § 32.57 or 10 CFR Part 70, § 70.39 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 10 CFR Part 32, § 32.57 or 10 CFR Part 70, § 70.39.

(5) The general licenses provided in 105 CMR 120.122(G)(1) through (3) are subject to the provisions of 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

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

(b) 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:

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

120.122: continued

CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)[3].
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of Manufacturer or Importer

2. 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

(c) 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;
(d) 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,
(e) 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) Requirements for Other General Licenses (Reserved).

(I) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[4]

(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 105 CMR 120.122(I)(2) through (6), the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:
(a) Carbon-14, in units not exceeding ten microcuries (370 kBq) each.
(b) Cobalt-57, in units not exceeding ten microcuries (370 kBq) each.
(c) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
(d) Iodine-125, in units not exceeding ten microcuries (370 kBq) each.
(e) 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.
(f) Iodine-131, in units not exceeding ten microcuries (370 kBq) each.
(g) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
(h) Selenium-75, in units not exceeding ten microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 105 CMR 120.122(I)(1) until he has filed form MRCP 120.100-2, "Certificate - *In Vitro* Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of form MRCP 120.100-2 with certification number assigned, or, has a license that authorizes the medical use of radioactive material that was issued under 105 CMR 120.500. The physician, veterinarian, clinical laboratory or hospital shall furnish on form MRCP 120.100-2 the following information and such other information as may be required by that form:

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

[4] 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.

120.122: continued

(a) Name and address of the physician, veterinarian, clinical laboratory or hospital;
(b) The location of use; and,
(c) A statement that the physician, veterinarian, 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 105 CMR 120.122(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 105 CMR 120.122(I)(1) shall comply with the following:

(a) The general licensee shall not possess at any one time, pursuant to the general license in 105 CMR 120.122(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).
(b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
(c) The general licensee shall use the radioactive material only for the uses authorized by 105 CMR 120.122(I)(1)
(d) 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.
(e) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 105 CMR 120.122(I)(1)(e) as required by 105 CMR 120.251.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 105 CMR 120.122(I)(1):

(a) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 105 CMR 120.128(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 105 CMR 120.122(I) or its equivalent; and
(b) 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:

1. 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 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

2. 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

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(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 105 CMR 120.122(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", form MRCP 120.100-2. 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 105 CMR 120.122(I)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 105 CMR 120.122(I)(1)(e) shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.

(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 10 CFR Part 32, § 32.61.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 105 CMR 120.122(J)(1),

(a) 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 105 CMR 120.251;

(b) 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,

(c) are exempt from the requirements of 105 CMR 120.200 and 120.750 except that such persons shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.

(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 105 CMR 120.001 through 120.019, 120.131, 120.140, 120.150, and 120.770.

120.124: Filing Application for Specific Licenses

(A) Applications for specific licenses shall be filed in duplicate on form MRCP 120.100-4 as 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 or her behalf.

(D) An application for a license may include a request for a license authorizing one or more activities. The Agency will not grant the request if the proposed activities are not under the control of the same facility, administrator and radiation safety officer. In addition, when evaluating the request, the Agency will consider complexity, similarity and proximity of the proposed activities.

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(E) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

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

(G)(1) Except as provided in 105 CMR 120.124(G)(2), (3), and (4), an application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

(a) identify the sealed source or device that contains a sealed source by manufacturer and model number as registered with the Agency under 105 CMR 120.128(N), with the NRC or an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 105 CMR 120.128(N); or

(b) contain the information identified in 105 CMR 120.128(N)(3).

(2) for sources or devices manufactured prior to October 23, 2012 that are not registered with the Agency under 105 CMR 120.128(N) or with the NRC or an Agreement State, and for which the applicant is unable to provide all categories of information specified in 105 CMR 120.128(N)(3), the applicant must provide:

(a) All available information identified in 105 CMR 120.128(N)(3) concerning the source, and, if applicable, the device; and

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

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 105 CMR 120.128(N)(7)(a), 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.

120.125: General Requirements for the Issuance of Specific Licenses

(A) A license application will be approved only 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 105 CMR 120.000 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; and,

(4) the applicant satisfies any applicable special requirements in 105 CMR 120.050 through 120.080, 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 and 120.900.

(B) Environmental Report, Commencement of Construction.

(1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, a license application shall be reviewed and approved by the Agency before commencement of construction of the plant or facility in which the activity will be conducted. Issuance of the license shall be based upon a consideration by the Agency of the environmental, economic, technical and other benefits in comparison with the environmental costs and available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;

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(2) 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.

(C) Financial Surety Arrangements and Recordkeeping for Decommissioning.

(1) Unless exempted by 105 CMR 120.125(C)(3), issuance, renewal or amendment of a license shall be dependent upon satisfactory financial surety arrangements to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements of M.G.L. c. 111H, § 9 and 105 CMR 120.000.

(2) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 105 CMR 120.196: *Appendix B*, Table II shall submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6). 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 as the sum of the ratios of the quantity of each isotope to the applicable value in 105 CMR 120.196: *Appendix B*, Table II.

(3) 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 105 CMR 120.125(C)(5) shall either:

(a) submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 105 CMR 120.125(C)(5) using one of the methods described in 105 120.125(C)(7). 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. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) is to be submitted to the Agency.

(4) (a) Each holder of a specific license issued on or after March 11, 1994, which is of a type described in 105 CMR 120.125(C)(2) or (3), shall provide financial assurance for decommissioning in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(b) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(2) shall submit, on or before March 11, 1995, a decommissioning funding plan 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 part. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(3) shall submit, on or before March 11, 1995, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(d) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G must establish an Agency-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility. The decommissioning funding plan must include the cost of disposal of the maximum radioactivity (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that 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 105 CMR 120.200. The decommissioning funding plan must be submitted by April 6, 2007.

(e) If, in surveys made under 105 CMR 120.225(A), 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 105 CMR 120.245 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

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(5) Table of Required Amounts of Financial Assurance for Decommissioning by Quantity of Material:

-1	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
-2a	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000
-2b	Greater than 10 mCi but less than 100 mCi of source material	$225,000
-3	Greater than 10^{10} times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^{10} is greater than 1.)	$113,000

(a) Licensees required to submit the $1,125,000 amount must do so by October 6, 2006.
(b) Licensees required to submit the $113,000 or $225,000 amount must do so by April 6, 2007.

(6) (a) Each decommissioning funding plan must be submitted for review and approval and must contain:

1. 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 105 CMR 120.245 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 105 CMR 120.246, the cost estimate may be based on meeting the 105 CMR 120.246 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.
2. Identification of and justification for using the key assumptions contained in the cost estimate for decommissioning;
3. A description of the method of assuring funds for decommissioning from 105 CMR 120.125(C)(7), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;
4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and
5. A signed original of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(b) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1. Spills of radioactive material producing additional residual radioactivity in on-site subsurface material;
2. Waste inventory increasing above the amount previously estimated;
3. Waste disposal costs increasing above the amount previously estimated;
4. Facility modifications;

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5. Changes in authorized possession limits;
6. Actual remediation costs that exceed the previous cost estimate;
7. On-site disposal; and
8. Use of a settling pond.

(7) The financial instrument must include the licensee's name, license number, and docket 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:

(a) 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 trust must be acceptable to the Agency.

(b) A Surety Method, Insurance or Other Guarantee Method. These methods guarantee that decommissioning costs will be paid should the licensee default.

1. A surety method may be in the form of a surety bond, issued by a corporate surety company authorized to transact business in the Commonwealth; or an irrevocable letter of credit.

2. A parent company guarantee of funds for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix D*. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 105 CMR 120.125(C).

3. 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 105 CMR 120.198: *Appendix E*.

4. 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 105 CMR 120.198: *Appendix F*.

5. 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 105 CMR 120.198: *Appendix G*.

6. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

a. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the 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.

b. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

c. The surety method or insurance must remain in effect until the Agency has terminated the license.

(c) An External Sinking Fund. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund 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 or insurance provisions must be as stated in 105 CMR 120.125(C)(7)(b).

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(d) Statement of Intent. In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount pursuant to 105 CMR 120.125(C)(5), and indicating that funds for decommissioning will be obtained when necessary.

(8) Each person licensed under 105 CMR 120.100 shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. 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:

(a) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas, as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(b) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes that 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.

(c) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. all areas designated and formerly designated restricted areas as defined in 105 CMR 120.005;

2. all areas outside of restricted areas that require documentation under 105 CMR 120.125(C)(8)(a);

3. all areas outside of restricted areas where current and previous wastes have been buried as documented under 105 CMR 120.269; and

4. all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 105 CMR 120.252.

(d) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(9) The following specific licensees are required to make financial surety arrangements:

(a) major processors;

(b) waste handling licensees;

(c) former U.S. Atomic Energy Commission or NRC licensed facilities; and

(d) all others except persons exempt pursuant to 105 CMR 120.125(C)(10).

(10) The following persons are exempt from the requirements of 105 CMR 120.125(C)(1):

(a) persons authorized to possess no more than 1,000 times the quantity specified in 105 CMR 120.196: *Appendix B*, Table 1 or combination of radioactive material listed therein as given in 105 CMR 120.196: *Appendix B*, Table 1, Note 1;

(b) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

120.126: Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material

Uses of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 105 CMR 120.125, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) the applicant will have an adequate program for training radiographic personnel and submits to the Agency a schedule or description of such program which specifies the:

(a) initial training;

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(b) periodic training;
(c) on-the-job training; and
(d) means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with Agency regulations and licensing requirements, and the operating and emergency procedures of the applicant.

(2) the applicant has established and submits to the Agency satisfactory written operating and emergency procedures described in 105 CMR 120.325;

(3) the applicant will have an internal inspection system adequate to assure that 105 CMR 120.001, 120.020, 120.200, 120.300, 120.750, 120.770, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for five years;

(4) the applicant submits to the Agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) the applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:
(a) instrumentation to be used;
(b) method of performing tests; and
(c) pertinent experience of the individual who will perform the test.

(6) the licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

120.127: Special Requirements for Specific Licenses of Broad Scope

105 CMR 120.127 prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.

(A) The different types of broad scope licenses are set forth in 105 CMR 120.127(A):

(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 105 CMR 120.197: *Appendix C*, 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 105 CMR 120.197: *Appendix C*, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 105 CMR 120.197: *Appendix C*, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in 105 CMR 120.197: *Appendix C*, 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 105 CMR 120.197: *Appendix C*, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 105 CMR 120.197: *Appendix C*, 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 105 CMR 120.125;

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(2) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

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

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

1. control of procurement and use of radioactive material;

2. completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

3. review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(B)(3)(c)2. 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 105 CMR 120.125; and,

(2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

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

(b) the establishment of appropriate administrative procedures to assure;

1. control of procurement and use of radioactive material;

2. completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and,

3. review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(C)(2)(b)2. 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 105 CMR 120.125;

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

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

(b) at least 40 hours of 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 105 CMR 120.127 shall not:

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

(b) 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;

(c) conduct activities for which a specific license issued by the Agency under 105 CMR 120.126, 120.128 or 120.500, and 120.800 is required; or

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(d) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under 105 CMR 120.127 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 105 CMR 120.127 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 105 CMR 120.127 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 105 CMR 120.127(D).

120.128: Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material

(A) Licensing Requirements to Produce for Noncommercial Transfer Positron Emission Tomography (PET) Radioactive Drugs. An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 105 CMR 120.500, or equivalent Nuclear Regulatory Commission, or Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 105 CMR 120.100 or equivalent Nuclear Regulatory Commission, or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 105 CMR 120.128(J)(1)(b).

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 105 CMR 120.128(J)(2)(b).

(4) Information identified in 105 CMR 120.128(J)(1)(c) on the PET drugs to be noncommercially transferred to members of its consortium.

(B) Licensing Requirements to Initially Transfer Source Material to Persons Generally Licensed under 105 CMR 120.121(A).

(1) An application for a specific license to initially transfer source material for use under 105 CMR 120.121(A), or equivalent regulations of the NRC or an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in 105 CMR 120.125; and

(b) 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) Each person licensed under 105 CMR 120.128(B) 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".

(3) Each person licensed under 105 CMR 120.128(B) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(4) Each person licensed under 105 CMR 120.128(B) shall provide the information specified in 105 CMR 120.128(B)(4) to each person to whom source material is transferred for use under 105 CMR 120.121(A) or equivalent provisions in the NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(a) A copy of 105 CMR 120.121(A) through (C), (F), and (G) and 105 CMR 120.140, or relevant equivalent regulations of the NRC or Agreement State.

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

(5) Each person licensed under 105 CMR 120.128(B) shall report transfers as follows:

(a) File a report with the Agency by an appropriate method listed in 105 CMR 120.013. 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 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions 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 NRC or Agreement State agency that identifies all persons, operating under provisions equivalent to 105 CMR 120.121(A), 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 NRC or Agreement State being reported to:

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

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

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the NRC's jurisdiction or the Agreement State.

(c) Submit each report by January 31st of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions during the current period, a report shall be submitted to the Agency indicating so. 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 request of that agency. If no transfers have been made to NRC general licensees during the reporting period, this information shall be reported to the NRC.

(6) Each person licensed under 105 CMR 120.128(B) shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the NRC or to an Agreement State agency.

(C) Requirements for Other Specific Licenses (Reserved).

(D) Licensing Requirements to Manufacture or Initially Transfer Devices Containing Radioactive Material to Persons Generally Licensed under 105 CMR 120.122(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 105 CMR 120.122(D) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

(a) the applicant satisfies the general requirements of 105 CMR 120.125;

(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

1. the device can be safely operated by persons not having training in radiological protection;

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2. under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A), and

3. under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

a. Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . . . 15 rems (150 mSv)

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

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

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

1. instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

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

3. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ , 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. [The model, serial number, and name of the manufacturer or distributor may be omitted from the label provided the information is elsewhere specified in labeling affixed to the device.]

CAUTION - RADIOACTIVE MATERIAL

_____

Name of Manufacturer or Distributor

[Note: Devices licensed under 10 CFR 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.]

(d) each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, “Caution-Radioactive Material”, the radiation symbol described in 105 CMR 120.237, and the name of the manufacturer or initial distributor.

(e) each device meeting the criteria of 105 CMR 120 122(D)(3)(m)1., bears a permanent (*e.g.*, embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, “Caution-Radioactive Material”, and, if practicable, the radiation symbol described in 105 CMR 120.237.

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

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant 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:

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(a) primary containment or source capsule;
(b) protection of primary containment;
(c) method of sealing containment;
(d) containment construction materials;
(e) form of contained radioactive material;
(f) maximum temperature withstood during prototype tests;
(g) maximum pressure withstood during prototype tests;
(h) maximum quantity of contained radioactive material;
(i) radiotoxicity of contained radioactive material; and
(j) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 105 CMR 120.122(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 basis 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 dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A).

(4) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall:

(a) if a device containing radioactive material is to be transferred for use under the general license contained in 105 CMR 120.122(D), each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 120.128(D)(4) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

1. a copy of the general license contained in 105 CMR 120.122(D); if 105 CMR 120.122(D)(3)(b) through (d) do not apply to the particular device, those paragraphs may be omitted;
2. a copy of 105 CMR 120.122, 120.009(A), 120.281, and 120.282;
3. a list of the services that can only be performed by a specific licensee; and,
4. information on acceptable disposal options including estimated costs of disposal;

(b) if radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 105 CMR 120.128(D)(4)(b) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

1. a copy of NRC or Agreement State regulations equivalent to 105 CMR 120.122(D), 120.009(A), 120.281, and 120.282. If a copy of the 105 CMR 120.000 is provided to a prospective general licensee in *lieu* of the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the U.S. Nuclear Regulatory Commission, the Agreement State; or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;
2. a list of the services that can only be performed by a specific licensee;
3. information on acceptable disposal options including estimated costs of disposal; and,
4 the name or title, address, and phone number of the contact at the U.S. Nuclear Regulatory Commission, the Agreement State, or Licensing State from which additional information may be obtained;

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(c) an alternative approach to informing customers may be proposed by the licensee for approval by the Agency;

(d) each device that is transferred after February 19, 2002 must meet the labeling requirements in 105 CMR 120.128(D)(1)(c) through (e);

(e) if a notification of bankruptcy has been made under 105 CMR 120.131(E) or the license is to be terminated, each person licensed under 105 CMR 120.128(D) shall provide, upon request, to the Agency and to any appropriate Agreement State or NRC, records of final disposition required under 105 CMR 120.128(D)(5)(c).

(5) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall comply with the requirements of 105 CMR 120.128(D)(5).

(a) The person shall report to the Agency all transfers of devices to persons for use under the general license in 105 CMR 120.122(D) and all receipts of devices from persons licensed under 105 CMR 120.122(D). The report must be submitted on a quarterly basis on NRC Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

1. The required information for transfers to general licensees includes:

a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

c. the date of transfer;

d. the type, model number, and serial number of the device transferred; and

e. the quantity and type of byproduct material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a 105 CMR 120.122(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.

4. If the licensee makes changes to a device possessed by a 105 CMR 120.122(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.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

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

7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.

(b) The person shall report all transfers of devices to persons for use under a general license in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's regulations that are equivalent to 105 CMR 120.122(D) and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's jurisdiction to the responsible agency. The report must be submitted on Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

1. The required information for transfers to general licensees includes:

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a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

c. the date of transfer;

d. the type, model number, and serial number of the device transferred; and

e. the quantity and type of byproduct material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

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

7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 105 CMR 120.128(D)(5). Records required by 105 CMR 120.128(D)(5)(c) must be maintained for a period of three 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 105 CMR 120.122(B) will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125; and

(2) the applicant satisfies the requirements of 10 CFR Part 32 §§ 32.53 through 32.56.

(F) Special Requirements for License to Manufacture or Initially Transfer Calibration or Reference Sources Containing Americium-241, or Radium-226 for Distribution to Persons Generally Licensed under 105 CMR 120.122(G). 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 105 CMR 120.122(G), will be approved if:

(1) the applicant satisfies the general requirement of 105 CMR 120.125; and

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

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

(b) Details of construction and design;

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

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(d) 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;

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

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

(g) Any additional information, including experimental studies and tests, required by the Commission 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:

(a) 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

(b) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR 32.57(e).

(5) Each person licensed under 105 CMR 120.128(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 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. 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

(6) Each person licensed under 105 CMR 120.128(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 105 CMR 120.122(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 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 105 CMR 120.128(F)(6), the source shall be rejected and shall not be transferred to a general licensee under 105 CMR 120.122(G) or equivalent regulations of NRC or an Agreement State.

(G) Requirements for Other Specific Licenses (Reserved).

(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 105 CMR 120.122(I) will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125.

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

(a) carbon-14 in units not exceeding ten microcuries (370 kBq) each.

(b) cobalt-57 in units not exceeding ten microcuries (370 kBq) each.

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

(d) iodine-125 in units not exceeding ten microcuries (370 kBq) each.

(e) 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.

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(f) iodine-131 in units not exceeding ten microcuries (370 kBq) each.
(g) iron-59 in units not exceeding 20 microcuries (740 kBq) each.
(h) selenium-75 in units not exceeding ten microcuries (370 kBq) each.

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

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten 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; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

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

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

_____
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 105 CMR 120.251.

(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 105 CMR 120.122(J) will be approved if:

(1) the applicant satisfies the general requirements of 105 CMR 120.125; and
(2) the criteria of 10 CFR Part 32, §§ 32.61 and 32.62 are met.

(J) Manufacture, Preparation, or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Medical Use under 105 CMR 120.500.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 105 CMR 120.500 will be approved if:

(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits evidence that the applicant is at least one of the following:

1. 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);
2. registered or licensed with a State agency as a drug manufacturer;
3. licensed as a pharmacy by a State Board of Pharmacy;
4. operating as a nuclear pharmacy pursuant to 247 CMR 13.00: *Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies*;
5. operating as a nuclear pharmacy within a Federal medical institution; or
6. a Positron Emission Tomography (PET) drug production facility registered with a State agency.

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(c) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

(d) the applicant commits to the following labeling requirements:

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

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

(2) A licensee pursuant to 105 CMR 120.128(J)(1)(b)3. or (b)4. or (b)5.:

(a) may prepare radioactive drugs for medical use, as defined in 105 CMR 120.502, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 105 CMR 120.128(J)(2)(b) and (d), or an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

(b) may allow a pharmacist to work as an authorized nuclear pharmacist if:

1. this individual qualifies as an authorized nuclear pharmacist as defined in 105 CMR 120.502; or

2. this individual meets the requirements specified in 105 CMR 120.526(B) and 120.529 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

3. this individual is designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128(J)(2)(d).

(c) is permitted to perform the actions authorized in 105 CMR 120.128(J)(2)(a) and (b) in spite of more restrictive language in license conditions.

(d) may designate a pharmacist, as defined in 105 CMR 120.005, as an authorized nuclear pharmacist if:

1. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

2. The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(e) shall provide to the Agency:

1. A copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State as specified in 105 CMR 120.526(A); or

2. The Agency, Agreement State or Nuclear Regulatory Commission license; or

3. The Nuclear Regulatory Commission master materials licensee permit; or

4. The permit issued by a licensee or Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

5. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

6. A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 105 CMR 120.128(J)(2)(b)1. and 3. of 105 CMR 120.128(J), 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:

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(a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

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

(4) A licensee shall satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d).

(5) Nothing in 105 CMR 120.128(J) 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[5]. 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 105 CMR 120.100 for the uses listed in 105 CMR 120.547 will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(2) the applicant submits evidence that:

(a) 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

(b) 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:

(a) 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

(b) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to 105 CMR 120.547 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 105 CMR 120.128(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.

(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 105 CMR 120.500 for use as a calibration, transmission, or reference source or for the uses listed in 105 CMR 120.559, 120.568, 120.570 and 120.589 will be approved if:

(1) the applicant satisfies the general requirements in 105 CMR 120.125;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

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[5] Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioacitve 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 105 CMR 120.547 may submit the pertinent information specified in 105 CMR 120.128(K).

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

(3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Agency has approved the distribution of the (name of source or device) to persons licensed to use radioactive material identified in 105 CMR 120.535, 120.559, 120.568, and 120.570 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State;

(4) the source or device has been registered in the Sealed Source and Device Registry;

(5) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he or she shall include in his or her application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; 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:

(a) primary containment or source capsule;
(b) protection of primary containment;
(c) method of sealing containment;
(d) containment construction materials;
(e) form of contained radioactive material;
(f) maximum temperature withstood during prototype tests;
(g) maximum pressure withstood during prototype tests;
(h) maximum quantity of contained radioactive material;
(i) radiotoxicity of contained radioactive material; and
(j) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(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 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive a radiation dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A); and

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(c) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under 105 CMR 120.128(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 105 CMR 120.128(M) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 105 CMR 120.128(M)(1) shall:

(a) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(b) label or mark each unit to:

1. 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

2. 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.

(c) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(d) 1. furnish a copy of the general license contained in 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 to each person to whom he or she transfers depleted uranium in a product or device for use pursuant to the general license contained in 105 CMR 120.121(E); or

2. furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 105 CMR 120.121(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 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 to each person to whom he or she 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 105 CMR 120.121(E).

(e) report to the Agency all transfers of industrial products or devices to persons for use under the general license in 105 CMR 120.121(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 105 CMR 120.121(E) during the reporting period, the report shall so indicate;

(f) 1. 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 10 CFR Part 40, § 40.25;

2. report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 105 CMR 120.128(M) for use under a general license in that State's regulations equivalent to 105 CMR 120.121(E);

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3. 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;

4. 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

5. 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.

(g) keep records showing the name, address, and point of contact for each general licensee to whom he or she transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two 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 105 CMR 120.100.

(N) Sealed Source and Device Registration - Registration of Product Information and Inactivation of Certificates of Registration of Sealed Sources and Devices.

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

(2) The request for review must be sent to the Agency in duplicate by an appropriate method listed in 105 CMR 120.013.

(3) 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.

(4) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the 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.

(5) After completing the evaluation and determining that requirements for registration have been met, the Agency shall 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.

(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

(7) 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:

(a) Calibration and reference sources containing no more than:

1. 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

2. 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

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(b) 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

1. The intended recipients are licensed under 105 CMR 120.127 or comparable provisions of NRC or an Agreement State;
2. The recipients are authorized for research and development; or
3. 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.

(8) 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 105 CMR 120.128(N). 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.

(9) 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 listed in 105 CMR 120.013 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.

(10) If a distribution license is to be terminated in accordance with 105 CMR 120.132, 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.

(11) 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.

120.130: Issuance of Specific Licenses

(A)(1) Upon a determination that an application meets the requirements of M.G.L. c. 111, §§ 3, 5M through 5P and 105 CMR 120.000 and upon payment of the required fee as specified in 105 CMR 120.130(A)(2), 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.

(2) Each initial application for a license or a certificate of registration for which a fee is established in 801 CMR 4.00: *Rates* shall be accompanied by a nonrefundable fee, payable to the Commonwealth of Massachusetts, in the amount specified for the corresponding annual fee. Thereafter, the Radiation Control Program will issue an annual fee invoice based on the applicable annual fee specified in 801 CMR 4.00. Fees are payable within 30 days after receipt of a fee invoice.

(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 105 CMR 120.100 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 105 CMR 120.100.

120.131: Specific Terms and Conditions of Licenses

(A) Each license issued pursuant to 105 CMR 120.000 shall be subject to all the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all rules, regulations, orders of the Agency and license conditions as provided for in 105 CMR 120.130(B).

(B) (1) No license issued or granted under 105 CMR 120.000 and no right to possess or utilize radioactive material granted by any license issued pursuant to 105 CMR 120.131 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 M.G.L. c. 111, §§ 3, 5M through 5P, 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:

1. The identity, technical and financial qualifications of the proposed transferee; and
2. Financial assurance for decommissioning information required by 105 CMR 120.125(C), as applicable.

(C) Each person licensed by the Agency pursuant to 105 CMR 120.100 shall confine use and possession of the material licensed to the locations and purposes authorized in the license. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of 10 CFR Part 71 and 105 CMR 120.770.

(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 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 105 CMR 120.131(E) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(G) 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.

(H) 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 105 CMR 120.548. The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 105 CMR 120.548(A) at the time of generator elution, in accordance with 105 CMR 120.594(F).

(I) (1) Authorization under 105 CMR 120.128(A) 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 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. Satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.
2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 105 CMR 120.128(J)(3).

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(3) A licensee that is a pharmacy authorized under 105 CMR 120.128(A) 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:

1. an authorized nuclear pharmacist that meets the requirements in 105 CMR 120.128(J)(2)(b); or
2. an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

(4) A pharmacy, authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 105 CMR 120.128(J)(2)(e).

120.132: Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

(A) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 105 CMR 120.133 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(B) 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.

(C) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) Limit actions involving radioactive material to those related to decommissioning; and,

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

(D) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in 105 CMR 120.013, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 105 CMR 120.132(G)(1) and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to 105 CMR 120.132(A) or (B); or

(2) The licensee has decided to permanently cease principal activities, as defined in 105 CMR 120.005, 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; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

(E) Coincident with the notification required by 105 CMR 120.132(D), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 105 CMR 120.125(C) in conjunction with a license issuance or renewal or as required by 105 CMR 120.132. 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 105 CMR 120.132(G)(4)(e).

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

(F) The Agency may grant a request to extend the time periods established in 105 CMR 120.132(D) 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 105 CMR 120.132(D). The schedule for decommissioning set forth in 105 CMR 120.132(D) may not commence until the Agency has made a determination on the request.

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(G) (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor 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:

(a) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(b) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(c) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or,

(d) procedures could result in significantly greater releases of radioactive 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 105 CMR 120.132(D) 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 105 CMR 120.132(G)(1) 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:

(a) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(b) a description of planned decommissioning activities;

(c) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(d) a description of the planned final radiation survey; and,

(e) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(f) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 105 CMR 120.132(H).

(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.

(H) (1) Except as provided in 105 CMR 120.132(I), 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 105 CMR 120.132(I), 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.

(I) 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 reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,

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(5) other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(J) As the final step in decommissioning, the licensee shall:
(1) Certify the disposition of all licensed material including accumulated wastes, by submitting a completed Agency Form MRCP 120.100-3 or equivalent information; and,
(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:
(a) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and
(b) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(K) 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;
(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and
(3) (a) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Agency requirements; or
(b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Agency requirements.

120.133: Renewal of Licenses

(A) Applications for renewal of specific licenses shall be filed in accordance with 105 CMR 120.124.

(B) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

120.134: Amendment of Licenses and Registration Certificates at Request of Licensee

(A) Applications for amendment of a license shall be filed in accordance with 105 CMR 120.124 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment. Applications for amendment of sealed source and device registration certificates must be filed in accordance with 105 CMR 120.128(N) and any other applicable provisions and must specify the respects in which the certificate holder desires its certificate to be amended and the grounds for the amendment.

(B) An invoice for an amendment fee will be issued on receipt of a request to amend a license. The amendment will not be issued until after the invoiced amount has been paid.

120.135: Agency Action on Applications to Renew or Amend

In considering an application by a licensee to renew or amend the license or to amend a sealed source or device registration certificate, the Agency will apply the criteria set forth in 105 CMR 120.125, 120.126, 120.127, and 120.128 and in 120.300, 120.500, 120.800 or 120.900, as applicable.

120.136: Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on March 21, 1997

Any person who, on March 21, 1997, date of the Agreement between the Commonwealth and the NRC pursuant to section 274b of the Atomic Energy Act of 1954, as amended (42 USC 2021), possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under 105 CMR 120.136 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, such license to expire either 90 days after receipt from the Agency of a notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

120.137: Persons Possessing Naturally Occurring and Accelerator-produced Radioactive Material (NARM) on March 21, 1997

Any person who, on October 6, 2006, possesses NARM for which a specific license is required by M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P or 105 CMR 120.137 shall be deemed to possess such a license issued under M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P and 105 CMR 120.137. Such license shall expire on January 6, 2007; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Agency.

120.140: Transfer of Material

(A) No licensee shall transfer radioactive material except as authorized pursuant to 105 CMR 120.140.

(B) Except as otherwise provided in his license and subject to the provisions of 105 CMR 120.140(C) and (D), any licensee may transfer radioactive material:

(1) to the Agency (Only after receiving prior approval from the Agency.);

(2) to the U.S. Department of Energy;

(3) to any person exempt from 105 CMR 120.000 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 in writing.

(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 105 CMR 120.140(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 ten days.

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(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 105 CMR 120.140(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 105 CMR 120.770.

120.142: Reporting Requirements

(A) Immediate Report. Each licensee shall notify the Agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, *etc*.).

(B) 24 Hour Report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:
(1) An unplanned contamination event that:
(a) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
(b) Involves a quantity of material greater than five times the lowest annual limit on intake specified in 105 CMR 120.296: *Appendix B* for the material; and,
(c) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
(2) An event in which equipment is disabled or fails to function as designed when:
(a) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
(b) The equipment is required to be available and operable when it is disabled or fails to function; and,
(c) No redundant equipment is available and operable to perform the required safety function.
(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
(a) The quantity of material involved is greater than five times the lowest annual limit on intake specified in 105 CMR 120 296: *Appendix B* for the material; and,
(b) 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 105 CMR 120.142 must be made as follows:
(1) Licensees shall make reports required by 105 CMR 120.142(A) and (B) by telephone to the Agency during normal working hours or the Nuclear Incident Advisory Team (NIAT) at all other times. To the extent that the information is available at the time of notification, the information provided in these reports must include:
(a) The caller's name and call back telephone number;
(b) A description of the event, including date and time;
(c) The exact location of the event;
(d) The isotopes, quantities, and chemical and physical form of the licensed material involved; and,
(e) Any personnel radiation exposure data available.

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(2) Written Report. Each licensee who makes a report required by 105 CMR 120.142(A) or (B) 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 written reports must be sent to the Massachusetts Department of Public Health, Radiation Control Program. The report must include the following:

(a) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(b) The exact location of the event;

(c) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(d) Date and time of the event;

(e) Corrective actions taken or planned and the results of any evaluations or assessments; and,

(f) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

120.146: Emergency Plan for Responding to a Release

(A) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 105 CMR 120.196: *Appendix B*, Table III 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 105 CMR 120.146 and 120.760:

(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 105 CMR 120.196: *Appendix B*, Table III 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 engineered safety features in the facility would cause the release fraction to be lower than shown in 105 CMR 120.196: *Appendix B*, Table III;

(6) Operating restrictions or procedures would prevent a release fraction as large as that shown in 105 CMR 120.196: *Appendix B*, Table III; or

(7) Other factors appropriate for the specific facility.

(C) An emergency plan for responding to a release of radioactive material submitted pursuant to 105 CMR 120.146 and 120.760 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 Releases. A brief description of the methods and equipment to assess releases of radioactive materials.

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(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 response 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 the means 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 the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios 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.

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

(D) The license 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.

120.150: 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 M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, or by reason of rules, regulations, and orders issued by the Agency.

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

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(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 M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, 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 M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, 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.

120.190: 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 105 CMR 120.000, 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 to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

(a) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(b) the out-of-state licensee notifies the Agency in writing at least three 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 three 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 105 CMR 120.190(A)(1);

(c) 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;

(d) the out-of-state licensee supplies such other information as the Agency may request; and

(e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 105 CMR 120.190(A)(1) except by transfer to a person:

1. specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material; or,

2. exempt from the requirements for a license for such material under 105 CMR 120.104(A).

(2) Notwithstanding the provisions of 105 CMR 120.190(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 105 CMR 120.122(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:

(a) Filing a report with the Agency (Reserved);

(b) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

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(c) 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,

(d) 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 105 CMR 120.122(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) Exceptions to the General License.

(1) The general license granted in 105 CMR 120.190(A) to conduct activities in the State does not include activities in areas of exclusive Federal jurisdiction within the State or offshore waters.

(2) Authorization for use of radioactive materials in areas of exclusive Federal jurisdiction within the State or offshore waters may be obtained from the U.S. Nuclear Regulatory Commission as provided for in 10 CFR 150.20.

(3) Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained from the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

NON-TEXT PAGE

120.195: Appendix A -- Exempt Concentrations

Element (Atomic Number)	Isotope	Column I Gas Concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Antimony (51)	Sb-122 Sb-124 Sb-125		$3X10^{-4}$ $2X10^{-4}$ $1X10^{-3}$
Argon (18)	Ar-37 Ar-41	$1X10^{-3}$ $4X10^{-7}$	
Arsenic (33)	As-73 As-74 As-76 As-77		$5X10^{-3}$ $5X10^{-4}$ $2X10^{-4}$ $8X10^{-4}$
Barium (56)	Ba-131 Ba-140		$2X10^{-3}$ $3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109 Cd-115m Cd-115		$2X10^{-3}$ $3X10^{-4}$ $3X10^{-4}$
Calcium (20)	Ca-45 Ca-47		$9X10^{-5}$ $5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141 Ce-143 Ce-144		$9X10^{-4}$ $4X10^{-4}$ $1X10^{-4}$
Cesium (55)	Cs-131 Cs-134m Cs-134		$2X10^{-2}$ $6X10^{-2}$ $9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57 Co-58 Co-60		$5X10^{-3}$ $1X10^{-3}$ $5X10^{-4}$
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165 Dy-166		$4X10^{-3}$ $4X10^{-4}$
Erbium (68)	Er-169 Er-171		$9X10^{-4}$ $1X10^{-3}$

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Element (Atomic Number)	Isotope	Column I Gas Concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Europium (63)	Eu-152/ (9.2h) Eu-155		$6X10^{-4}$ $2X10^{-3}$
Fluorine (9)	F-18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd-153 Gd-159		$2X10^{-3}$ $8X10^{-4}$
Gallium (31)	Ga-72		$4X10^{-4}$
Germanium (32)	Ge-71		$2X10^{-2}$
Gold (79)	Au-196 Au-198 Au-199		$2X10^{-3}$ $5X10^{-4}$ $2X10^{-3}$
Hafnium (72)	Hf-181		$7X10^{-4}$
Hydrogen (1)	H-3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In-113m In-114m		$1X10^{-2}$ $2X10^{-4}$
Iodine (53)	I-126 I-131 I-132 I-133 I-134	$3X10^{-9}$ $3X10^{-9}$ $8X10^{-8}$ $1X10^{-8}$ $2X10^{-7}$	$2X10^{-5}$ $2X10^{-5}$ $6X10^{-4}$ $7X10^{-5}$ $1X10^{-3}$
Iridium (77)	Ir-190 Ir-192 Ir-194		$2X10^{-3}$ $4X10^{-4}$ $3X10^{-4}$
Iron (26)	Fe-55 Fe-59		$8X10^{-3}$ $6X10^{-4}$
Krypton (36)	Kr-85m Kr-85	$1X10^{-6}$ $3X10^{-6}$	
Lanthanum (57)	La-140		$2X10^{-4}$
Lead (82)	Pb-203		$4X10^{-3}$
Lutetium (71)	Lu-177		$1X10^{-3}$
Manganese (25)	Mn-52 Mn-54 Mn-56		$3X10^{-4}$ $1X10^{-3}$ $1X10^{-3}$
Mercury (80)	Hg-197m Hg-197 Hg-203		$2X10^{-3}$ $3X10^{-3}$ $2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147 Nd-149		$6X10^{-4}$ $3X10^{-3}$
Nickel (28)	Ni-65		$1X10^{-3}$
Niobium (Columbium) (41)	Nb-95 Nb-97		$1X10^{-3}$ $9X10^{-3}$

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Element (Atomic Number)	Isotope	Column I Gas Concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Osmium (76)	Os-185 Os-191m Os-191 Os-193		$7X10^{-4}$ $3X10^{-2}$ $2X10^{-3}$ $6X10^{-4}$
Palladium (46)	Pd-103 Pd-109		$3X10^{-3}$ $9X10^{-4}$
Phosphorus (15)	P-32 P-33		$2X10^{-4}$ $1X10^{-3}$
Platinum (78)	Pt-191 Pt-193m Pt-197m Pt-197		$1X10^{-3}$ $1X10^{-2}$ $1X10^{-2}$ $1X10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142 Pr-143		$3X10^{-4}$ $5X10^{-4}$
Promethium (61)	Pm-147 Pm-149		$2X10^{-3}$ $4X10^{-4}$
Rhenium (75)	Re-183 Re-186 Re-188		$6X10^{-3}$ $9X10^{-4}$ $6X10^{-4}$
Rhodium (45)	Rh-103m Rh-105		$1X10^{-1}$ $1X10^{-3}$
Rubidium (37)	Rb-86		$7X10^{-4}$
Ruthenium (44)	Ru-97 Ru-103 Ru-105 Ru-106		$4X10^{-3}$ $8X10^{-4}$ $1X10^{-3}$ $1X10^{-4}$
Samarium (62)	Sm-153		$8X10^{-4}$
Scandium (21)	Sc-46 Sc-47 Sc-48		$4X10^{-4}$ $9X10^{-4}$ $3X10^{-4}$
Selenium (34)	Se-75		$3X10^{-3}$
Silicon (14)	Si-31		$9X10^{-3}$
Silver (47)	Ag-105 Ag-110m Ag-111		$1X10^{-3}$ $3X10^{-4}$ $4X10^{-4}$
Sodium (11)	Na-24		$2X10^{-3}$
Strontium (38)	Sr-85 Sr-89 Sr-91 Sr-92		$1X10^{-3}$ $1X10^{-4}$ $7X10^{-4}$ $7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$
Technetium (43)	Tc-96m Tc-96		$1X10^{-1}$ $1X10^{-3}$

120.195: continued

Element (Atomic Number)	Isotope	Column I Gas Concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Tellurium (52)	Te-125m Te-127m Te-127 Te-129m Te-131m Te-132		$2X10^{-3}$ $6X10^{-4}$ $3X10^{-3}$ $3X10^{-4}$ $6X10^{-4}$ $3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$
Thallium (81)	Tl-200 Tl-201 Tl-202 Tl-204		$4X10^{-3}$ $3X10^{-3}$ $1X10^{-3}$ $1X10^{-3}$
Thulium (69)	Tm-170 Tm-171		$5X10^{-4}$ $5X10^{-3}$
Tin (50)	Sn-113 Sn-125		$9X10^{-4}$ $2X10^{-4}$
Tungsten (Wolfram) (74)	W-181 W-187		$4X10^{-3}$ $7X10^{-4}$
Vanadium (23)	V-48		$3X10^{-4}$
Xenon (54)	Xe-131m Xe-133 Xe-135	$4X10^{-6}$ $3X10^{-6}$ $1X10^{-6}$	
Ytterbium (70)	Yb-175		$1X10^{-3}$
Yttrium (39)	Y-90 Y-91m Y-91 Y-92 Y-93		$2X10^{-4}$ $3X10^{-2}$ $3X10^{-4}$ $6X10^{-4}$ $3X10^{-4}$
Zinc (30)	Zn-65 Zn-69m Zn-69		$1X10^{-3}$ $7X10^{-4}$ $2X10^{-2}$
Zirconium (40)	Zr-95 Zr-97		$6X10^{-4}$ $2X10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life of less than three years.		$1X10^{-10}$	$1X10^{-6}$

120.195: continued

Note 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in 105 CMR 120.195: *Appendix A*, the activity stated is that of the parent isotope and takes into account the daughters.

Note 2: For purposes of 105 CMR 120.104(A) where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in 120.195: *Appendix A* for the specific isotope when not in combination. The sum of such ratios may not exceed "1".

Example:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} +$$

$$\frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

Note 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40) Zr-97 (2x10-4 μCi/ml multiplied by 37 is equivalent to 74 x 10-4 MBq/l)

120.196: Appendix B -- Table I 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
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

120.196 Table 1: continued

Radioactive Material	Micro-curies
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
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
Phosphorus-33 (P 33)	100
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

120.196 Table 1: continued

Radioactive Material	Micro-curies
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
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

120.196 Table 1: continued

Radioactive Material	Micro-curies
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 105 CMR 100.125(C)(3) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in 105 CMR 120.196: *Appendix B, Table 1* for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

$$\frac{\textit{Amt. of Isotope A possessed}}{\textbf{1000 } \textit{x Appendix B Table 1 quantity for Isotope A}} + \frac{\textit{Amt. of Isotope B possessed}}{\textbf{1000 } \textit{x Appendix B Table 1 quantity for Isotope B}} < 1$$

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).

120.196: Table II -- Quantities For Use With 105 CMR 120.125(C)(1)

Material	Microcuries
Americium-241	0.01
Antimony-122	100.00
Antimony-124	10.00
Antimony-125	10.00
Arsenic-73	100.00
Arsenic-74	10.00
Arsenic-76	10.00
Arsenic-77	100.00
Barium-131	10.00
Barium-133	10.00
Barium-140	10.00
Bismuth-210	1.00
Bromine-82	10.00
Cadmium-109	10.00
Cadmium-115m	10.00
Cadmium-115	100.00
Calcium-45	10.00
Calcium-47	10.00
Carbon-14	100.00
Cerium-141	100.00
Cerium-143	100.00
Cerium-144	1.00
Cesium-131	1,000.00
Cesium-134m	100.00
Cesium-134	1.0
Cesium-135	10.00
Cesium-136	10.00
Cesium-137	10.00
Chlorine-36	10.00
Chlorine-38	10.00
Cobalt-57	10.00
Chromium-51	1,000.00
Cobalt-58m	10.00
Cobalt-58	10.00
Cobalt-60	1.00
Copper-64	100.00
Dysprosium-165	10.00
Dysprosium-166	100.00
Erbium-169	100.00
Erbium-171	100.00
Europium-152 (9.2 h)	100.00
Europium-152 (13 yr)	1.00
Europium-154	1.00
Europium-155	10.00
Fluorine-18	1,000.00
Gadolinium-153	10.00
Gadolinium-159	100.00
Gallium-72	10.00
Germanium-71	100.00
Gold-198	100.00
Gold-199	100.00
Hafnium-181	10.00
Holmium-166	100.00
Hydrogen-3	1,000.00
Indium-113m	100.00
Indium-114m	10.00
Indium-115m	100.00
Indium-115	10.00
Iodine-125	1.00

120.196 Table II: continued

Material	Microcuries
Iodine-126	1.00
Iodine-129	0.1
Iodine-131	1.0
Iodine-132	10.00
Iodine-133	1.00
Iodine-134	10.00
Iodine-135	10.00
Iridium-192	10.00
Iridium-194	100.00
Iron-55	100.00
Iron-59	10.00
Krypton-85	100.00
Krypton-87	10.00
Lanthanum-140	10.00
Lutetium-177	100.00
Manganese-52	10.00
Manganese-54	10.00
Manganese-56	10.00
Mercury-197m	100.00
Mercury-197	100.00
Mercury-203	10.00
Molybdenum-99	100.00
Neodymium-147	100.00
Neodymium-149	100.00
Nickel-59	100.00
Nickel-63	10.00
Nickel-65	100.00
Niobium-93m	10.00
Niobium-95	10.00
Niobium-97	10.00
Osmium-185	10.00
Osmium-191m	100.00
Osmium-191	100.00
Osmium-193	100.00
Palladium-103	100.00
Palladium-109	100.00
Phosphorus-32	10.00
Phosphorus-33	100.00
Platinum-191	100.00
Platinum-193m	100.00
Platinum-193	100.00
Platinum-197m	100.00
Platinum-197	100.00
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10.00
Praseodymium-142	100.00
Praseodymium-143	100.00
Promethium-147	10.00
Promethium-149	10.00
Radium-226	0.01
Rhenium-186	100.00
Rhenium-188	100.00
Rhodium-103m	100.00
Rhodium-105	100.00
Rubidium-86	10.00
Rubidium-87	10.00
Ruthenium-97	100.00

120.196 Table II: continued

Material	Microcuries
Ruthenium-103	10.00
Ruthenium-105	10.00
Ruthenium-106	1.00
Samarium-151	10.00
Samarium-153	100.00
Scandium-46	10.00
Scandium-47	100.00
Scandium-48	10.00
Selenium-75	10.00
Silicon-31	100.00
Silver-105	10.00
Silver-110m	1.00
Silver-111	100.00
Sodium-22	1.0
Sodium-24	10.00
Strontium-85	10.00
Strontium-89	1.00
Strontium-90	0.1
Strontium-91	10.00
Strontium-92	10.00
Sulphur-35	100.00
Tantalum-182	10.00
Technetium-96	10.00
Technetium-97m	100.00
Technetium-97	100.00
Technetium-99m	100.00
Technetium-99	10.00
Tellurium-125m	10.00
Tellurium-127m	10.00
Tellurium-127	100.00
Tellurium-129m	10.00
Tellurium-129	100.00
Tellurium-131m	10.00
Tellurium-132	10.00
Terbium-160	10.00
Thallium-200	100.00
Thallium-201	100.00
Thallium-202	100.00
Thallium-204	10.00
Thorium (natural)	100.00
Thulium-170	10.00
Thulium-171	10.00
Tin-113	10.00
Tin-125	10.00
Tungsten-181	10.00
Tungsten-185	10.00
Tungsten-187	100.00
Uranium (natural)	100.00
Uranium-233	0.01
Uranium-234/235	0.01
Vanadium-48	10.00
Xenon-131m	1,000.00
Xenon-133	100.00
Xenon-135	100.00
Ytterbium-175	100.00
Yttrium-90	10.00
Yttrium-91	10.00
Yttrium-92	100.00

120.196 Table II: continued

Material	Microcuries
Yttrium-93	100.00
Zinc-65	10.00
Zinc-69m	100.00
Zinc-69	1,000.00
Zirconium-93	10.00
Zirconium-95	10.00
Zirconium-97	10.00
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha-emittingradionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

Note: For purposes of 105 CMR 120.125(C)(1), where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: Determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all the radionuclides in the combination is R.

Note: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 μCi) (37) = 370 kBq.
(10 μCi multiplied by 37 is equivalent to 370 kBq)

120.196: Table III Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

Radioactive Material [1]	Release fraction	Quantity(Ci)
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000
Bismuth-207	0.01	5,000
Bismuth-210	0.01	600
Cadmium-109	0.01	1,000
Cadmium-113	0.01	80
Calcium-45	0.01	20,000
Californium-252	0.001	9 (20mg)
Carbon-14	0.01	50,000
	Non CO	
Cerium-141	0.01	10,000
Cerium-144	0.01	300
Cesium-134	0.01	2,000
Cesium-137	0.01	3,000
Chlorine-36	0.5	100
Chromium-51	0.01	300,000
Cobalt-60	0.001	5,000
Copper-64	0.01	200,000
Curium-242	0.001	60
Curium-243	0.001	3
Curium-244	0.001	4
Curium-245	0.001	2
Europium-152	0.01	500
Europium-154	0.01	400
Europium-155	0.01	3,000
Germanium-68	0.01	2,000
Gadolinium-153	0.01	5,000
Gold-198	0.01	30,000
Hafnium-172	0.01	400
Hafnium-181	0.01	7,000
Holmium-166m	0.01	100
Hydrogen-3	0.5	20,000
Indium-114m	0.01	1,000
Iodine-125	0.5	10
Iodine-131	0.5	10
Iridium-192	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6000000
Lead-210	0.01	8
Manganese-56	0.01	60,000
Mercury-203	0.01	10,000
Molybdenum-99	0.01	30,000
Neptunium-237	0.001	2
Nickel-63	0.01	20,000
Niobium-94	0.01	300
Phosphorus-32	0.5	100

[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 Table III exceeds one.

120.196 Table III: continued

Radioactive Material [1]	Release fraction	Quantity(Ci)
Phosphorus-33	0.5	1,000
Polonium-210	0.01	10
Potassium-42	0.01	9,000
Promethium-145	0.01	4,000
Promethium-147	0.01	4,000
Radium-226	0.001	100
Ruthenium-106	0.01	200
Samarium-151	0.01	4,000
Scandium-46	0.01	3,000
Selenium-75	0.01	10,000
Silver-110m	0.01	1,000
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulphur-35	0.5	900
Technetium-99	0.01	10,000
Technetium-99m	0.01	400,000
Tellurium-127m	0.01	5,000
Tellurium-129m	0.01	5,000
Terbium-160	0.01	4,000
Thulium-170	0.01	4,000
Tin-113	0.01	10,000
Tin-123	0.01	3,000
Tin-126	0.01	1,000
Titanium-44	0.01	100
Vanadium-48	0.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	0.01	2,000
Zinc-65	0.01	5,000
Zirconium-93	0.01	400
Zirconium-95	0.01	5,000
Any other beta-gamma emitter	0.01	10,000
Mixed fission products	0.01	1,000
Mixed corrosion products	0.01	10,000
Contaminated equipment β-γ	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material, solid noncombustible	0.001	10,000
Mixed radioactive waste, β-γ	0.01	1,000
Packaged mixed waste [3]	0.001	10,000
Contaminated equipment, alpha	0.0001	20
Any other alph emitter	0.001	2
Packaged waste alpha [2]	0.0001	20
Combinations of radioactive materials listed[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 Table III exceeds one.

[2] 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 the material in Table III exceeds one.

[3] Waste packaged in Type B containers does not require an emergency plan.

120.197: Appendix C -- Limits for Broad Licenses

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Antimony-122	1.0	0.01
Antimony-124	1.0	0.01
Antimony-125	1.0	0.01
Arsenic-73	10.0	0.1
Arsenic-74	1.0	0.01
Arsenic-76	1.0	0.01
Arsenic-77	10.0	0.1
Barium-131	10.0	0.1
Barium-140	1.0	0.01
Beryllium-7	10.0	0.1
Bismuth-210	0.1	0.001
Bromine-82	10.0	0.1
Cadmium-109	1.0	0.01
Cadmium-115m	1.0	0.01
Cadmium-115	10.0	0.1
Calcium-45	1.0	0.01
Calcium-47	10.0	0.1
Carbon-14	100.0	1.0
Cerium-141	10.0	0.1
Cerium-143	10.0	0.1
Cerium-144	0.1	0.001
Cesium-131	100.0	1.0
Cesium-134m	100.0	1.0
Cesium-134	0.1	0.001
Cesium-135	1.0	0.01
Cesium-136	10.0	0.1
Cesium-137	0.1	0.001
Chlorine-36	1.0	0.01
Chlorine-38	100.0	1.0
Chromium-51	100.0	1.0
Cobalt-57	10.0	0.1
Cobalt-58m	100.0	1.0
Cobalt-58	1.0	0.01
Cobalt-60	0.1	0.001
Copper-64	10.0	0.1
Dysprosium-165	100.0	1.0
Dysprosium-166	10.0	0.1
Erbium-169	10.0	0.1

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Erbium-171	10.0	0.1
Europium-152 (9.2 h)	10.0	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1.0	0.01
Fluorine-18	100.0	1.0
Gadolinium-153	1.0	0.01
Gadolinium-159	10.0	0.1
Gallium-72	10.0	0.1
Germanium-71	100.0	1.0
Gold-198	10.0	0.1
Gold-199	10.0	0.1
Hafnium-181	1.0	0.01
Holmium-166	10.0	0.1
Hydrogen-3	100.0	1.0
Indium-113m	100.0	1.0
Indium-114m	1.0	0.01
Indium-115m	100.0	1.0
Indium-115	1.0	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	0.1
Iodine-133	1.0	0.01
Iodine-134	10.0	0.1
Iodine-135	1.0	0.01
Iridium-192	1.0	0.01
Iridium-194	10.0	0.1
Iron-55	10.0	0.1
Iron-59	1.0	0.01
Krypton-85	100.0	1.0
Krypton-87	10.0	0.1
Lanthanum-140	1.0	0.01
Lutetium-177	10.0	0.1
Manganese-52	1.0	0.01
Manganese-54	1.0	0.01

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Manganese-56	10.0	0.1
Mercury-197m	10.0	0.1
Mercury-197	10.0	0.1
Mercury-203	1.0	0.01
Molybdenum-99	10.0	0.1
Neodymium-147	10.0	0.1
Neodymium-149	10.0	0.1
Nickel-59	10.0	0.1
Nickel-63	1.0	0.01
Nickel-65	10.0	0.1
Niobium-93m	1.0	0.01
Niobium-95	1.0	0.01
Niobium-97	100.0	1.0
Osmium-185	1.0	0.01
Osmium-191m	100.0	1.0
Osmium-191	10.0	0.1
Osmium-193	10.0	0.1
Palladium-103	10.0	0.1
Palladium-109	10.0	0.1
Phosphorus-32	1.0	0.01
Phosphorus-33	10.0	0.1
Platinum-191	10.0	0.1
Platinum-193m	100.0	1.0
Platinum-193	10.0	0.1
Platinum-197m	100.0	1.0
Platinum-197	10.0	0.1
Polonium-210	0.01	0.0001
Potassium-42	1.0	0.01
Praseodymium-142	10.0	0.1
Praseodymium-143	10.0	0.1
Promethium-147	1.0	0.01
Promethium-149	10.0	0.1
Radium-226	0.01	0.0001
Rhenium-186	10.0	0.1
Rhenium-188	10.0	0.1
Rhodium-103m	1,000.0	10.0
Rhodium-105	10.0	0.1
Rubidium-86	1.0	0.01

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Rubidium-87	1.0	0.01
Ruthenium-97	100.0	1.0
Ruthenium-103	1.0	0.01
Ruthenium-105	10.0	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1.0	0.01
Samarium-153	10.0	0.1
Scandium-46	1.0	0.01
Scandium-47	10.0	0.1
Scandium-48	1.0	0.01
Selenium-75	1.0	0.01
Silicon-31	10.0	0.1
Silver-105	1.0	0.01
Silver-110m	0.1	0.001
Silver-111	10.0	0.1
Sodium-22	0.1	0.001
Sodium-24	1.0	0.01
Strontium-85m	1,000.0	10.0
Strontium-85	1.0	0.01
Strontium-89	1.0	0.01
Strontium-90	0.01	0.0001
Strontium-91	10.0	0.1
Strontium-92	10.0	0.1
Sulphur-35	10.0	0.1
Tantalum-182	1.0	0.01
Technetium-96	10.0	0.1
Technetium-97m	10.0	0.1
Technetium-97	10.0	0.1
Technetium-99m	100.0	1.0
Technetium-99	1.0	0.01
Tellurium-125m	1.0	0.01
Tellurium-127m	1.0	0.01
Tellurium-127	10.0	0.1
Tellurium-129m	1.0	0.01
Tellurium-129	100.0	1.0
Tellurium-131m	10.0	0.1
Tellurium-132	1.0	0.01
Terbium-160	1.0	0.01

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Thallium-200	10.0	0.1
Thallium-201	10.0	0.1
Thallium-202	10.0	0.1
Thallium-204	1.0	0.01
Thulium-170	1.0	0.01
Thulium-171	1.0	0.01
Tin-113	1.0	0.01
Tin-125	1.0	0.01
Tungsten-181	1.0	0.01
Tungsten-185	1.0	0.01
Tungsten-187	10.0	0.1
Vanadium-48	1.0	0.01
Xenon-131m	1,000.0	10.0
Xenon-133	100.0	1.0
Xenon-135	100.0	1.0
Ytterbium-175	10.0	0.1
Yttrium-90	1.0	0.01
Yttrium-91	1.0	0.01
Yttrium-92	10.0	0.1
Yttrium-93	1.0	0.01
Zinc-65	1.0	0.01
Zinc-69m	10.0	0.1
Zinc-69	100.0	1.0
Zirconium-93	1.0	0.01
Zirconium-95	1.0	0.01

120.197: continued

RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Zirconium-97	1.0	0.01
Any Radioactive material other than source material, special nuclear material, or alpha emitting radioactive 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)

120.198: Appendix D: 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. 105 CMR 120.198: *Appendix D* 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 II.A.1 or II.A.2:

(1) The parent company must have:

(a) 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;

(b) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used);

(c) Tangible net worth of at least $21 million; and

(d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

(2) The parent company must have:

(a) 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 adjustments of 1, 2, or 3) as issued by Moody's;

(b) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used);

(c) Tangible net worth of at least $21 million; and

(d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

(B) The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(C) (1) After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(2) If the parent company no longer meets the requirements of II.A, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Agency's regulations. 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.

120.198: continued

III. Parent Company Guarantee. The terms of a parent company guarantee that 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 such alternative financial assurance in the name of the licensee.

(C) The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

(D) If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

120.198: Appendix E: 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 105 CMR 120.198: *Appendix E*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix E*, Section III. 105 CMR 120.198: *Appendix E* 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 following criteria:

(1) Tangible net worth of at least $21 million, and at least ten 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.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten 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 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 Poors (S&P), 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 have compared the data used by the company in the financial test which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(C) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix E*, Section II.(A), the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations 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 receipts.

(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.

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(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) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of 105 CMR 120 198: *Appendix E*, Section II.(A).

(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 set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198: Appendix F: Criteria Relating to Use of Financial Tests and Self Guarantees 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 105 CMR 120.198: *Appendix F*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix F*, Section III. 105 CMR 120.198: *Appendix F* 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 following criteria:

(1) Tangible net worth greater than $21 million, or at least ten 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 company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten 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 net worth less than 1.5.

(B) In addition, to pass the financial test, a company must meet all of the following additional requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters that may 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 repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix F*, Section II.(A), the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in 105 CMR 120.125(C). 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 Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

120.198: continued

(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 set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198: Appendix G: 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 105 CMR 120.198: *Appendix G*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix G*, Section III. 105 CMR 120.198: *Appendix G* 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 105 CMR 120.198: *Appendix G*, Section II.(A)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(2).

(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 (S&P) 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 105 CMR 120.198: *Appendix G*, Section II.(B)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(2):

(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 (S&P) 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 license.

(C) In addition, to pass the financial test, a licensee must meet the following requirements: (for institutions using 105 CMR 120.198: *Appendix G*: Section II, (A)(2) method of qualifying; for a self-guarantee 105 CMR 120.198: *Appendix G*: Sections II(C)(1) and II(C)(2) will apply.

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

120.198: continued

(2) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix G*: Section I, 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, and/or 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 105 CMR 120.125(C) 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 set up and fund a trust in the amount of the current cost estimates for decommissioning.

(E) 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 provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service.

(F) 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 will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor’s and Moody’s, the licensee no longer meets the requirements of 105 CMR 120 199: *Appendix E*, Section II.(A).

120.200: STANDARDS FOR PROTECTION AGAINST RADIATION

120.201: Purpose

(A) 105 CMR 120.200 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. The requirements of 105 CMR 120.200 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 105 CMR 120.200. However, nothing in 105 CMR 120.200 shall be construed as limiting actions that may be necessary to protect health and safety.

(B) 105 CMR 120.200 is issued pursuant to M.G.L. c. 111, §§ 3, 5M, 5N, 5O, 5P.

120.202: Scope

Except as otherwise specifically provided in other Parts of 105 CMR 120.000, 105 CMR 120.200 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in 105 CMR 120.200 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 105 CMR 120.540 or to voluntary participation in medical research programs.

120.203: Definitions

As used in 105 CMR 120.200, the following definitions apply:

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 one year. ALI is the smaller value of intake of a given radionuclide in one year by Reference Man that would result in a committed effective dose equivalent of 0.05 sievert (5 rem) or a committed dose equivalent of 0.5 sievert (50 rems) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in 105 CMR 120.296: *Appendix B*, Table I, Columns 1 and 2.

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 ten days, for Class W, Weeks, from ten to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of 105 CMR 120.000, "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.

Derived Air Concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by 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 105 CMR 120.000, 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 105 CMR 120.296: *Appendix B*, Table I, Column 3.

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 sievert (5 rems).

120.203: continued

Dosimetry Processor means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the monitoring equipment.

Inhalation Class *see* Class.

Lung Class *see* Class.

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 105 CMR 120.298: *Appendix D*. 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.

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 105 CMR 120.000: Deterministic Effect is an equivalent term.

Planned Special Exposure means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

Quarter means a period of time equal to ¼ of the year observed by the licensee or registrant, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Reference Man means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of 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 Device 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 or registrant.

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 105 CMR 120.000: Probabilistic Effect is an equivalent term.

Very High Radiation Area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (five grays) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. (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.)

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:

120.203: continued

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*
Whole Body	1.00**

* 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

** For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

120.204 Implementation

(A) Any existing license or certificate of registration condition that is more restrictive than 105 CMR 120.200 remains in force until there is an amendment or renewal of the license or registration.

(B) If a license or certificate of registration condition exempts a licensee or registrant from a provision of 105 CMR 120.200 in effect on or before July 9, 1999, it also exempts the licensee or registrant from the corresponding provision of 105 CMR 120.200.

(C) If a license or registration condition cites provisions of 105 CMR 120.200 in effect prior to July 9, 1999, which do not correspond to any provisions of the revised 105 CMR 120.200, 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.

120.210: Radiation Protection Programs

(A) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of 105 CMR 120.200. *See* 105 CMR 120.262 for recordkeeping requirements relating to these programs.

(B) The 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 members of the public that are as low as is reasonably achievable (ALARA).

(C) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

(D) To implement the ALARA requirements of 105 CMR 120.210(B), and notwithstanding the requirements in 105 CMR 120.221, 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 0.1 mSv (ten mrem) 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 105 CMR 120.283 and promptly take appropriate corrective action to ensure against recurrence.

120.211: 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 105 CMR 120.216, to the following dose limits:

(1) An annual limit, which is the more limiting of:

(a) the total effective dose equivalent being equal to .05 sievert (five rems); or

(b) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert (50 rems).

(2) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(a) a lens dose equivalent of 0.15 sievert (15 rems); and

(b) a shallow dose equivalent of 0.5 sievert (50 rems) 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* 105 CMR 120.216(E)(1) and (2).

(C) (1) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the 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 ten square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable;

(2) When a protective apron is worn while working medical fluoroscopic equipment and monitoring is conducted as specified in 105 CMR 120.226(A)(5), the effective dose equivalent for external radiation shall be determined as follows:

(a) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

(b) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25% of the limit specified in 105 CMR 120.211(A), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(c) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation 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.

(D) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in 105 CMR 120.296: *Appendix B*, Table I and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. *See* 105 CMR 120.267.

(E) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. *See* footnote 3 of 105 CMR 120.296: *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 during the current year. *See* 105 CMR 120.265(E).

120.212: Compliance with Requirements for Summation of External and Internal Doses

(A) If the licensee is required to monitor pursuant to both 105 CMR 120.226(A) and (B), the licensee 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 105 CMR 120.226(A) or only pursuant to 105 CMR 120.226(B), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 105 CMR 120.212(B), (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:

(1) the sum of the fractions of the inhalation ALI for each radionuclide;

(2) the total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(3) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data 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% 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 receives an intake of radionuclides by oral ingestion greater than 10% 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.

120.213: 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* 105 CMR 120.296: *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.

120.214: 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 105 CMR 120.226, take suitable and timely measurements of:

(1) concentrations of radioactive materials in air in work areas; or

(2) quantities of radionuclides in the body; or

(3) quantities of radionuclides excreted from the body; or

(4) combinations of these measurements.

(B) Unless respiratory protective equipment is used, as provided in 105 CMR 120.233, 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.

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(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:

(1) use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;

(2) 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,

(3) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. *See* 105 CMR 120.296: *Appendix B*.

(D) If the licensee chooses to assess intakes of Class Y material using the measurements given in 105 CMR 120.214(A)(2) or (3), the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 105 CMR 120.282 or 105 CMR 120.283. 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:

(1) the sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from 105 CMR 120.296: *Appendix B* for each radionuclide in the mixture; or,

(2) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(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:

(1) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 105 CMR 120.211 and in complying with the monitoring requirements in 105 CMR 120.226(B);

(2) the concentration of any radionuclide disregarded is less than 10% of its DAC; and,

(3) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.

(H) When determining the committed effective dose equivalent, the following information may be considered:

(1) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 sievert (5 rems) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 sievert (50 rems), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 sievert (5 rems), that is, the stochastic ALI, is listed in parentheses in 105 CMR 120.296: *Appendix B*, Table I. 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 105 CMR 120.211(A)(1)(b) is met.

120.216: 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 105 CMR 120.211 provided that each of the following conditions is satisfied:

(A) 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.

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(B) 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.

(C) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

(1) informed of the purpose of the planned operation;

(2) 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

(3) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(D) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 105 CMR 120.265(B) during the lifetime of the individual for each individual involved.

(E) Subject to 105 CMR 120.211(B), 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:

(1) the numerical values of any of the dose limits in 105 CMR 120.211(A) in any year; and

(2) five times the annual dose limits in 105 CMR 120.211(A) during the individual's lifetime.

(F) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 105 CMR 120.266 and submits a written report to the Agency in accordance with 105 CMR 120.284.

(G) 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 105 CMR 120.211(A) but shall be included in evaluations required by 105 CMR 120.216(D) and (E).

120.217: Occupational Dose Limits for Minors

The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in 105 CMR 120.211.

120.218: Dose Equivalent 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 five millisieverts (0.5 rems). *See* 105 CMR 120.267 for recordkeeping requirements.

(B) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 105 CMR 120.218(A).

(C) The dose equivalent to the embryo/fetus is the sum of:

(1) the deep dose equivalent to the declared pregnant woman; and

(2) the dose equivalent 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 5.0 mSv (0.5 rem), or is within 0.5 mSv (0.05 rem) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with 105 CMR 120.218(A), if the additional dose to the embryo/fetus does not exceed 0.5 millisievert (0.05 rem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS

120.221: Dose Limits for Individual Members of the Public

(A) Each licensee or registrant shall conduct operations so that:

(1) the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one millisievert (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 105 CMR 120.540, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 105 CMR 120.253; and

(2) the dose in any unrestricted area from external sources exclusive of the dose contributions from patients administered radioactive material and released in accordance with 105 CMR 120.540, does not exceed 0.02 millisievert (0.002 rem) in any one hour; and

(3) the total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 5mSv (0.5 rem).

(B) 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.

(C) A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of five millisieverts (0.5 rem). This application shall include the following information:

(1) demonstration of the need for and the expected duration of operations in excess of the limit in 105 CMR 120.221(A);

(2) the licensee's or registrant's program to assess and control dose within the five millisieverts (0.5 rem) annual limit; and

(3) the procedures to be followed to maintain the dose ALARA.

(D) In addition to the requirements of 105 CMR 120.200, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those requirements.

(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.

120.222: 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 105 CMR 120.221.

(B) A licensee or registrant shall show compliance with the annual dose limit in 105 CMR 120.221 by:

(1) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or,

(2) demonstrating that:

(a) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in 105 CMR 120.296: *Appendix B*, Table II; and,

(b) if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 millisievert) in an hour and 0.05 rem (0.5 millisievert) in a year.

(C) Upon approval from the Agency, the licensee may adjust the effluent concentration values in 105 CMR 120.296: *Appendix B*, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

120.223: Testing for Leakage or Contamination of Sealed Sources

(A) The licensee or registrant in possession of any sealed source shall assure that:

(1) Each sealed source, except as specified in 105 CMR 120.223(B), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant.

(2) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Agency, after evaluation of information specified by 105 CMR 120.128(N), an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

(3) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Agency, after evaluation of information specified by 105 CMR 120.128(N), an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

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

(5) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, 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. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

(6) The test for leakage for brachytherapy sources manufactured to contain radium 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.

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

(B) A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

(1) Sealed sources containing only radioactive material with a half-life of less than 30 days;

(2) Sealed sources containing only radioactive material as a gas;

(3) Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material;

(4) Sealed sources containing only hydrogen-3;

(5) Seeds of iridium-192 encased in nylon ribbon; and

(6) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

(C) Tests for leakage or contamination from sealed sources 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.

(D) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.

(E) The following shall be considered evidence that a sealed source is leaking:

(1) The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample.

(2) Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

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(3) The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

(F) The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this 105 CMR 120.200.

(G) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 105 CMR 120.288.

SURVEYS AND MONITORING

120.225: General

(A) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

(1) are necessary for the licensee or registrant to comply with 105 CMR 120.200; and

(2) are necessary under the circumstances to evaluate:

(a) the magnitude and extent of radiation levels;

(b) concentrations or quantities of radioactive material residual radioactivity; and

(c) the potential radiological hazards of the radiation levels and residual radioactivity detected.

(B) Notwithstanding the provisions in 105 CMR 120.263(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 105 CMR 120.125(C)(8), as applicable.

(C) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable section of 105 CMR 120.000 or license condition.

(D) 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 105 CMR 120.211, with other applicable provisions of 105 CMR 120.000, or with conditions specified in a license or certificate of registration, shall be processed and evaluated by a dosimetry processor:

(1) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(E) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

120.226: 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 105 CMR 120.200. As a minimum:

(A) Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under its control and shall supply and require the use of individual monitoring devices by:

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 105 CMR 120.211(A);

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(2) minors likely to receive, in one year from sources external to the body, a deep dose equivalent in excess of one millisievert (0.1 rem) a lens dose equivalent in excess of 1.5 millisievert (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of five millisieverts (0.5 rem);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of one millisievert (0.1 rem). [Note: All of the occupational doses in 105 CMR 120.211 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded];

(4) individuals entering a high or very high radiation area;

(5) individuals working medical fluoroscopic equipment.

(a) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to 105 CMR 120.218(A), shall be located under the protective apron at the waist.

(b) An individual monitoring device used for lens dose equivalent shall be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron.

(c) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 105 CMR 120.211(C)(2), it shall be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(B) Each licensee shall monitor, to determine compliance with 105 CMR 120.214, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in 105 CMR 120.296: *Appendix B*, Table I, Columns 1 and 2; and

(2) minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 millisievert (0.01 rem).

(3) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1m Sv (0.1 rem).

(C) Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 105 CMR 120.226(A) wear individual monitoring devices as follows:

(1) An individual monitoring device used for monitoring the dose to whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to 105 CMR 120.218(A), shall be located at the waist under any protective apron being worn by the woman.

(3) An individual monitoring device used for monitoring lens dose equivalent, to demonstrate compliance with 105 CMR 120.211(A)(2)(a), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 105 CMR 120.211(A)(2)(b), shall be worn on the extremity most likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

120.227: 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:

(1) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (one millisievert) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates;

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(2) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or,

(3) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

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(B) In place of the controls required by 105 CMR 120.227(A) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(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 105 CMR 120.227(A) and 120.227(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:

(1) the packages do not remain in the area longer than three days; and,

(2) the dose rate at one meter from the external surface of any package does not exceed 0.1 millisievert (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 this part and to operate within the ALARA provisions of the licensee's radiation protection program.

(G) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 105 CMR 120.227 if the registrant has met all the specific requirements for access and control specified in other applicable parts of 105 CMR 120.000, such as, 105 CMR 120.300 for industrial radiography, 105 CMR 120.430 for x-rays in the healing arts, and 105 CMR 120.700 for particle accelerators.

120.228: Control of Access to Very High Radiation Areas

(A) In addition to the requirements in 105 CMR 120.227, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five grays (500 rads) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates at this level. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation.

(B) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 105 CMR 120.228(A) if the registrant has met all the specific requirements for access and control specified in other applicable parts of 105 CMR 120.000, such as, 105 CMR 120.300 for industrial radiography, 105 CMR 120.430 for x-rays in the healing arts, and 105 CMR 120.700 for particle accelerators.

120.229: Control of Access to Very High Radiation Areas -- Irradiators

(A) 105 CMR 120.229 applies to licensees with sources of radiation in non-self-shielded irradiators. 105 CMR 120.229 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(B) Each area in which there may exist radiation levels in excess of five grays (500 rads) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

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(1) Each entrance or access point shall be equipped with entry control devices which:

(a) function automatically to prevent any individual from inadvertently entering a very high radiation area;

(b) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one millisievert (0.1 rem) in one hour; and,

(c) prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of one millisievert (0.1 rem) in one hour.

(2) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 105 CMR 120.229(B)(1):

(a) the radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one millisievert (0.1 rem) in one hour; and,

(b) conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(3) The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(a) the radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one millisievert (0.1 rem) in one hour; and,

(b) conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(4) When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(5) 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 105 CMR 120.229(B)(3) and 120.229(B)(4).

(6) 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.

(7) 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.

(8) 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 one millisievert (0.1 rem) in one hour.

(9) The entry control devices required in 105 CMR 120.229(B)(1) shall be tested for proper functioning. *See* 105 CMR 120.270 for recordkeeping requirements.

(a) 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.

(b) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption.

(c) The licensee shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(10) The licensee 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.

120.229: continued

(11) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

(C) Licensees or applicants for licenses for sources of radiation within the purview of 105 CMR 120.229(B) 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 105 CMR 120.229(B), 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 105 CMR 120.229(B). 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 105 CMR 120.229(B) and (C) shall be established in such a way that no individual will be prevented from leaving the area.

120.231: Use of Process or Other Engineering Controls

The licensee shall use, to the extent practical, process or other engineering controls, such as, containment, decontamination or ventilation, to control the concentrations of radioactive material in air.

120.232: Use of Other Controls

(A) When it is not practicable 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:

(1) control of access;
(2) limitation of exposure times;
(3) use of respiratory protection equipment; and,
(4) other controls.

(B) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may also consider the impact of respirator use on workers' industrial health and safety.

120.233: Use of Individual Respiratory Protection Equipment

If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to 105 CMR 120.232:

(A) Except as provided in 105 CMR 120.233(A)(2), the licensee or registrant shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health.

(B) If the licensee or registrant wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety, or for which there is no schedule for testing or certification, the licensee shall submit an application to the Agency for authorization to use this equipment, except as otherwise noted in 105 CMR 120.200. 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 the licensee's or registrant's testing or on the basis of reliable test information;

120.233: continued

(C) The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(1) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) surveys and bioassays, as necessary, to evaluate actual intakes;

(3) testing of respirators for operability user seal check for face sealing devices and functional check for others immediately prior to each use;

(4) written procedures regarding:

(a) Monitoring, including air sampling and bioassays;

(b) Supervision and training or respirator users;

(c) Fit testing;

(d) Respirator selection;

(e) Breathing air quality;

(f) Inventory and control;

(g) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(h) Recordkeeping; and,

(i) Limitations on periods of respirator use and relief from respirator use.

(5) determination by a physician that the individual user is medically fit to use the respiratory protection equipment before:

(a) The initial fitting of a face sealing respirator;

(b) Before the first field use of non-face sealing respirators, and

(c) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

(6) Fit testing, with a fit factor $\geq$ 10 times the APF for negative pressure devices, and a fit factor $\geq$ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(D) The licensee or registrant 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 or registrant shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee or registrant shall provide for vision correction, adequate communication, low temperature work environments and the concurrent use of other safety or radiological protection equipment. The licensee or registrant 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:

(1) Oxygen content (v/v) of 19.5-23.5%;

(2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(3) Carbon Monoxide (CO) content of 10 ppm or less;

120.233: continued

(4) Carbon Dioxide content of 1,000 ppm or less; and,
(5) 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 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 the 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.

120.234: Further Restrictions on the Use of Respiratory Protection Equipment

The Agency may impose restrictions in addition to the provisions of 105 CMR 120.232 and 120.233, and 120.295: *Appendix A*, in order to:

(A) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of 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.

120.235: Application for Use of Higher Assigned Protection Factors

The licensee or registrant shall obtain authorization from the Agency before using assigned respiratory protection factors in excess of those specified in 105 CMR 120.295: *Appendix A*. The Agency may authorize a licensee or registrant to use higher 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.

120.236: Security and Control of Licensed or Registered Sources of Radiation

(A) The licensee shall secure licensed radioactive material from unauthorized removal or access.

(B) The licensee shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed radioactive material that is in an unrestricted area and that is not in storage.

(C) The registrant shall secure registered radiation machines from unauthorized removal.

(D) The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

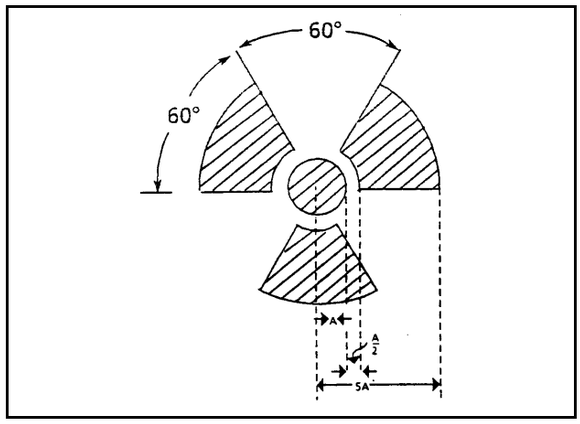
120.237: Caution Signs

(A) Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by 105 CMR 120.237 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

120.237: continued

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



(B) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 105 CMR 120.237(A), 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 this part, 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.

120.238: 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 [not required to use the word GRAVE, this may be omitted], 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 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 ten times the quantity of such material specified in 105 CMR 120.297: *Appendix C* with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

120.239: Exceptions to Posting Requirements

(A) A licensee or registrant is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than eight hours, if each of the following conditions is met:

(1) the radioactive materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radioactive materials in excess of the limits established in 105 CMR 120.200; and,

(2) the area or room is subject to the licensee's or registrant'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 105 CMR 120.242 provided that patient could be released from confinement pursuant to 105 CMR 120.540.

(C) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs, provided that:

(1) A patient being treated with a permanent implant could be released from confinement pursuant 105 CMR 120.540; or

(2) A patient being treated with a therapeutic radiopharmaceutical could be released from confinement pursuant 105 CMR 120.540.

(D) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(E) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

(F) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 105 CMR 120.238 if:

(1) Access to the room is controlled pursuant to 105 CMR 120.573; and,

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in 105 CMR 120.200.

120.240: 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.

120.241: Exemptions to Labeling Requirements

A licensee is not required to label:

(A) containers holding licensed material in quantities less than the quantities listed in 105 CMR 120.297: *Appendix C*; or

(B) containers holding licensed material in concentrations less than those specified in 105 CMR 120.296: *Appendix B*, Table III; or

120.241: continued

(C) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by 105 CMR 120.200;

(D) containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation[1];

(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 these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record 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 piping and tanks.

120.242: Procedures for Receiving and Opening Packages

(A) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 105 CMR 120.772 and 105 CMR 120.798: *Appendix A*, shall make arrangements to receive:

(1) the package when the carrier offers it for delivery; or

(2) the notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(B) Each licensee or registrant shall:

(1) monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 105 CMR 120.005;

(2) monitor the external surfaces of a labeled[2] 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 105 CMR 120.772 and 105 CMR 120.798: *Appendix A*; and

(3) monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(C) The licensee or registrant shall perform the monitoring required by 105 CMR 120.242 as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

(D) The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:

(1) removable radioactive surface contamination exceeds the limits of 105 CMR 120.786(I); or

(2) External radiation levels exceed the limit of 105 CMR 120.783.

(E) Each licensee or registrant shall:

(1) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

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[1] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.424.

[2] 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 through 172.440.

120.242: continued

(F) Licensees or registrants 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 105 CMR 120.246(B), but are not exempt from the monitoring requirement in 105 CMR 120.246(B) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

120.243: Vacating Premises

Each licensee, registrant, or person possessing non-exempt sources of radiation shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activity, notify the Agency, in writing, of the intent to vacate. When deemed necessary by the Agency, the licensee, registrant, or person possessing non-exempt sources of radiation shall decontaminate the premises in such a manner as the Agency may specify.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

120.244: General Provisions and Scope

The criteria in 105 CMR 120.244 apply to the decommissioning of facilities licensed under 105 CMR 120.100,120.300, 120.500, 120.800 and 120.900.

(A) The criteria in 105 CMR 120.244 does not apply to sites, which have been decommissioned prior to October 6, 2006.

(B) After a site has been decommissioned and the license terminated in accordance with the criteria in 105 CMR 120.244, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of 105 CMR 120.244 were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(C) 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.

(D) Specific time limits for completion of the decommissioning process are as specified in 105 CMR 120.132(G).

(1) Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but not later than 24 months following the initiation of decommissioning.

(2) When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but not later than 24 months following the initiation of decommissioning.

(E) The Agency may approve a request for an alternative schedule for completion of the decommissioning of the site or separate building or outdoor area, and license termination is appropriate, if the Agency determines that the alternative is warranted.

120.245: 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 shall not exceed 0.10 mSv (10 mrem) 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.

120.246: Criteria for License Termination Under Restricted Conditions

A site will be considered acceptable for license termination under restricted conditions if:

120.246: continued

(A) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 105 CMR 120.245 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 deaths from transportation 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 TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.10 mSv (10 mrem) 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% real rate of return on investment;

(2) A statement of intent in the case of State, or local Government licensees, as described in 105 CMR 120.125(C)(7)(d); 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 Agency indicating the licensee's intent to decommission in accordance with 105 CMR 120.132(D), 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:

(a) Whether provisions for institutional controls proposed by the licensee:

1. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.10 mSv (10 mrem) TEDE per year;
2. Will be enforceable; and
3. Will not impose undue burdens on the local community or other affected parties.

(b) Whether the licensee has provided sufficient financial assurance to enable a 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 105 CMR 120.246D(1), the licensee shall provide for:

(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(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) 1mSv (100 mrem) per year; or

(2) 5mSv (500 mrem) per year provided the licensee:

(a) Demonstrates that further reductions in residual radioactivity necessary to comply with the one mSv/yr (100 mrem/yr) value of 105 CMR 120.246(E)(1) are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

120.246: continued

(b) Makes provisions for durable institutional controls;
(c) 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 three years to assure that the institutional controls remain in place as necessary to meet the criteria of 105 CMR 120.246(B) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in 105 CMR 120.246(C).

120.247: Alternate Criteria for License Termination

(A) The Agency may terminate a license using alternate criteria greater than the dose criterion of 105 CMR 120.245, 120.246(B), and 120.246(D)(1)(a)1., 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 one mSv/yr (100 mrem/yr) limit, by submitting an analysis of possible sources of exposure;
(2) Has employed to the extent practical restrictions on the site use according to the provisions of 105 CMR 120.246 in minimizing exposures at the site; and
(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.
(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with 105 CMR 120.132(D), and 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 license shall provide for:
(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.
(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(B) The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of the Agency's staff's recommendations that will address any comments by other appropriate agencies and any public comments submitted pursuant to 105 CMR 120.248.

120.248: 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 105 CMR 120.246 and 120.247, or whenever the Agency deems such notice to be in the public interest, the Agency shall:

(A) Notify and solicit comments from:
(1) Local 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) Other appropriate agencies for cases where the licensee proposes to release a site pursuant to 105 CMR 120.247.

(B) Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

120.249: Minimization of Contamination

(A) Applicants for licenses, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(B) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 105 CMR 120.210 and radiological criteria for license termination in 105 CMR 120.244 through 120.249.

120.251: General Requirements

(A) Unless otherwise exempted, a licensee shall transfer waste containing licensed material for disposal, discharge or decay only:
(1) by transfer to an authorized recipient as provided in 105 CMR 120.256 or in 105 CMR 120.100, or 105 CMR 120.800, or to the U.S. Department of Energy;
(2) by decay in storage;
(3) by release in effluents within the limits in 105 CMR 120.221; or
(4) as authorized pursuant to 105 CMR 120.253 or 120.254.

(B) A person shall be specifically licensed to receive waste containing licensed material from other persons for:
(1) treatment prior to disposal;
(2) treatment by incineration;
(3) decay in storage;
(4) disposal at a land disposal facility licensed pursuant to 105 CMR 120.800; or
(5) storage until transferred to a storage or disposal facility authorized to receive the waste.

120.252: Method for Obtaining Approval of Proposed Disposal Procedures

A licensee or registrant or applicant for a license or registration may apply to the Agency for approval of proposed procedures, not otherwise authorized in 105 CMR 120.000, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

(A) A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal;

(B) An analysis and evaluation of pertinent information on the nature of the environment;

(C) The nature and location of other potentially affected facilities; and

(D) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in 105 CMR 120.200.

120.253: Discharge by Release into Sanitary Sewerage

(A) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:
(1) the material is readily soluble, or is readily dispersible biological material, in water;
(2) the quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in 105 CMR 120.296: *Appendix B*, Table III; and
(3) if more than one radionuclide is released, the following conditions must also be satisfied:
(a) the licensee shall determine the fraction of the limit in 105 CMR 120.296: *Appendix B*, Table III 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 105 CMR 120.296: *Appendix B*, Table III; and

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(b) the sum of the fractions for each radionuclide required by 105 CMR 120.253(A)(3)(a) does not exceed unity; and

(4) the total quantity of licensed or other radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed five curies (185 gigabecquerels) of hydrogen-3, one curie (37 gigabecquerels) of carbon-14, and one curie (37 gigabecquerels) 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 105 CMR 120.253(A).

120.254: Treatment or Disposal by Incineration

A licensee may treat licensed material by incineration only in the form and concentration specified in 105 CMR 120.255 or as specifically approved by the Agency pursuant to 105 CMR 120.252.

120.255: Disposal of Specific Wastes

(A) A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

(1) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(B) A licensee or registrant shall not dispose of tissue pursuant to 105 CMR 120.255(A)(2) in a manner that would permit its use either as food for humans or as animal feed.

(C) The licensee or registrant shall maintain records in accordance with 105 CMR 120.269.

120.256: Transfer for Disposal and Manifests

(A) The requirements of 105 CMR 120.256 and 10 CFR 20: *Appendix G*, herein incorporated into 105 CMR120.256 by reference are designed to:

(1) Control transfers of low-level waste by any waste generator, waste collector, or waste processor licensee, as defined in 10 CFR 20: *Appendix G*, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in 105 CMR 120.803;

(2) Establish a manifest tracking system; and

(3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

(B) (1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-level Radioactive Waste Manifest and transfer this recorded information to the intended consignee in accordance with 10 CFR 20: *Appendix G*.

(2) Any licensee shipping by-product material as defined in 105 CMR 120.005: By-product Material(2) and (3) intended for ultimate disposal at a land disposal facility licensed under 105 CMR 120.800 or equivalent NRC or Agreement State regulations 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 10 CFR Part 20: *Appendix G*.

(C) Each shipment manifest shall include a certification by the waste generator as specified in 10 CFR 20: *Appendix G*.

(D) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, and waste processor, shall comply with the requirements specified in 105 CMR 120.256 and 10 CFR 20: *Appendix G*.

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(E) Reports and notifications required to be made to the nearest NRC regional administrator by 10 CFR 20: *Appendix G* shall, instead, be made to the Agency.

120.257: Compliance with Environmental and Health Protection Regulations

Nothing in 105 CMR 120.251, 120.253, 20.254, or 120.256 relieves the licensee from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of in accordance with 105 CMR 120.251, 120.253, 120.254, or 120.256.

120.258: Disposal of Certain Byproduct Material

(A) Licensed material as defined in 105 CMR 120.005: By-product Material(2) and (3) may be disposed of in accordance with 105 CMR 120.800, even though it is not defined as low-level radioactive waste. Therefore, any licensed by-product material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 105 CMR 120.800 or equivalent Nuclear Regulatory Commission or Agreement State requirements, must meet the requirements of 105 CMR 120.256.

(B) A licensee may dispose of byproduct material, as defined in 105 CMR 120.005: By-product Material(2) and (3), 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

120.261: General Provisions

(A) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by 105 CMR 120.261.

(B) Not withstanding the requirements of 105 CMR 120.261(A), when recording information on shipment manifests, as required in 105 CMR 120.256, information must be recorded in SI units or in SI units and special units as specified in 105 CMR 120.261(A).

(C) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by 105 CMR 120.200, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

120.262: Records of Radiation Protection Programs

(A) Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) the provisions of the program; and

(2) audits and other reviews of program content and implementation.

(B) The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(2) for three years after the record is made.

120.263: Records of Surveys

(A) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 105 CMR 120.225 and 120.242(B). The licensee or registrant shall retain these records for three years after the record is made.

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(B) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

(1) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(2) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) records showing the results of air sampling, surveys, and bioassays required pursuant to 105 CMR 120.233(A)(3)(a) and (b); and

(4) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

120.264: Records of Tests for Leakage or Contamination of Sealed Sources

Records of tests for leakage or contamination of sealed sources required by 105 CMR 120.223 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for five years after the records are made.

120.265: Determination and Records of Prior Occupational Dose

(A) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 105 CMR 120.226, the licensee or registrant shall:

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of cumulative occupational radiation dose.

(B) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(1) The internal and external doses from all previous planned special exposures;

(2) All doses in excess of the limits, including doses received during accidents; and emergencies, received during the lifetime of the individual.

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NON-TEXT PAGE

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(C) In complying with the requirements of 105 CMR 120.265(A), a licensee or registrant may:
(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year;
(2) Accept, as the record of cumulative radiation dose, an up-to-date Agency Form MRCP 120.200-2 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and
(3) Obtain reports of the individual's dose equivalent(s) 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, other electronic media 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) The licensee or registrant shall record the exposure history, as required by 105 CMR 120.265(A), on Agency Form MRCP 120.200-2, or other clear and legible record, of all the information required on that form.
(1) 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 MRCP 120.200-2 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 Y or equivalent indicating the periods of time for which data are not available.
(2) For the purposes of complying with this requirement, licensees or registrants are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further, occupational exposure histories obtained and recorded on Agency Form MRCP 120.200-2 or equivalent before October 6, 2006, 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:
(1) In establishing administrative controls pursuant to 105 CMR 120.211(F) for the current year, that the allowable dose limit for the individual is reduced by 12.5 millisievert (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
(2) That the individual is not available for planned special exposures.

(F) The licensee or registrant shall retain the records on Agency Form MRCP 120.200-2 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 MRCP 120.200-2 or equivalent for three years after the record is made.

(G) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form MRCP 120.200-2 or equivalent, or shall make provision with the Agency for transfer to the Agency.

120.266: Records of Planned Special Exposures

(A) For each use of the provisions of 105 CMR 120.216 for planned special exposures, the licensee or registrant shall maintain records that describe:
(1) the exceptional circumstances requiring the use of a planned special exposure;
(2) the name of the management official who authorized the planned special exposure and a copy of the signed authorization;
(3) what actions were necessary;
(4) why the actions were necessary;
(5) what precautions were taken to assure that doses were maintained ALARA;
(6) what individual and collective doses were expected to result; and,
(7) the doses actually received in the planned special exposure.

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(B) The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

120.267: 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 105 CMR 120.226, 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 January 1, 1994 need not be changed. These records shall include, when applicable:

(1) the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;
(2) the estimated intake of radionuclides, see 105 CMR 120.212;
(3) the committed effective dose equivalent assigned to the intake of radionuclides;
(4) the specific information used to calculate the committed effective dose equivalent pursuant to 105 CMR 120.214(A) and 120.214(C) and when required 105 CMR 120.226;
(5) the total effective dose equivalent when required by 105 CMR 120.212; and
(6) 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 105 CMR 120.267(A) at least annually.

(C) Recordkeeping Format. The licensee or registrant shall maintain the records specified in 105 CMR 120.267(A) on Form MRCP 120.200-3, in accordance with the instructions for Form MRCP 120.200-3, or in clear and legible records containing all the information required by Form MRCP 120.200-3.

(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.

(F) Upon termination of the license or registration, the records of doses received by individuals shall be transferred to the Agency.

120.268: 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* 105 CMR 120.221.

(B) The licensee or registrant shall retain the records required by 105 CMR 120.268(A) until the Agency terminates each pertinent license or registration requiring the record.

120.269: Records of Waste Transfers

(A) Each licensee shall maintain records of the disposal of licensed materials made pursuant to 105 CMR 120.252, 105 CMR 120.253, 105 CMR 120.254, 105 CMR 120.255, and 105 CMR 120.800.

(B) The licensee shall retain the records required by 105 CMR 120.269(A) until the Agency terminates each pertinent license requiring the record.

(C) If any burials of licensed material were made under the provisions of 10 CFR 20.304 prior to its repeal in 1981 the records of such burials shall be maintained by the licensee.

120.270: Records of Testing Entry Control Devices for Very High Radiation Areas

(A) Each licensee or registrant shall maintain records of tests made pursuant to 105 CMR 120.229(B)(9) 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 105 CMR 120.270(A) for three years after the record is made.

120.271: Form of Records

Each record required by 105 CMR 120.200 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 or registrant shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

120.281: Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation

(A) Telephone Reports. Each licensee or registrant shall report to the Agency by telephone as follows:

(1) immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 105 CMR 120.297: *Appendix C*, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas;

(2) within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than ten times the quantity specified in 105 CMR 120.297: *Appendix C* that is still missing;

(3) immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

(B) Written Reports. Each licensee or registrant required to make a report pursuant to 105 CMR 120.281(A) shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

(1) a description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(2) a description of the circumstances under which the loss or theft occurred;

(3) a statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

(4) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(5) actions that have been taken, or will be taken, to recover the source of radiation; and

(6) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(C) Subsequent to filing the written report, 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.

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(D) The licensee or registrant shall prepare any report filed with the Agency pursuant to 105 CMR 120.281 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

120.282: Notification of Incidents

(A) Immediate Notification. Notwithstanding any other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:
   (a) a total effective dose equivalent of 0.25 sievert (25 rems) or more;
   (b) a lens dose equivalent of 0.75 sievert (75 rems) or more;
   (c) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 grays (250 rads) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(B) 24 Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours:
   (a) a total effective dose equivalent exceeding 0.05 sievert (five rems);
   (b) a lens dose equivalent exceeding 0.15 sievert (15 rems);
   (c) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 sievert (50 rems); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(C) Licensees or registrants shall make the reports required by 105 CMR 120.282(A) and (B) by initial contact by telephone to the Agency and shall confirm the initial contact by telegram, mailgram, or facsimile to the Agency.

(D) The licensee or registrant shall prepare each report filed with the Agency pursuant to 105 CMR 120.282 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(E) The provisions of 105 CMR 120.282 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 105 CMR 120.284.

120.283: Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or the Limits

(A) Reportable Events. In addition to the notification required by 105 CMR 120.282, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(1) incidents for which notification is required by 105 CMR 120.282; or
(2) doses in excess of any of the following:
   (a) the occupational dose limits for adults in 105 CMR 120.211;
   (b) the occupational dose limits for a minor in 105 CMR 120.217;
   (c) the limits for an embryo/fetus of a declared pregnant woman in 105 CMR 120.218;
   (d) the limits for an individual member of the public in 105 CMR 120.221;
   (e) any applicable limit in the license or registration;
   (f) the ALARA constraints for air emissions established under 105 CMR 120.210(D); or

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(3) levels of radiation or concentrations of radioactive material in:
(a) a restricted area in excess of applicable limits in the license or registration;
(b) an unrestricted area in excess of ten times the applicable limit set forth in this part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 105 CMR 120.221; or,
(4) for licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(B) Contents of Reports.
(1) Each report required by 105 CMR 120.283(A) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
(a) estimates of each individual's dose;
(b) the levels of radiation and concentrations of radioactive material involved;
(c) the cause of the elevated exposures, dose rates, or concentrations; and,
(d) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints generally applicable environmental standards, and associated license or registration conditions.
(2) Each report filed pursuant to 105 CMR 120.283(A) shall include for each occupationally exposed individual: the name, social security number, and date of birth. With respect to the limit for the embryo/fetus in 105 CMR 120.218: *Dose Equivalent to an Embryo/Fetus*, 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.

(C) All licensees or registrants who make reports pursuant to 105 CMR 120.283(A) shall submit the report in writing to the Agency.

120.284: 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 105 CMR 120.216, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 105 CMR 120.266.

120.285: Reports to Individuals of Exceeding Dose Limits

When a licensee or registrant is required, pursuant to 105 CMR 120.283 or 120.284 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 shall also provide a copy of the report submitted to the Agency to the individual. This report must be transmitted at a time no later than the transmittal to the Agency.

120.286: Reports of Individual Monitoring

(A) The requirements of 105 CMR 120.286 apply to each person licensed or registered by the Agency:
(1) Possess or use sources of radiation for purposes of industrial radiography pursuant to 105 CMR 120.100 and 120.300; or
(2) Possess or use at any time, for processing or manufacturing for distribution pursuant to 105 CMR 120.100 or 120.500, radioactive material in quantities exceeding any one of the following quantities:

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Radionuclide, Activity

Radionuclide	Activity	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1000	37000
Promethium-147	10	370
Technetium-99m	1000	37000

[*Note*: The Agency may require as a license condition, or by rule, regulation, or order pursuant to 105 CMR 120.012, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.]

(B) Each licensee or registrant in a category listed in 105 CMR 120.286(A) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 105 CMR 120.226 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Agency Form MRCP 120.200-2 or equivalent or electronic media containing all the information required by Agency Form MRCP 120.200-2.

(C) The licensee or registrant shall file the report required by 105 CMR 120.286(A), covering the preceding year, on or before April 30th each year. The licensee or registrant shall submit the report to the Agency.

120.287: Notifications and Reports to Individuals

(A) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 105 CMR 120.750.

(B) When a licensee or registrant is required pursuant to 105 CMR 120.283 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of 105 CMR 120.754(A).

120.288: Reports of Leaking or Contaminated Sealed Sources

The licensee shall immediately notify the Agency if the test for leakage or contamination required pursuant to 105 CMR 120.223 indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source shall be submitted to the Agency within five days. The report shall include the equipment involved, the test results and the corrective action taken.

120.290: 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 105 CMR 120.290(A) through (E) for each type of transaction.

(A) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source TrackingTransaction Report. The report must include the following information:

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(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 container 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 TrackingTransaction Report. The report must include the following information:
(1) The name, address, and license number of the reporting licensee;
(2) The name of the individual preparing the report;
(3) The name, address, and license number of the person that provided the source;
(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
(5) The radioactive material in the source;
(6) The initial or current source strength in becquerels (curies);
(7) The date for which the source strength is reported;
(8) The date of receipt; and
(9) For material received under a Uniform Low-level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(D) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source TrackingTransaction Report. The report must include the following information:
(1) The name, address, and license number of the reporting licensee;
(2) The name of the individual preparing the report;
(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
(4) The radioactive material in the source;
(5) The initial or current source strength in becquerels (curies);
(6) The date for which the source strength is reported;
(7) The disassemble date of the source.

(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.

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(F) The reports discussed in 105 CMR 120.290(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 using:

(1) The on-line National Source Tracking System;
(2) Electronically using a computerreadable format;
(3) By facsimile;
(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or
(5) By telephone with followup by facsimile or mail.

(G) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five 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 105 CMR 120.290(A) through (E). By January 31st 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 31, 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 31, 2009. The information may be submitted by using any of the methods identified by 105 CMR 120.290(F)(1) through (4). The initial inventory report must include the following information:

(1) The name, address, and license number of the reporting licensee;
(2) The name of the individual preparing the report;
(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
(4) The radioactive material in the sealed source;
(5) The initial or current source strength in becquerels (curies); and
(6) The date for which the source strength is reported.

120.295: Appendix A – Assigned (APF) 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,	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loosefitting	Powered air-purifying respirators	25
II. Atmosphere suppling 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):	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
Facepiece, full		
III. Combination Respirators: Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operations as listed above	

FOOTNOTES

a. These assigned protection factors apply only in respiratory protection program that meets the requirements of 105 CMR 120.293: *Appendix A*. 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 105 CMR 120.296: *Appendix B*, Table 1, column 3 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

b. Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95% efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99% efficient. Air purifying respirators with APF >100 must be equipped with particulate filters that area t least 99.97% efficient.

c. The licensee may apply to the Agency for the use of an APF greater than one for sorbent cartridges as protection against airborne radioactive gases and vapors (*e.g.*, radioiodine).

FOOTNOTES - continued

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 105 CMR 120.233 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to ten 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 105 CMR 120.296: *Appendix A* 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% efficient and all other requirements of 105 CMR 120.298: *Appendix A* 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 ⅓ of the intake occurs by absorption through the skin so that an overall protection factor of three 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 atmospheric supplying units. 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.*, 105 CMR 120.233).

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.

120.296: 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. The class (D, W, or Y) given in the column headed "Class" applies only to the inhalation ALIs and DACs given in Table I, column 2 and 3. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents $6 \times 1O^{2}$ or 600, and 6E+0 represents 6×10^{0} or 6.

Table I "Occupational Values"

Note that the columns in 105 CMR 120.296: *Appendix B*, Table I captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in 105 CMR 120.296: *Appendix B* are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 5 rems (0.05 sievert), stochastic ALI, or (2) a committed dose equivalent of 50 rems (0.5 sievert) 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 five rems (0.05 sievert). 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 105 CMR 120.203. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract -- stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall	=	lower large intestine wall;
St wall	=	stomach wall;
Blad wall	=	bladder wall; and,
Bone surf	=	bone surface.

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The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the 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 50 rems (0.5 sievert) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, $\sum$ (intake (in μCi) of each radionuclide/ALI_{ns}) $\leq$ 1.0. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than 1 - (H_d/50), instead of $\leq$ 1.0.

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(in μCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute) = [ALI/2.4 x 10^9] μCi/ml,

where 2 x 10^4 ml is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 105 CMR 120.212. 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 105 CMR 120.296: *Appendix B*, Table II 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 105 CMR 120.222. The concentration values given in 105 CMR 120.296: *Appendix B*, Table II, Columns 1 and 2 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 0.05 rem (0.5 millisievert).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in the previous Appendix 105 CMR 120.295: *Appendix A*.

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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 ml, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5 rems (0.05 sievert) annual occupational dose limit to the one mSv (0.1 rem) limit for members of the public, a factor of three 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 two 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 105 CMR 120.296: *Appendix B*, 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 105 CMR 120.296: *Appendix B* 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 105 CMR 120.253. 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 ten, 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 five mSv (0.5 rem).

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List of Elements

Name	Symbol	Atomic No.	Name	Symbol	Atomic No.
Actinium	Ac	89	Molybdenum	Mo	42
Aluminium	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
Femium	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			

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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, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	=	9E+4	4E-5	1E-7	=	=
		Y, lanthanum fluoride	=	8E+4	3E-5	1E-7	=	=
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	=	1E+3	5E-7	2E-9	=	=
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	=	9E+1	4E-8	1E-10	=	=
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3

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Atomic No.	Radionuclide	Class	Table 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 Concen-tration (μCi/ml)
		W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
		Y, aluminosilicate glass	-	3E+4	1 E-5	4 E-8	-	-
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1 E-7	3E-10	-	-
			LLI wall (3E+3)	-	-	-	4 E-5	4 E-4
		W, see ^{31}Si	-	1E+2	5 E-8	2E-10	-	-
		Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4 E-7	1E-9	9 E-6	9 E-5
		W, phosphates of Zn^{2+}, S^{3+}, Mg^{2+}, Fe^{3+}, Bi^{3+}, and lanthanides	-	4E+2	2 E-7	5E-10	-	-
15	Phosphorus-33	D, see ^{32}P	6E+3	8E+3	1 E-8	1 E-8	8 E-5	8 E-4
		W, see ^{32}P	-	3E+3	1 E-68	4 E-9	-	-
16	Sulfur-35	Vapor		1E+4	6 E-6	2 E-8	-	-
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7 E-6	2 E-8	-	-
			LLI wall (8E+3)	-	-	-	1 E-4	1 E-3
		W, elemental sulfur,	6E+3					
		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	-	2E+3	9 E-7	3 E-9	-	-
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1 E-6	3 E-9	2 E-+	2 E-4
		W, chlorides of lantha- nides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1 E-7	3 E-10	-	--
17	Chlorine-38[2]	D, see ^{36}Cl	2E+4	4E+4	2 E-5	6 E-8	-	
			St wall (3E+4)	-	-	-		
		W, see ^{36}Cl	-	5E+4	2 E-5	6 E-8	-	-
17	Chlorine-39[2]	D, see ^{36}Cl	2E+4	5E+4	2 E-5	7 E-8	-	-
			St wall (4E+4)	-	-	-	5 E-4	5 E-3

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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 ^{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	3E+4	7E+4	3E-5	9E+-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
19	Potassium-45[2]	D, all compounds	3E+4	7E+4	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+4	1E+5	2E-6	-	-	-
			Bone surf (4E+3)	Bone surf (4E+3)	-	5E-9	6E-5	6-4E
20	Calcium-45	W, all compounds	E+3	4E+3	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	E-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	-	-

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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)
23	Vanadium-47[2]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-		
		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	-	3E+4	8E-6	2E-8	-	-
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
		Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24	Chromium-49[2]	D, see ^{48}Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{48}Cr	-	1E+5	4E-5	1E-7	-	-
		Y, see ^{48}Cr	-	9E+4	4E-5	1E-7	-	-
24	Chromium-51	D, see ^{48}Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see ^{48}Cr	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{48}Cr	-	2E+4	8E-6	3E-8	-	-
25	Manganese-51[2]	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	8E-8	-	-
25	Manganese-52m[2]	D, see ^{51}Mn	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{51}Mn	-	1E+5	4E-5	1E-7	-	-
25	Manganese-52	D, see ^{51}Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see ^{51}Mn	-	9E+2	4E-7	1E-9	-	-
25	Manganese-53	D, see ^{51}Mn	5E+4	1E+4	5E-6	-	7E-4	7E-5

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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 Concen-tration (μCi/ml)
				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	-	1E+2	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	-	4E+1		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	1E+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

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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	2 E+2	3 E+1	1 E-8	5 E-11	-	-
27	Cobalt-61[2]	W, see ^{55}Co	2 E+4	6 E+4	3 E-5	9 E-8	3 E-4	3 E-3
		Y, see ^{55}Co	2 E+4	6 E+4	2 E-5	8 E-8	-	-
27	Cobalt-62m[2]	W, see ^{55}Co	4 E+4	2 E+5	7 E-5	2 E-7	-	-
			St wall (5E+4)	-	-	-	7 E-1	7 E-3
		Y, see ^{55}Co	-	2 E+5	6 E-5	2 E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1 E+3	2 E+3	8 E-7	3 E-9	2 E-5	2 E-4
		W, oxides, hydroxides, and carbides	-	1 E+3	5 E-7	2 E-9	-	-
		Vapor	-	1 E+3	5 E-7	2 E-9	-	-
28	Nickel-57	D, see ^{56}Ni	2 E+3	5 E+3	2 E-6	7 E-9	2 E-5	2 E-4
		W, see ^{56}Ni	-	3 E+3	1 E-6	4 E-9	-	-
		Vapor	-	6 E+3	3 E-6	9 E-9	-	-
28	Nickel-59	D, see ^{56}Ni	2 E+4	4 E+3	2 E-6	5 E-9	3 E-4	3 E-3
		W, see ^{56}Ni	-	7 E+3	3 E-6	1 E-8	-	-
		Vapor	-	2 E+3	8 E-7	3 E-9	-	-
28	Nickel-63	D, see ^{56}Ni	9 E+3	2 E+3	7 E-7	2 E-9	1 E-4	1 E-3
		W, see ^{56}Ni	-	3 E+3	1 E-6	4 E-9	-	-
		Vapor	-	8 E+2	3 E-7	1 E-9	-	-
28	Nickel-65	D, see ^{56}Ni	8 E+3	2 E+4	1 E-5	3 E-8	1 E-4	1 E-3
		W, see ^{56}Ni	-	3 E+4	1 E-5	4 E-8	-	-
		Vapor	-	2 E+4	7 E-6	2 E-8	-	-
28	Nickel-66	D, see ^{56}Ni	4 E+2	2 E+3	7 E-7	2 E-9	-	-
			LLI wall (5E+2)	-	-	-	6 E-6	6 E-5
		W, see ^{56}Ni	-	6 E+2	3 E-7	9 E-10	-	-
		Vapor	-	3 E+3	1 E-6	4 E-9	-	-
29	Copper-60[2]	D, all compounds except those given for W and Y	3 E+4	9 E+4	465	1 E-7	-	-
			St wall (3E+4)	-	-	-	4 E-4	4 E-5
		W, sulfides, halides, and nitrates	-	1 E+5	5 E-5	2 E-7	-	-
		Y, oxides and hydroxides	-	1 E+5	4 E-6	1 E-7	-	-
29	Copper-61	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3

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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 ^{60}Cu	-	4E+4	2E-5	6E-8	-	-
		Y, see ^{60}Cu	-	4E+4	1E-5	5E-8	-	-
29	Copper-64	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{60}Cu	-	2E+4	9E-6	3E-8	-	-
29	Copper-67	D, see ^{60}Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see ^{60}Cu	-	5E+3	2E-6	7E-9	-	-
		Y, see ^{60}Cu	-	5E+3	2E-6	6E-9	-	-
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63[2]	Y, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69[2]	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65[2]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31	Gallium-66	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see ^{65}Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ^{65}Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68[2]	D, see ^{65}Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{65}Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70[2]	D, see ^{65}Ga	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		W, see ^{65}Ga	-	2E+5	8E+5	3E-7	-	-
31	Gallium-72	D, see ^{65}Ga	1E+3	4E+2	1E-6	5E-9	2E-5	2E-4

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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 ^{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	8E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see ^{66}Ge	-	6E+3	2E-6	8E-9	-	-
32	Germanium-78[2]	D, see ^{66}Ge	2E+4	2E+4	9E-6	3E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see ^{66}Ge	-	2E+4	9E-6	3E-8	-	-
33	Arsenic-69[2]	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
33	Arsenic-70[2]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4

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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 Concen-tration (μCi/ml)
33	Arsenic-77	W, all compounds	4E+3	5E+5	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	6E-5	6E-4
33	Arsenic-78[2]	W, all compounds	8E+6	2E+4	9E-6	3E-8	1E-4	1E-3
34	Selenium-70[2]	D, all compounds except those given for W	2E+4	4E+8	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	5E+5	2E-5	5E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, bromides of lantha- nides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-

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			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			oral Ingestion	Inhalation				Monthly Average Concen-
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	tration (μCi/ml)
35	Bromine-74[2]	D, see ^{74m}Br	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	53E-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-8	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-5	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-5	5E-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	-	-

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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)
36	Krypton-85m	Submersion[1]	-	-	2E-5	1E-7	-	-
36	Krypton-85	Submersion[1]	-	-	1E-4	7E-7	-	-
36	Krypton-87[2]	Submersion[1]	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion[1]	-	-	2E-6	9E-9	-	-
37	Rubidium-79[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
37	Rubidium-81m[2]	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-8	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 $SrTiO_3$	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and $SrTi0_3$	-	1E+4	5E-6	2E-8	-	-
38	Strontium-81[2]	D, see ^{80}Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{80}Sr	2E+4	8E+4	3E-5	1E-7	-	-
38	Strontium-82	D, see ^{80}Sr	3E+2	4E+2	2E-7	6E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		Y, see ^{80}Sr	2E+2	9E+1	4E-8	1E-10	-	-
38	Strontium-83	D, see ^{80}Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{80}Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m[2]	D, see ^{80}Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2

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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 ^{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	3E-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	-	-
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	E- 88	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

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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 Concen-tration (μCi/ml)
		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-5	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	9 E-8	3E-10	5E-5	5E-4
		W, see ^{86}Zr	-	5E+2	2E-7	7E-10	-	-
		Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-89	D, see ^{86}Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
		Y, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-93	D, see ^{86}Zr	1E+3	6E+0	3E-9	-	-	-
			Bone surf (3E+3)	Bone surf (2E+1)	-	2E-11	4E-5	4E-4
		W, see ^{86}Zr	-	2E+1	E- 18	-	-	-
			-	Bone surf (6E+1)	-	9E-11	-	-
		Y, see ^{86}Zr	-	6E+1	2E-8	-	-	-

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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 (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-8	2E-9	-	-
41	Niobium-88[2]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41	Niobium-89[2] (66 min)	W, see ^{88}Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see ^{88}Nb	-	4E+4	2E-5	5E-8	-	-
41	Niobium-89 (122 min)	W, see ^{88}Nb	5E+3	2E+4	8E-6	3E-8	7E-4	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-6	1E-4
		Y, see ^{88}Nb	-	2E+1	6E-9	2E-11	-	-
41	Niobium-95m	W, see ^{88}Nb	2E+3	3E+3	1E-4	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	-	-

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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)
41	Niobium-96	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-97[2]	W, see ^{88}Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{88}Nb	-	7E+4	3E-5	1E-7	-	-
41	Niobium-98[2]	W, see ^{88}Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see ^{88}Nb	-	5E+4	2E-5	7E-8	-	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS_2	2E+3	5E+2	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	-	6E+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

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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 ^{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+1	3E-6	-	6E-5	6E-4
			-	St wall (7E+3)	-	1E-8	-	-
		W, see ^{93m}Tc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see ^{93m}Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m}Tc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see ^{93m}Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m}Tc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see ^{93m}Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see ^{93m}Tc	4E+3	5E+3	2E-6	-	6E-5	6E-4
			-	St wall (6E+3)	-	8E-9	-	-
		W, see ^{93m}Tc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101[2]	D, see ^{93m}Tc	9E+4	3E+5	1E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, see ^{93m}Tc	-	4E+5	2E-4	5E-7	-	-
43	Technetium-104[2]	D, see ^{93m}Tc	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		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	-	-

120.296: continued

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)
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-7	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	E- 35	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+5	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	-	-

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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 ^{99m}Rh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m[2]	D, see ^{99m}Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
		Y, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
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-4	-	-
			St wall (9E+4)	-	-	-	1E-3	12 E-
		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-8	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

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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 ^{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-5	3E-3
		W, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-
		Y, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-
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	-	-

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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-111	D, see ^{102}Ag	E+ 92	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	34 E-	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	-	-
48	Cadmium-113	D, see ^{104}Cd	2E+1	2E+0	9E-10	-	-	-

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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)
			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	13 E+	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	-	E+ 14	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]	D, see ^{109}In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	(69.1 min)	W, see ^{109}In	-	6E+4	2E-5	8E-8	-	-
49	Indium-110	D, see ^{109}In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
	(4.9 h)	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

120.296: continued

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	-	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+6	3E-4	1E-6	-	-
49	Indium-113m[2]	D, see ^{109}In	5E+4	1E+4	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-5	3E-3
		W, see ^{109}In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m[2]	D, see ^{109}In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{109}In	-	4E+4	2E-5	6E-8	-	-
49	Indium-117[2]	D, see ^{109}In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see ^{109}In	-	2E+5	9E-5	3E-7	-	-
49	Indium-119m[2]	D, see ^{109}In	4E+4	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	-	-

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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-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-6	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	38	9E-11	-	-
50	Tin-127	D, see ^{110}Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see ^{110}Sn	-	2E+4	8E-6	3E-8	-	-
50	Tin-128[2]	D, see ^{110}Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{110}Sn	-	4E+4	1E-5	5E-8	-	-
51	Antimony-115[2]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2

120.296: continued

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, 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]	D, see [115]Sb	1E+5	4E+5	2E-4	6E-7	-	-
	(16 min)		St wall (2E+5)	-	-	-	2E-3	2E-2
		W, see [115]Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120	D, see [115]Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
	(5.76 d)	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	39	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

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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 ^{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]	D, see ^{115}Sb	8E+4	4E+5	2E-4	5E-7	-	-
	(10.4 min)		St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ^{115}Sb	-	4E+5	2E-4	6E-7	-	-
51	Antimony-128	D, see ^{115}Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
	(9.01 h)	W, see ^{115}Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see ^{115}Sb	3E+3	9E+6	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	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (4E+4)	-	6E-8	2E-4	2E-3
		W, see ^{115}Sb	-		2E-4	1E-5	-	-
			-	Thyroid (4E+4)	-	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	2E+2	8E-8	-	-	-
			Bone surf (7E+2)	Bone surf (4E+2)	-	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	E- 49	-	-
52	Tellurium-123m	D, see ^{116}Te	6E+2	3E+3	9E-8	-	-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	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	2E+2	8E-8		-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	7E-10	2E-5	2E-4

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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 ^{116}Te	-	4E+2	2E-7	-	-	-
			-	Bone surf (1E+3)	-	2E-9	-	-
52	Tellurium-125m	D, see ^{116}Te	1E+3	4E+2	2E-7	-	-	-
			Bone surf (1E+3)	Bone surf (1E+3)	-	1E-9	2E-5	2E-4
		W, see ^{116}Te	-	7E+2	3E-7	1E-9	-	-
52	Tellurium-127m	D, see ^{116}Te	6E+2	3E+2	1E-7	-	9E-6	9E-6
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see ^{116}Te	-	3E+2	1E-7	1E-0	-	-
52	Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{116}Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ^{116}Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129[2]	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{116}Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see ^{116}Te	3E+2	4E+2	2E-7	-	-	-
			Thyroid (6E+2)	Thyroid (1E+3)	-	2E-9	8E-3	8E-5
		W, see ^{116}Te	-	4E+2	2E-7	-	-	-
			-	Thyroid (9E+2)	-	1E-9	-	-
52	Tellurium-131[2]	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	8E-5	8E-4
		W, see ^{116}Te	-	8E+3	E- 26	-	-	-
			-	Thyroid (1E+4)	-	2E-8	-	-
52	Tellurium-132	D, see ^{116}Te	2E+2	2E+2	9E-8	-	-	-
			Thyroid (7E+2)	Thyroid (8E+2)	-	1E-9	8E-6	9E-5
		W, see ^{116}Te	-	2E+2	9E-8	-	-	-
			-	Thyroid (6E+2)	-	9E-10	-	-
52	Tellurium-133m[2]	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	9E-5	9E-4

120.296: continued

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 ^{116}Te	-	5E+3	2E-6	-	-	-
			-	Thyroid (1E+4)	-	2E-8	-	-
52	Tellurium-133[2]	D, see ^{116}Te	1E+4	2E+4	9E-6	-	-	-
			Thyroid (3E+4)	Thyroid (6E+4)	-	8E-8	4E-4	4E-3
		W, see ^{116}Te	-	2E+4	9E-6	-	-	-
			-	Thyroid (6E+4)	-	8E-8	-	-
52	Tellurium-134[2]	D, see ^{116}Te	2E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (5E+4)	-	7E-8	3E-4	3E-3
		W, see ^{116}Te	-	2E+4	1E-5	-	-	-
			-	Thyroid (5E+4)	-		7E-8	-
53	Iodine-120m[2]	D, all compounds	1E+4	2E+4	9E-5	3E-8	-	-
			Thyroid (1E+4)	-	-	-	2E-4	2E-3
53	Iodine-120[2]	D, all compounds	4E+3	8E+3	4E-6	-	-	-
			Thyroid (8E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3
53	Iodine-121	D, all compounds	1E+4	2E+4	8E-6	-	-	-
			Thyroid (3E+4)	Thyroid (5E+4)	-	7E-8	4E-4	4E-3
53	Iodine-123	D, all compounds	3E+3	6E+3	3E-6	-	-	-
			Thyroid (1E+4)	Thyroid (2E+4)	-	2E-8	1E-4	1E-3
53	Iodine-124	D, all compounds	5E+1	8E+1	3E-8	-	-	-
			Thyroid (2E+2)	Thyroid (3E+2)	-	4E-10	2E-6	2E-5
53	Iodine-125	D, all compounds	4E+1	6E+1	3E-8	-	-	-
			Thyroid (1E+2)	Thyroid (2E+2)	-	3E-10	2E-6	2E-5
53	Iodine-126	D, all compounds	2E+1	4E+1	1E-8	-	-	-
			Thyroid (7E+1)	Thyroid (1E+2)	-	2E-10	1E-6	1E-5
53	Iodine-128[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
53	Iodine-129	D, all compounds	5E+0	9E+0	4E-9	-	-	-

120.296: continued

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)
			Thyroid (2E+1)	Thyroid (3E+1)	-	4E-11	2E-7	2E-6
53	Iodine-130	D, all compounds	4E+2	7E+2	3E-7	-	-	-
			Thyroid (1E+3)	Thyroid (2E+3)	-	3E-9	2E-5	2E-4
53	Iodine-131	D, all compounds	3E+1	5E+1	2E-8	-	-	-
			Thyroid (9E+1)	Thyroid (2E+2)	-	2E-10	1E-6	1E-5
53	Iodine-132m[2]	D, all compounds	4E+3	8E+3	4E-6	-	-	-
			Thyroid (1E+4)	Thyroid (2E+4)	-	3E-8	1E-4	1E-3
53	Iodine-132	D, all compounds	4E+3	8E+3	3E-6	-	-	-
			Thyroid (9E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3
53	Iodine-133	D, all compounds	1E+2	3E+2	1E-7	-	-	-
			Thyroid (5E+2)	Thyroid (9E+2)	-	1E-9	7E-6	7E-5
53	Iodine-134[2]	D, all compounds	2E+4	5E+4	2E-5	6E-8	-	-
			Thyroid (3E+4)	-	-	-	4E-4	4E-3
53	Iodine-135	D, all compounds	8E+2	2E+3	7E-7	-	-	-
			Thyroid (3E+3)	Thyroid (4E+3)	-	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]	-	-	66	3E-8	-	-
54	Xenon-125	Submersion[1]	-	-	25	7E-8	-	-
54	Xenon-127	Submersion[1]	-	-	15	6E-8	-	-
54	Xenon-129m	Submersion[1]	-	-	24	9E-7	-	-
54	Xenon-131m	Submersion[1]	-	-	44	2E-6	-	-
54	Xenon-133m	Submersion[1]	-	-	1E-4	6E-7	-	-
54	Xenon-133	Submersion[1]	-	-	1E-4	5E-7	-	-
54	Xenon-135m[2]	Submersion[1]	-	-	9E-6	4E-8	-	-
54	Xenon-135	Submersion[1]	-	-	1E-5	7E-8	-	-
54	Xenon-138[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
55	Cesium-125[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	-	-

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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)
			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-5	5E-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	22 E-
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	43 E-
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	72 E-
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)	-	-	-	86	8E-5
56	Barium-141[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3

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			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			oral Ingestion	Inhalation				Monthly Average Concen-
Atomic No.	Radionuclide	Class	ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	tration (µCi/ml)
56	Barium-142[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131[2]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57	Lanthanum-132	D, see ^{131}La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-135	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{131}La	-	94	4E-5	1E-7	-	-
57	Lanthanum-137	D, see ^{131}La	1E+4	6E+1	3E-8		2E-4	2E-3
			-	Liver (7E+1)	-	1E-10	-	-
		W, see ^{131}La	-	3E+2	1E-7	-	-	-
			-	Liver (3E+2)	-	4E-10	-	-
57	Lanthanum-138	D, see ^{131}La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see ^{131}La	-	1E+1	6E-9	2E-11	-	-
57	Lanthanum-140	D, see ^{131}La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{131}La	-	1E+3	5E-7	2E-9	-	-
57	Lanthanum-141	D, see ^{131}La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-142[2]	D, see ^{131}La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{131}La	-	3E+4	1E-5	5E-8	-	-
57	Lanthanum-143[2]	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-

120.296: continued

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)
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see ^{134}Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ^{134}Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see ^{134}Ce	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	4E+3	2E-6	5E-9	-	-
58	Cerium-137	W, see ^{134}Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ^{134}Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see ^{134}Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ^{134}Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see ^{134}Ce	2E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see ^{134}Ce	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{134}Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see ^{134}Ce	2E+2	3E+1	1E-8	4E-11	-	-
			LLI wall (3E+2)	-	-	-	3E-6	3E-5
		Y, see ^{134}Ce	-	1E+1	6E-9	2E-11	-	-
59	Praseodymium-136[2]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-
59	Praseodymium-137[2]	W, see ^{136}Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ^{136}Pr	-	1E+5	65	27	-	-
59	Praseodymium-138m	W, see ^{136}Pr	1E+4	5E+4	25	88	14	13
		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-3	

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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 ^{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	-	14	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	25	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see ^{136}Nd	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see ^{136}Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{136}Nd	-	8E+2	4E-7	1E-9	-	-

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			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			oral Ingestion	Inhalation				Monthly Average Concen-
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	tration (μCi/ml)
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	68	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	-	-

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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 (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	-	33	1E-6	4E-9	-	-
62	Samarium-141m[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141[2]	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
62	Samarium-142[2]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	5E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E+2	1E-1	-	-	-
			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)	-	3E-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	8E+7	3E-9	2E-5	2E-4	
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-4	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-6	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

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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)
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[2]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[2]	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64	Gadolinium-146	D, see ^{145}Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see ^{145}Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see ^{145}Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{145}Gd	-	4E+3	1E-6	5E-9	-	-
64	Gadolinium-148	D, see ^{145}Gd	1E+1	8E+3	3E-12	-	-	-
			Bone surf (2E+1)	Bone surf (2E-2)	-	3E-4	3E-7	3E-6
		W, see ^{145}Gd	-	32	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

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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 ^{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-6	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	4E+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	-	-
			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

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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)
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	1E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m[2]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162[2]	W, all compounds	5E+5	2E+6	1E-3	3E-6	-	-
			St wall (8E+5)	-	-	-	1E-2	1E-1
67	Holmium-164m[2]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164[2]	W, all compounds	2E+5	6E+5	3E-4	9E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (9E+2)	-	-	-	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
69	Thulium-162[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	31E-0	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-

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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 (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	-	-
			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
24		Y, see ^{169}Lu	-	2E+3	8E-7	39 E-	-	-
71	Lutetium-171	W, see ^{169}Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4

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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 ^{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	29	-	-
71	Lutetium-173	W, see ^{169}Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
			-	Bone surf (5E+2)	-	6E-10	-	-
		Y, see ^{169}Lu	-	3E+2	1E-7	4E-10	-	-
71	Lutetium-174m	W, see ^{169}Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall (3E+3)	Bone surf (3E+2)	-	5E-10	4E-5	4E-4
		Y, see ^{169}Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see ^{169}Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see ^{169}Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see ^{169}Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ^{169}Lu	-	2E+4	9E-6	38	-	-
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-0	-	-
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	27	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see ^{169}Lu	-	1E+5	5E-5	2E-7	-	-

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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-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	89 E-	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	-	41 E+	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+5	9E+2	4E-7	-	4E-5	4E-4
			-	Bone surf (1E+3)	-	1E-9	-	-
		W, see ^{170}Hf	-	1E+3	5E-7	2E-9	-	-
72	Hafnium-177m[2]	D, see ^{170}Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{170}Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see ^{170}Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
			-	Bone surf (2E+0)	-	3E-12	-	-
		W, see ^{170}Hf	-	5E+10	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-4	4E-8	-	-
72	Hafnium-181	D, see ^{170}Hf	13 E+	2E+2	7E-8	-	2E-5	2E-4
			-	Bone surf (4E+2)	-	6E-10	-	-

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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 ^{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	33
		W, see ^{170}Hf	-	6E+4	2E-5	8E-8	-	-
72	Hafnium-184	D, see ^{170}Hf	E+ 23	8E+3	36	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-6	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-4	8E-4
		Y, see ^{172}Ta	-	1E+4	6E-6	3E-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-4	-	-
73	Tantalum-179	W, see ^{172}Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ^{172}Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see ^{172}Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{172}Ta	-	6E+4	2E-5	8E-8	-	-

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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-180	W, see ^{172}Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ^{172}Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m[2]	W, see ^{172}Ta	2E+5	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-8	-	-
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+6	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-4	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+6	3E-6	9E-9	-	-
				-	-	-	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+3	1E+3	5E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
75	Rhenium-177[2]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-

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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)
75	Rhenium-178[2]	D, see ^{177}Re	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ^{177}Re	-	3E+5	1E-4	4E-7	-	-
75	Rhenium-181	D, see ^{177}Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see ^{177}Re	-	9E+3	4E-6	1E-8	-	-
75	Rhenium-182	D, see ^{177}Re	7E+6	1E+4	5E-6	2E-8	9E-5	9E-4
	(12.7 h)	W, see ^{177}Re	-	2E+4	6E-6	2E-8	-	-
75	Rhenium-182	D, see ^{177}Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	(64.0 h)	W, see ^{177}Re	-	2E+3	9E-7	3E-9	-	-
75	Rhenium-184m	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	4E+2	2E-7	6E-10	-	-
75	Rhenium-184	D, see ^{177}Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{177}Re	-	1E+3	6E-7	2E-9	-	-
75	Rhenium-186m	D, see ^{177}Re	1E+3	2E+3	7E-7	-	-	-
			St wall (2E+3)	St wall (2E+3)	-	3E-9	2E-5	2E-4
		W, see ^{177}Re	-	2E+2	6E-8	2E-10	-	-
75	Rhenium-186	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	2E+3	7E-7	2E-9	-	-
75	Rhenium-187	D, see ^{177}Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
			-	St wall (9E+5)	-	1E-6	-	-
		W, see ^{177}Re	-	1E+5	4E-5	1E-7	-	-
75	Rhenium-188m[2]	D, see ^{177}Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{177}Re	-	1E+5	6E-5	2E-7	-	-
75	Rhenium-188	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4

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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	-	3E+3	1E-4	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	4E-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+5	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	3E-5	3E-4
		W, see ^{180}Os	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{180}Os	-	1E+3	6E-7	2E-9	-	-
76	Osmium-193	D, see ^{180}Os	2E+3	5E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		W, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
76	Osmium-194	D, see ^{180}Os	4E+2	4E+1	2E-8	6E-11	-	-

120.296: continued

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 (6E+2)	-	-	-	8E-6	8E-5
		W, see ^{180}Os	-	6E+1	2E-8	8E-11	-	-
		Y, see ^{180}Os	-	8E+0	E- 39	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	3E-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	13
		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+5	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+6	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see ^{182}Ir	-	2E+5	9E-5	3E-7	-	-

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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 ^{182}Ir	-	2E+5	8E-5	3E-7	-	-
77	Iridium-190	D, see ^{182}Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see ^{182}Ir	-	1E+3	4E-7	1E-9	-	-
		Y, see ^{182}Ir	-	9E+2	4E-7	1E-9	-	-
77	Iridium-192m	D, see ^{182}Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
		Y, see ^{182}Ir	-	2E+1	6E-9	2E-11	-	-
77	Iridium-192	D, see ^{182}Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see ^{182}Ir	-	4E+2	2E-7	6E-10	-	-
		Y, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
77	Iridium-194m	D, see ^{182}Ir	6E+3	9E+1	4E-7	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	-	2E+4	1E-5	4E-8	-	-
		Y, see ^{182}Ir	-	24	9E-6	3E-8	-	-
77	Iridium-195	D, see ^{182}Ir	1E+4	44	2E-5	6E-8	2E-4	2E-3
		W, see ^{182}Ir	-	54	2E-5	7E-8	-	-
		Y, see ^{182}Ir	-	44	2E-5	6E-8	-	-
78	Platinum-186	D, all compounds	1E+4	44	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	23	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	34	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	83	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	63	3E-6	8E-9	-	-
			LLI wall (3E+4)	-	-	-	4E-6	4E-4
78	Platinum-193	D, all compounds	4E+4	24	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	-	-

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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 (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	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	24
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
		Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79	Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193}Au	-	5E+3	2E-6	8E-9	-	-
		Y, see ^{193}Au	-	5E+3	2E-6	7E-9	-	-
79	Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{193}Au	-	1E+3	6E-7	2E-9	-	-
		Y, see ^{193}Au	-	4E+2	2E-7	6E-10	-	-
79	Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
		Y, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
79	Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	-	2E+3	8E-7	3E-9	-	-
		Y, see ^{193}Au	-	2E+3	7E-7	2E-9	-	-
79	Gold-199	D, see ^{193}Au	3E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-6	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	-	-

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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)
			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	3E-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	-	-

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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-8	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	6E+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-5	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-2
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	86	38	14	13
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

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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)
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E+1	2E+1	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	5E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1	3E+1	1E-8	5E-11	-	-
			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	36	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

120.296: continued

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 ^{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	-	-
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 WLM)	9E-9 (or 1.0 WL)	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

120.296: continued

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)
87	Francium-223[2]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0	7E+1	3E-10	9E-13	-	-
			Bone surf (9E+0)	-	-	-	1E-7	1E-6
88	Radium-224	W, all compounds	8E+0	2E+0	7E-10	2E-12	-	-
			Bone surf (2E+1)	-	-	-	2E-7	2E-6
88	Radium-225	W, all compounds	8E+0	7E+1	3E-10	9E-13	-	-
			Bone surf (2E+1)	-	-	-	2E-7	2E-6
88	Radium-226	W, all compounds	2E+0	6E+1	3E-10	9E-13	-	-
			Bone surf (5E+0)	-	-	-	6E-8	6E-7
88	Radium-227[2]	W, all compounds	2E+4	1E+4	6E-6	-	-	-
			Bone surf (2E+4)	Bone surf (2E+4)	-	3E-8	3E-4	3E-3
88	Radium-228	W, all compounds	2E+0	1E+0	5E-10	2E-12	-	-
			Bone surf (4E+0)	-	-	-	6E-8	6E-7
89	Actinium-224	D, all compounds except those given for W and Y	2E+3	3E+1	1E-8	-	-	-
			LLI wall (2E+3)	Bone surf (4E+1)	-	5E-11	3E-5	3E-4
		W, halides and nitrates	-	5E+1	2E-8	7E-11	-	-
		Y, oxides and hydroxides	-	5E+1	2E-8	6E-11	-	-
89	Actinium-225	D, see ^{224}Ac	5E+1	3E+1	1E-10	-	-	-
			LLI wall (5E+1)	Bone surf (5E-1)	-	7E-13	7E-7	7E-6
		W, see ^{224}Ac	-	6E+1	3E-10	9E-13	-	-
		Y, see ^{224}Ac	-	6E+1	3E-10	9E-13	-	-
89	Actinium-226	D, see ^{224}Ac	1E+2	3E+0	1E-9	-	-	-
			LLI wall (1E+2)	Bone surf (4E+0)	-	5E-12	2E-6	2E-5
		W, see ^{224}Ac	-	5E+0	2E-9	7E-12	-	-
		Y, see ^{224}Ac	-	5E+0	2E-9	6E-12	-	-

120.296: continued

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	-	1 E+	5E-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-14	-	-	-
			-	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	-	-

120.296: continued

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)
90	Thorium-231	W, see ^{226}Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see ^{226}Th	-	6E+3	3E-6	9E-9	-	-
90	Thorium-232	W, see ^{226}Th	7E+1	1E+3	5E-13	-	-	-
			Bone surf (2E+0)	Bone surf (3E-3)	-	4E-15	3E-8	3E-7
		Y, see ^{226}Th	-	3E+3	1E-12	-	-	-
			-	Bone surf (4E-3)	-	6E-15	-	-
90	Thorium-234	W, see ^{226}Th	3E+2	2E+2	8E-8	3E-10	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		Y, see ^{226}Th	-	2E+2	6E-8	2E-10	-	-
91	Protactinium-227[2]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91	Protactinium-228	W, see ^{227}Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
		Y, see ^{227}Pa	-	1E+1	5E-9	2E-11	-	-
91	Protactinium-230	W, see ^{227}Pa	6E+2	5E+0	2E-9	7E-12	-	-
			Bone surf (9E+2)	-	-	-	1E-5	1E-4
		Y, see ^{227}Pa	-	4E+0	1E-9	5E-12	-	-
91	Protactinium-231	W, see ^{227}Pa	2E+1	2E+3	E- 613	-	-	-
			Bone surf (5E-1)	Bone surf (4E-3)	-	6E-15	6E-9	6E-8
		Y, see ^{227}Pa	-	4E+3	E- 212	-	-	-
			-	Bone surf (6E-3)	-	8E-15	-	-
91	Protactinium-232	W, see ^{227}Pa	E+ 13	2E+1	E- 99	-	2E-5	2E-4
			-	Bone surf (6E+1)	-	8E-11	-	-
		Y, see ^{227}Pa	-	E+ 61	E- 28	-	-	-
			-	Bone surf (7E+1)	-	1E-10	-	-
91	Protactinium-233	W, see ^{227}Pa	1E+3	7E+2	E- 37	1E-9	-	-

120.296: continued

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 (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	E- 36	1E-8	3E-5	3E-4
		Y, see ^{227}Pa	-	7E+3	E- 36	E- 99	-	-
92	Uranium-230	D, UF_6, UO_2F_2, $UO_2(NO_3)_2$	4E+0	4E+1	2E-10	-	-	-
			Bone surf (6E+0)	Bone surf (6E-1)	-	8E-13	8E-8	8E-7
		W, UO_3, UF_4, UCl_4	-	4E+1	1E-0	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	-	E+ 63	2E-6	8E-9	-	-
		Y, see ^{230}U	-	5E+3	2E-6	6E-9	-	-
92	Uranium-232	D, see ^{230}U	2E+0	2E+1	9E-11	-	-	-
			Bone surf (4E+0)	Bone surf (4E-1)	-	6E-13	6E-8	6E-7
		W, see ^{230}U	-	4E+1	2E-10	5E-13	-	-
		Y, see ^{230}U	-	8E+3	3E-12	1E-14	-	-
92	Uranium-233	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	7E+1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	E+ 42	2E-11	5E-14	-	-
92	Uranium-234[3]	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	7E+1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E+2	2E-11	5E-14	-	-
92	Uranium-235[3]	D, see ^{230}U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E+1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E+2	2E-11	6E-14	-	-

120.296: continued

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)
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	-	E+ 81	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	E- 67	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+1	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-2	4E-6	1E-2	4E-4
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	E- 49	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	W, all compounds	3E+0	2E+2	9E-12	-	-	-

120.296: continued

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)
	(1.15E+5 y)		Bone surf (6E+0)	Bone surf (5E-2)	-	8E-14	9E-8	9E-7
93	Neptunium-236	W, all compounds	3E+3	E+ 31	1E-8	-	-	-
	(22.5 h)		Bone surf (4E+3)	Bone surf (7E+1)	-	1E-10	55 E-	5E-4
93	Neptunium-237	W, all compounds	5E+1	4E+3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	1E-4	28 E-	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	E+ 23	2E+3	9E-7	3E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
93	Neptunium-240[2]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO_2	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO_2	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235[2]	W, see ^{234}Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ^{234}Pu	-	36	1E-3	3E-6	-	-
94	Plutonium-236	W, see ^{234}Pu	2E+0	2E+2	8E-12	-	-	-
			Bone surf (4E+0)	Bone surf (4E-2)	-	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	7E+3	3E-12	-	-	-
			Bone surf (2E+0)	Bone surf (1E-2)	-	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	6E+3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see ^{234}Pu	-	2E+2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-240	W, see ^{234}Pu	8E+1	6E+3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7

120.296: continued

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	-	2E+2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-241	W, see ^{234}Pu	E+ 41	3E+1	1E-10	-	-	-
			Bone surf (7E+1)	Bone surf (6E-1)	-	8E-13	1E-6	1E-5
		Y, see ^{234}Pu	-	8E+1	3E-10	-	-	-
			-	Bone surf (1E+0)	-	1E-12	-	-
94	Plutonium-242	W, see ^{234}Pu	8E+1	E+ 73	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see ^{234}Pu	-	2E+2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	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	E+ 81	7E+3	3E-12	-	-	-
			Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see ^{234}Pu	-	2E+2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see ^{234}Pu	-	4E+3	2E-6	6E-9	-	-
94	Plutonium-246	W, see ^{234}Pu	4E+2	3E+2	1E-7	4E-10	-	-
			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	
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	E- 56	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+5	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7

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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)
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	E+ 81	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	E+ 43	2E-6	-	-	-
			St wall (8E+4)	Bone surf (7E+3)	-	1E-8	1E-3	12 E-
95	Americium-244	W, all compounds	3E+3	2E+2	E- 88	-	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	E- 85	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	-	-	-
			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

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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)
96	Curium-246	W, all compounds	7E+1	6E+3	E- 312	-	-	-
			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-12	-	-	-
			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	E- 68	E- 29	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-12	-	-
98	Californium-249	W, see ^{244}Cf	5E+1	4E+3	2E-12	-	-	-

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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+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	-	1E+2	4E-12	-	-	-
			-	Bone surf (1E-2)	-	2E-14	-	-
98	Californium-250	W, see ^{244}Cf	1E+0	9E+3	4E-12	-	-	-
			Bone surf (2E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	-	3E+2	1E-11	4E-14	-	-
98	Californium-251	W, see ^{244}Cf	5E+1	4E+3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-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	2E-14		-	-
99	Einsteinium-250	W, all compounds	4E+4	5E+2	2E-7	6E-5	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	2E-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

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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)
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1	2E+1	7E-11	-	-	-
			Bone surf (4E+1)	Bone surf (2E-1)	-	3E-13	5E-7	5E-6
101	Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	-	1E-4	1E-3
			-	Bone surf (9E+1)	-	1E-10	-	-
101	Mendelevium-258	W, all compounds	3E+1	2E+1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	5E-13	6E-7	6E-6
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half- life less than 2 hours Submersion[1]		-	2E+2	E- 17	1E-9	-	-
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fis- sion 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 105 CMR 120.213).

[3]For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see 105 CMR 120.211(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

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$$SA = [0.4 + .38 \text{ (enrichment)} + 0.0034 \text{ (enrichment)}^2] \text{ E-6 , enrichment} \geq 0.72$$

where enrichment is the percentage by weight of U-235, expressed as percent.

NOTE:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

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	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
	Col.1	Col. 2	Col. 3	Col.1	Col. 2	
	Oral Ingestion	Inhalation				Monthly Average
	ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Concentration (µCi/ml)
If it is known that Ac-227-D and Cm-250-W are not present	-	0	3.00 e-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	-	0.007	3.00 e-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	-	0.07	3.00 e-11	-	-	-
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	-	0.7	3.00 e-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	-	7	3.00 e-09	-	-	-
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	-	-	-	1.00 e-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	-	-	-	1.00 e-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	-	-	-	1.00 e-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	-	-	-	-	0	0.00 001

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

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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 105 CMR 120.296: Appendix B for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

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Example: If radionuclides "A," "B," and "C" are present in concentrations CA, CB, and CC, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

120.297: Appendix C -- Quantities[1] of Licensed Material Requiring Labeling

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Hydrogen-3	1,000	Cobalt-61	1,000
Beryllium-7	1,000	Cobalt-62m	1,000
Beryllium-10	1	Nickel-56	100
Carbon-11	1,000	Nickel-57	100
Carbon-14	100	Nickel-59	100
Fluorine-18	1,000	Nickel-63	100
Sodium-22	10	Nickel-65	1,000
Sodium-24	100	Nickel-66	10
Magnesium-28	100	Copper-60	1,000
Aluminum-26	10	Copper-61	1,000
Silicon-31	1,000	Copper-64	1,000
Silicon-32	1	Copper-67	1,000
Phosphorus-32	10	Zinc-62	100
Phosphorus-33	100	Zinc-63	1,000
Sulfur-35	100	Zinc-65	10
Chlorine-36	10	Zinc-69m	100
Chlorine-38	1,000	Zinc-69	1,000
Chlorine-39	1,000	Zinc-71m	1,000
Argon-39	1,000	Zinc-72	100
Argon-41	1,000	Gallium-65	1,000
Potassium-40	100	Gallium-66	100
Potassium-42	1,000	Gallium-67	1,000
Potassium-43	1,000	Gallium-68	1,000
Potassium-44	1,000	Gallium-70	1,000
Potassium-45	1,000	Gallium-72	100
Calcium-41	100	Gallium-73	1,000
Calcium-45	100	Germanium-66	1,000
Calcium-47	100	Germanium-67	1,000
Scandium-43	1,000	Germanium-68	10
Scandium-44m	100	Germanium-69	1,000
Scandium-44	100	Germanium-71	1,000
Scandium-46	10	Germanium-75	1,000
Scandium-47	100	Germanium-77	1,000
Scandium-48	100	Germanium-78	1,000
Scandium-49	1,000	Arsenic-69	1,000
Titanium-44	1	Arsenic-70	1,000
Titanium-45	1,000	Arsenic-71	100
Vanadium-47	1,000	Arsenic-72	100
Vanadium-48	100	Arsenic-73	100
Vanadium-49	1,000	Arsenic-74	100
Chromium-48	1,000	Arsenic-76	100
Chromium-49	1,000	Arsenic-77	100
Chromium-51	1,000	Arsenic-78	1,000
Manganese-51	1,000	Selenium-70	1,000
Manganese-52m	1,000	Selenium-73m	1,000
Manganese-52	100	Selenium-73	100
Manganese-53	1,000	Selenium-75	100
Manganese-54	100	Selenium-79	100
Manganese-56	1,000	Selenium-81m	1,000
Iron-52	100	Selenium-81	1,000
Iron-55	100	Selenium-83	1,000
Iron-59	10	Bromine-74m	1,000
Iron-60	1	Bromine-74	1,000
Cobalt-55	100	Bromine-75	1,000
Cobalt-56	10	Bromine-76	100
Cobalt-57	100	Bromine-77	1,000
Cobalt-58m	1,000	Bromine-80m	1,000
Cobalt-58	100	Bromine-80	1,000
Cobalt-60m	1,000	Bromine-82	100
Cobalt-60	1	Bromine-83	1,000

120.297: continued

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Bromine-84	1,000	Niobium-97	1,000
Krypton-74	1,000	Niobium-98	1,000
Krypton-76	1,000	Molybdenum-90	100
Krypton-77	1,000	Molybdenum-93m	100
Krypton-79	1,000	Molybdenum-93	10
Krypton-81	1,000	Molybdenum-99	100
Krypton-83m	1,000	Molybdenum-101	1,000
Krypton-85m	1,000	Technetium-93m	1,000
Krypton-85	1,000	Technetium-93	1,000
Krypton-87	1,000	Technetium-94m	1,000
Krypton-88	1,000	Technetium-94	1,000
Rubidium-79	1,000	Technetium-96m	1,000
Rubidium-81m	1,000	Technetium-96	100
Rubidium-81	1,000	Technetium-97m	100
Rubidium-82m	1,000	Technetium-97	1,000
Rubidium-83	100	Technetium-98	10
Rubidium-84	100	Technetium-99m	1,000
Rubidium-86	100	Technetium-99	100
Rubidium-87	100	Technetium-101	1,000
Rubidium-88	1,000	Technetium-104	1,000
Rubidium-89	1,000	Ruthenium-94	1,000
Strontium-80	100	Ruthenium-97	1,000
Strontium-81	1,000	Ruthenium-103	100
Strontium-83	100	Ruthenium-105	1,000
Strontium-85m	1,000	Ruthenium-106	1
Strontium-85	100	Rhodium-99m	1,000
Strontium-87m	1,000	Rhodium-99	100
Strontium-89	10	Rhodium-100	100
Strontium-90	0.1	Rhodium-101m	1,000
Strontium-91	100	Rhodium-101	10
Strontium-92	100	Rhodium-102m	10
Yttrium-86m	1,000	Rhodium-102	10
Yttrium-86	100	Rhodium-103m	1,000
Yttrium-87	100	Rhodium-105	100
Yttrium-88	10	Rhodium-106m	1,000
Yttrium-90m	1,000	Rhodium-107	1,000
Yttrium-90	10	Palladium-100	100
Yttrium-91m	1,000	Palladium-101	1,000
Yttrium-91	10	Palladium-103	100
Yttrium-92	100	Palladium-107	10
Yttrium-93	100	Palladium-109	100
Yttrium-94	1,000	Silver-102	1,000
Yttrium-95	1,000	Silver-103	1,000
Zirconium-86	100	Silver-104m	1,000
Zirconium-88	10	Silver-104	1,000
Zirconium-89	100	Silver-105	100
Zirconium-93	1	Silver-106m	100
Zirconium-95	10	Silver-106	1,000
Zirconium-97	100	Silver-108m	1
Niobium-88	1,000	Silver-11Om	10
Niobium-89m (66 min)	1,000	Silver-111	100
Niobium-89 (122 min)	1,000	Silver-112	100
Niobium-90	100	Silver-115	1,000
Niobium-93m	10	Cadmium-104	1,000
Niobium-94	1	Cadmium-107	1,000
Niobium-95m	10	Cadmium-109	1
Niobium-95	100	Cadmium-113m	0.1
Niobium-96	100	Cadmium-113	100

120.297: continued

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Cadmium-115m	10	Tellurium-129m	10
Cadmium-115	100	Tellurium-129	1,000
Cadmium-117m	1,000	Tellurium-131m	10
Cadmium-117	1,000	Tellurium-131	100
Indium-109	1,000	Tellurium-132	10
Indium-110m (69.1m)	1,000	Tellurium-133m	100
Indium-11O (4.9h)	1,000	Tellurium-133	1,000
Indium-111	100	Tellurium-134	1,000
Indium-112	1,000	Iodine-120m	1,000
Indium-113m	1,000	Iodine-120	100
Indium-114m	10	Iodine-121	1,000
Indium-115m	1,000	Iodine-123	100
Indium-115	100	Iodine-124	10
Indium-116m	1,000	Iodine-125	1
Indium-117m	1,000	Iodine-126	1
Indium-117	1,000	Iodine-128	1,000
Indium-119m	1,000	Iodine-129	1
Tin-110	100	Iodine-130	10
Tin-111	1,000	Iodine-131	1
Tin-113	100	Iodine-132m	100
Tin-117m	100	Iodine-132	100
Tin-119m	100	Iodine-133	10
Tin-121m	100	Iodine-134	1,000
Tin-121	1,000	Iodine-135	100
Tin-123m	1,000	Xenon-120	1,000
Tin-123	10	Xenon-121	1,000
Tin-125	10	Xenon-122	1,000
Tin-126	10	Xenon-123	1,000
Tin-127	1,000	Xenon-125	1,000
Tin-128	1,000	Xenon-127	1,000
Antimony-115	1,000	Xenon-129m	1,000
Antimony-116m	1,000	Xenon-131m	1,000
Antimony-116	1,000	Xenon-133m	1,000
Antimony-117	1,000	Xenon-133	1,000
Antimony-118m	1,000	Xenon-135m	1,000
Antimony-119	1,000	Xenon-135	1,000
Antimony-120 (16m)	1,000	Xenon-138	1,000
Antimony-120 (5.76d)	100	Cesium-125	1,000
Antimony-122	100	Cesium-127	1,000
Antimony-124m	1,000	Cesium-129	1,000
Antimony-124	10	Cesium-130	1,000
Antimony-125	100	Cesium-131	1,000
Antimony-126m	1,000	Cesium-132	100
Antimony-126	100	Cesium-134m	1,000
Antimony-127	100	Cesium-134	10
Antimony-128 (10.4m)	1,000	Cesium-135m	1,000
Antimony-128 (9.O1h)	100	Cesium-135	100
Antimony-129	100	Cesium-136	10
Antimony-130	1,000	Cesium-137	10
Antimony-131	1,000	Cesium-138	1,000
Tellurium-116	1,000	Barium-126	1,000
Tellurium-121m	10	Barium-128	100
Tellurium-121	100	Barium-131m	1,000
Tellurium-123m	10	Barium-131	100
Tellurium-123	100	Barium-133m	100
Tellurium-125m	10	Barium-133	100
Tellurium-127m	10	Barium-135m	100
Tellurium-127	1,000	Barium-139	1,000

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Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Barium-140	100	Samarium-156	1,000
Barium-141	1,000	Europium-145	100
Barium-142	1,000	Europium-146	100
Lanthanum-131	1,000	Europium-147	100
Lanthanum-132	100	Europium-148	10
Lanthanum-135	1,000	Europium-149	100
Lanthanum-137	10	Europium-150 (12.62h)	100
Lanthanum-138	100	Europium-150 (34.2y)	1
Lanthanum-140	100	Europium-152m	100
Lanthanum-141	100	Europium-152	1
Lanthanum-142	1,000	Europium-154	1
Lanthanum-143	1,000	Europium-155	10
Cerium-134	100	Europium-156	100
Cerium-135	100	Europium-157	100
Cerium-137m	100	Europium-158	1,000
Cerium-137	1,000	Gadolinium-145	1,000
Cerium-139	100	Gadolinium-146	10
Cerium-141	100	Gadolinium-147	100
Cerium-143	100	Gadolinium-148	0.001
Cerium-144	1	Gadolinium-149	100
Praseodymium-136	1,000	Gadolinium-151	10
Praseodymium-137	1,000	Gadolinium-152	100
Praseodymium-138m	1,000	Gadolinium-153	10
Praseodymium-139	1,000	Gadolinium-159	100
Praseodymium-142m	1,000	Terbium-147	1,000
Praseodymium-142	100	Terbium-149	100
Praseodymium-143	100	Terbium-150	1,000
Praseodymium-144	1,000	Terbium-151	100
Praseodymium-145	100	Terbium-153	1,000
Praseodymium-147	1,000	Terbium-154	100
Neodymium-136	1,000	Terbium-155	1,000
Neodymium-138	100	Terbium-156m (5.Oh)	1,000
Neodymium-139m	1,000	Terbium-156m (24.4h)	1,000
Neodymium-139	1,000	Terbium-156	100
Neodymium-141	1,000	Terbium-157	10
Neodymium-147	100	Terbium-158	1
Neodymium-149	1,000	Terbium-160	10
Neodymium-151	1,000	Terbium-161	100
Promethium-141	1,000	Dysprosium-155	1,000
Promethium-143	100	Dysprosium-157	1,000
Promethium-144	10	Dysprosium-159	100
Promethium-145	10	Dysprosium-165	1,000
Promethium-146	1	Dysprosium-166	100
Promethium-147	10	Holmium-155	1,000
Promethium-148m	10	Holmium-157	1,000
Promethium-148	10	Holmium-159	1,000
Promethium-149	100	Holmium-161	1,000
Promethium-150	1,000	Holmium-162m	1,000
Promethium-151	100	Holmium-162	1,000
Samarium-141m	1,000	Holmium-164m	1,000
Samarium-141	1,000	Holmium-164	1,000
Samarium-142	1,000	Holmium-166m	1
Samarium-145	100	Holmium-166	100
Samarium-146	1	Holmium-167	1,000
Samarium-147	100	Erbium-161	1,000
Samarium-151	10	Erbium-165	1,000
Samarium-153	100	Erbium-169	100
Samarium-155	1,000	Erbium-171	100

120.297: continued

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Erbium-172	100	Tantalum-186	1,000
Thulium-162	1,000	Tungsten-176	1,000
Thulium-166	100	Tungsten-177	1,000
Thulium-167	100	Tungsten-178	1,000
Thulium-170	10	Tungsten-179	1,000
Thulium-171	10	Tungsten-181	1,000
Thulium-172	100	Tungsten-185	100
Thulium-173	100	Tungsten-187	100
Thulium-175	1,000	Tungsten-188	10
Ytterbium-162	1,000	Rhenium-177	1,000
Ytterbium-166	100	Rhenium-178	1,000
Ytterbium-167	1,000	Rhenium-181	1,000
Ytterbium-169	100	Rhenium-182 (12.7h)	1,000
Ytterbium-175	100	Rhenium-182 (64.Oh)	100
Ytterbium-177	1,000	Rhenium-184m	10
Ytterbium-178	1,000	Rhenium-184	100
Lutetium-169	100	Rhenium-186m	10
Lutetium-170	100	Rhenium-186	100
Lutetium-171	100	Rhenium-187	1,000
Lutetium-172	100	Rhenium-188m	1,000
Lutetium-173	10	Rhenium-188	100
Lutetium-174m	10	Rhenium-189	100
Lutetium-174	10	Osmium-180	1,000
Lutetium-176m	1,000	Osmium-181	1,000
Lutetium-176	100	Osmium-182	100
Lutetium-177m	10	Osmium-185	100
Lutetium-177	100	Osmium-189m	1,000
Lutetium-178m	1,000	Osmium-191m	1,000
Lutetium-178	1,000	Osmium-191	100
Lutetium-179	1,000	Osmium-193	100
Hafnium-170	100	Osmium-194	1
Hafnium-172	1	Iridium-182	1,000
Hafnium-173	1,000	Iridium-184	1,000
Hafnium-175	100	Iridium-185	1,000
Hafnium-177m	1,000	Iridium-186	100
Hafnium-178m	0.1	Iridium-187	1,000
Hafnium-179m	10	Iridium-188	100
Hafnium-180m	1,000	Iridium-189	100
Hafnium-181	10	Iridium-190m	1,000
Hafnium-182m	1,000	Iridium-190	100
Hafnium-182	0.1	Iridium-192m (1.4m)	10
Hafnium-183	1,000	Iridium-192 (73.8d)	1
Hafnium-184	100	Iridium-194m	10
Tantalum-172	1,000	Iridium-194	100
Tantalum-173	1,000	Iridium-195m	1,000
Tantalum-174	1,000	Iridium-195	1,000
Tantalum-175	1,000	Platinum-186	1,000
Tantalum-176	100	Platinum-188	100
Tantalum-177	1,000	Platinum-189	1,000
Tantalum-178	1,000	Platinum-191	100
Tantalum-179	100	Platinum-193m	100
Tantalum-180m	1,000	Platinum-193	1,000
Tantalum-180	100	Platinum-195m	100
Tantalum-182m	1,000	Platinum-197m	1,000
Tantalum-182	10	Platinum-197	100
Tantalum-183	100	Platinum-199	1,000
Tantalum-184	100	Platinum-200	100
Tantalum-185	1,000	Gold-193	1,000

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Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Gold-194	100	Astatine-207	100
Gold-195	10	Astatine-211	10
Gold-198m	100	Radon-220	1
Gold-198	100	Radon-222	1
Gold-199	100	Francium-222	100
Gold-200m	100	Francium-223	100
Gold-200	1,000	Radium-223	0.1
Gold-201	1,000	Radium-224	0.1
Mercury-193m	100	Radium-225	0.1
Mercury-193	1,000	Radium-226	0.1
Mercury-194	1	Radium-227	1,000
Mercury-195m	100	Radium-228	0.1
Mercury-195	1,000	Actinium-224	1
Mercury-197m	100	Actinium-225	0.01
Mercury-197	1,000	Actinium-226	0.1
Mercury-199m	1,000	Actinium-227	0.001
Mercury-203	100	Actinium-228	1
Thallium-194m	1,000	Thorium-226	10
Thallium-194	1,000	Thorium-227	0.01
Thallium-195	1,000	Thorium-228	0.001
Thallium-197	1,000	Thorium-229	0.001
Thallium-198m	1,000	Thorium-230	0.001
Thallium-198	1,000	Thorium-231	100
Thallium-199	1,000	Thorium-232	100
Thallium-201	1,000	Thorium-234	10
Thallium-200	1,000	Thorium-natural	100
Thallium-202	100	Protactinium-227	10
Thallium-204	100	Protactinium-228	1
Lead-195m	1,000	Protactinium-230	0.1
Lead-198	1,000	Protactinium-231	0.001
Lead-199	1,000	Protactinium-232	1
Lead-200	100	Protactinium-233	100
Lead-201	1,000	Protactinium-234	100
Lead-202m	1,000	Uranium-230	0.01
Lead-202	10	Uranium-231	100
Lead-203	1,000	Uranium-232	0.001
Lead-205	100	Uranium-233	0.001
Lead-209	1,000	Uranium-234	0.001
Lead-210	0.0	Uranium-235	0.001
Lead-211	100	Uranium-236	0.001
Lead-212	1	Uranium-237	100
Lead-214	100	Uranium-238	100
Bismuth-200	1,000	Uranium-239	1,000
Bismuth-201	1,000	Uranium-240	100
Bismuth-202	1,000	Uranium-natural	100
Bismuth-203	100	Neptunium-232	100
Bismuth-205	100	Neptunium-233	1,000
Bismuth-206	100	Neptunium-234	100
Bismuth-207	10	Neptunium-235	100
Bismuth-210m	0.1	Neptunium-236 (1.15E+5y)	0.001
Bismuth-210	1	Neptunium-236 (22.5h)	1
Bismuth-212	10	Neptunium-237	0.001
Bismuth-213	10	Neptunium-238	10
Bismuth-214	100	Neptunium-239	100
Polonium-203	1,000	Neptunium-240	1,000
Polonium-205	1,000	Plutonium-234	10
Polonium-207	1,000	Plutonium-235	1,000
Polonium-210	0.1	Plutonium-236	0.001

120.297: continued

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Plutonium-237	100	Curium-247	0.001
Plutonium-238	0.001	Curium-248	0.001
Plutonium-239	0.001	Curium-249	1,000
Plutonium-240	0.001	Berkelium-245	100
Plutonium-241	0.01	Berkelium-246	100
Plutonium-242	0.001	Berkelium-247	0.001
Plutonium-243	1,000	Berkelium-249	0.1
Plutonium-244	0.001	Berkelium-250	10
Plutonium-245	100	Californium-244	100
Americium-237	1,000	Californium-246	1
Americium-238	100	Californium-248	0.01
Americium-239	1,000	Californium-249	0.001
Americium-240	100	Californium-250	0.001
Americium-241	0.001	Californium-251	0.001
Americium-242m	0.001	Californium-252	0.001
Americium-242	10	Californium-253	0.1
Americium-243	0.001	Californium-254	0.001
Americium-244m	100	Einsteinium-250	100
Americium-244	10	Einsteinium-251	100
Americium-245	1,000	Einsteinium-253	0.1
Americium-246m	1,000	Einsteinium-254m	1
Americium-246	1,000	Einsteinium-254	0.01
Curium-238	100	Fermium-252	1
Curium-240	0.1	Fermium-253	1
Curium-241	1	Fermium-254	10
Curium-242	0.01	Fermium-255	1
Curium-243	0.001	Fermium-257	0.01
Curium-244	0.001	Mendelevium-257	10
Curium-245	0.001	Mendelevium-258	0.01
Curium-246	0.001		

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Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
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

NOTE: For purposes of 105 CMR 120.242(E), 120.245(A), and 120.281(A) where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

[1] The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in 105 CMR 120.296: *Appendix B*, Table I, Columns 1 and 2, rounding to the nearest factor of 10, and constraining the values listed between 0.001 and 1,000 microcuries (37 becquerels and 37 megabecquerels). Values of 100 microcuries (3.7 megabecquerels) have been assigned for radionuclides having a radioactive half-life in excess of 10^9 years, except rhenium, 1,000 microcuries (37 megabecquerels), to take into account their low specific activity.

120.298: Appendix D - Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1(TBq)	Category 1(Ci)	Category 2(TBq)	Category 2(Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	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

NON-TEXT PAGE

120.299: Appendix E -- Classification and Characteristics of Low-level Radioactive Waste

(A) Classification of Radioactive Waste for Land Disposal.

(1) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(2) Classes of Waste.

(a) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in 105 CMR 120.299(B)(1). If Class A waste also meets the stability requirements set forth in 105 CMR 120.299(B)(2), it is not necessary to segregate the waste for disposal.

(b) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in 105 CMR 120.299(B).

(c) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in 105 CMR 120.299(B).

(3) Classification Determined by Long-lived Radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

(a) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

(b) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

(c) If the concentration exceeds the value in Table I, the waste is not generally acceptable for disposal at a facility licensed by the Agency.

(d) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in 105 CMR 120.299(A)(7).

TABLE I

Radionuclide	Concentration curie/cubic meter[a]	nanocurie/gram[b]
C-14	8.0	
C-14 in activated metal	80.0	
Ni-59 in activated metal	220.0	
Nb-94 in activated metal	0.2	
Tc-99	3.0	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100.0
Pu-241		3,500.0
Cm-242		20,000.0
Ra-226		100.0

[a] To convert the Ci/m^3 values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m^3 value by 37.

[b] To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

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(4) Classification Determined by Short-lived Radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in 105 CMR 120.299(A)(6), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

(a) If the concentration does not exceed the value in Column 1, the waste is Class A.

(b) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

(c) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

(d) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

(e) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in 105 CMR 120.299(A)(7).

TABLE II

Radionuclide	Concentration, curie/cubic meter*		
	Column 1	Column 2	Column 3
Total of all radio-nuclides with less than 5-year half-life	700.0	*	*
H-3	40.0	*	*
Co-60	700.0	*	*
Ni-63	3.5	70.0	700.0
Ni-63 in activated metal	35.0	700.0	7000.0
Sr-90	0.04	150.0	7000.0
Cs-137	1.0	44.0	4600.0

* AGENCY NOTE: To convert the Ci/m^3 value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m^3 value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

(5) Classification Determined by Both Long- and Short-lived Radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

(a) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

(b) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

(6) Classification of Wastes with Radionuclides other than those Listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

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(7) The Sum of the Fractions Rule for Mixtures of Radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m^3 (50 Ci/m^3) and Cs-137 in a concentration of 814 GBq/m^3 (22 Ci/m^3). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33., for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

(8) Determination of Concentrations in Wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

(B) Radioactive Waste Characteristics.

(1) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(a) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of Part D, the site license conditions shall govern.

(b) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(c) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(d) Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

(e) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(f) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with 105 CMR 120.299(B)(1)(h).

(g) Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(h) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity shall not exceed 3.7 TBq (100 Ci) per container.

(i) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

(2) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(a) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

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(b) Notwithstanding the provisions in 105 CMR 120.299(B)(1)(c) and (d), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

(c) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

(C) Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with 105 CMR 120.299(A).

120.300: RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

120.301: Purpose and Scope

(A) Establish radiation safety requirements for persons using sources of radiation for industrial radiography,

(B) Apply to all licensees and registrants who use sources of radiation for industrial radiography,

(C) Apply to sealed radioactive sources and radiation machines, except for those regulations clearly applicable only to sealed radioactive sources; and,

(D) Supplement, but do not replace, other applicable requirements of 105 CMR 120.000.

120.302: Definitions

As used in 105 CMR 120.300, the following definitions apply:

Annual Refresher Safety Training means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal audits, 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.

ANSI means American National Standards Institute.

Associated Equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (such as, guide tube, control tube, control cable (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 so shielded that doses to individual members of the public at every location on the exterior meet the limitations specified in 105 CMR 120.221(A).

Cabinet X-Ray System means an x-ray system with the x-ray tube installed in an enclosure which, independent of existing architectural structures except the floor on which it may be placed, is intended to:

(1) Contain at least that portion of a material being irradiated;
(2) Provide radiation attenuation; and,
(3) Exclude personnel from its interior during generation of x 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.

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Certification means the authorization by the Massachusetts Radiation Control Program (Agency) of an individual to perform industrial radiography in the Commonwealth of Massachusetts.

Certification Identification (ID) Card means the document issued by the Agency to individuals who have completed the requirements stated in 105 CMR 120.320(B).

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.

Certified Industrial Radiographer means an individual who has met prescribed training and experience requirements and has passed an approved examination and is authorized by the Agency, pursuant to 105 CMR 120.321(H)(1), to perform industrial radiography.

Certifying Entity means an independent certifying organization or an Agreement State whose industrial radiographer certification program has been reviewed and found to have met the applicable parts of Appendix A of 10 CFR Part 34 for radioactive materials; or an independent certifying organization or radiation control agency whose x-ray/or combination certification requirements have been reviewed and found to be equivalent to criteria established by CRCPD.

Collimator means a small radiation shield of lead or other heavy metal which is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

Control Cable (Drive Cable) means the cable that is connected to the source assembly and used to drive the source from and return it to the shielded position.

Control Mechanism (Drive Mechanism) means a device that enables the source assembly to be moved from and returned to the shielded position. A drive mechanism is also known as a crank assembly.

Control Tube means a protective sheath for guiding the drive cable. The control tube connects the drive mechanism to the radiographic exposure device.

Crank-out Device means the cable, protective sheath, and hand crank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.

Enclosed Radiography means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.

Exposure Head (Source Stop) 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.

Guide Tube means a flexible or rigid tube, such as a "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.

Independent Certifying Organization means an independent organization that meets all of the applicable parts of Appendix A of 10 CFR Part 34 for radioactive materials, and/or comparable criteria for x-ray/combination established by CRCPD.

Industrial Radiography means the examination of the macroscopic structure of materials by nondestructive methods using sources of radiation derived from radioactive materials or radiation machines. For purposes of 105 CMR 120.300, industrial radiography does not include radiography performed with Lixiscopes or cabinet x-ray systems, nor does it include computed tomography or computer-based digital radiography in which the useful beam of radiation is collimated to detectors.

120.302: continued

Industrial Radiography -Radiation Machines means the process of performing industrial radiography using radiation producing machines.

Industrial Radiography -Radioactive Materials means the process of performing industrial radiography using radioactive materials.

Lay-barge Radiography means industrial radiography performed on any water vessel used for laying pipe.

Lixiscope means a portable light-intensified imaging device using iodine-125 as a sealed source.

Lock-out Survey means a radiation survey performed to determine that a sealed source is in its shielded position. The lock-out survey is performed before moving the radiographic exposure device or source changer to a new location or securing the radiographic exposure device or source changer.

Offshore Platform Radiography means industrial radiography conducted from a platform over a body of water.

Permanent Radiographic Installation means an installation or structure designed or intended for radiography and in which radiography is regularly performed and meets all the requirements of 105 CMR 120.319

Personnel Monitoring Badge means a whole body individual monitoring device that meets the requirements of 105 CMR 120.323(B).

Personal Supervision means supervision provided by a Certified Industrial Radiographer who is physically present at the site where sources of radiation and associated equipment are being used, visually evaluating the Radiographer Trainee and in such proximity that immediate assistance can be given if required.

Radiation Machine means any device capable of producing ionizing radiation except those which produce radiation only from radioactive material.

Radiation Safety Officer means an individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee and/or registrant and who meets the requirements of 105 CMR 120.380 and 120.005.

Radiographer means any individual who has successfully completed the training, testing and documentation requirements of 105 CMR 120.320(B), and who performs or personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of 105 CMR 120.000 and all license and/or certificate of registration conditions.

Radiographer Trainee means any individual who has successfully completed the training and testing requirements of 105 CMR 120.320(A) and who uses sources of radiation and related handling tools or radiation survey instruments under the personal supervision of a radiographer trainer.

Radiographic Exposure Device (Camera or Projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

Radiographic Personnel means any radiographer or radiographer trainee.

Sealed Source (Pill) means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

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Shielded Position means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

Shielded-room Radiography means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in 105 CMR 120.221(A).

Source Assembly (Pigtail) means a component to which the sealed source is affixed or in which the sealed source is contained. The source assembly includes the sealed source.

Source Changer means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

Source Stop *see* "Exposure Head".

Storage Area means any location, facility, or vehicle which is used to store, to transport, 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, machine, container, or sealed source.

Storage Container means a device other than a source changer in which sealed sources are stored.

Temporary Job Site means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration.

Transport Container means a package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the U.S. Department of Transportation.

Underwater Radiography means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

120.303: Exemptions

(A) Certified cabinet x-ray systems are exempt from the requirements of 105 CMR 120.300 except for the requirements of 105 CMR 120.337(C) and (D).

(B) Industrial uses of lixiscopes are exempt from the rules in 105 CMR 120.300. Lixiscope use is regulated under 105 CMR 120.100.

120.305: Licensing and Registration Requirements for Industrial Radiographic Operations

The Agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

(A) The applicant satisfies the general requirements specified in 105 CMR 120.020 for radiation machine facilities or 105 CMR 120.100 for radioactive material, as applicable, and any special requirements contained in 105 CMR 120.300;

(B) The applicant submits an adequate program for training radiographers and radiographer trainees that meets the requirements of 105 CMR 120.320;

(C) 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;

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(D) The applicant submits written operating and emergency procedures as described in 105 CMR 120.325;

(E) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer trainee at intervals not to exceed six months as described in 105 CMR 120.320(C);

(F) 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;

(G) The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 105 CMR 120.380(B) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures;

(H) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test and analyzing the samples. The description must include the:

(1) Methods of collecting the samples;
(2) Instruments to be used;
(3) Methods of analyzing the samples; and
(4) Pertinent experience of the person who will analyze the wipe samples.

(I) If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 105 CMR 120.314 and 120.323(B)(8);

(J) the applicant identifies and describes the location(s) of all field stations and permanent radiographic installations; and

(K) The applicant identifies the location(s) where all records required by 105 CMR 120.300 and other parts of 105 CMR 120.000 will be maintained.

120.310: Records of Receipt, Transfer, and Disposal of Sources of Radiation

Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sources of radiation. These records shall include the date, the individual making the record, the radionuclide, number of curies, and make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for Agency inspection until disposal is authorized by the Agency.

120.311: Limits on Levels of Radiation for Radiographic Exposure Devices, Source Changers, and Transport Containers

The maximum exposure rate limits for storage containers and source changers are 2 mSv/hr (200 mrem/hr) at any exterior surface, and 0.1 mSv/hr (10 mrem/hr) at one meter from any exterior surface with the sealed source in the shielded position.

120.312: Locking of Sources of Radiation, Storage Containers and Source Changers

(A) The control panel of each radiation machine shall be equipped with a locking device which will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or radiographer trainee, or an individual specifically authorized by the Agency.

120.312: continued

(B) Each radiographic exposure device must have a lock or outer lockable container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked and, if a keyed lock, the key removed at all times when not under the direct surveillance of a radiographer or radiographer trainee, or an individual specifically authorized by the Agency except at permanent radiograhic installations as stated in 105 CMR 120.319. 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.

(C) Each sealed storage container and source changer must have a lock or outer lockable 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 the key removed when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer trainee.

(D) The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to 105 CMR 120.333(B).

120.314: Radiation Survey Instruments

(A) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by 105 CMR 120.300 and 120.225(A). Instrumentation required by 105 CMR 120.300 shall have a range from 0.02 mSv/hr (2 mrem/hr) through 0.01 Sv/hr (1 rem/hr).

(B) Each radiation survey instrument shall be calibrated:

(1) By a person licensed or registered by the Agency, another Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such service;

(2) At energies appropriate for the licensee's or registrant's use;

(3) At intervals not to exceed six months and after each instrument servicing other than battery replacement;

(4) To demonstrate an accuracy within plus or minus 20%; and

(5) At two points located approximately ⅓ and ⅔ of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and for digital instruments, at three points between 0.02 and 10 mSv/hr (2 and 1,000 mrem/hr).

(C) Records of these calibrations shall be maintained for Agency inspection for five years after the calibration date.

(D) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

120.315: Performance Requirements for Industrial Radiography Equipment

(A) Conformance with ANSI Standards. Equipment used in industrial radiographic operations shall meet the following minimum criteria:

(1) Each radiographic exposure device, source assembly, sealed source, and associated equipment shall meet the criteria set forth by ANSI N432-1980: *Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography*, (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone: (212) 642–4900.

(2) Radiation machines manufactured after January 10, 1992 used in industrial radiographic operations shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537- 1976, except accelerators used in industrial radiography.

(3) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of 105 CMR 120.315.

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(4) In *lieu* of 105 CMR 120.315(A)(1), equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

(5) Engineering analysis may be submitted by a licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component in accordance with 105 CMR 120.315(A)(1).

(6) In addition to the requirements specified in 105 CMR 120.315(A)(1), the following requirements apply to radiographic exposure devices, source changers, source assemblies, sealed sources and associated equipment.

(a) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

1. Chemical symbol and mass number of the radionuclide in the device;
2. Activity and the date on which this activity was last measured;
3. Model or product code and serial number of the sealed source;
4. Name of the manufacturer of the sealed source; and,
5. Licensee's name, address, and telephone number.

(b) Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of 10 CFR part 71.

(c) Opening, repair or modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the Agency, the U.S. Nuclear Regulatory Commission (NRC) or Agreement State.

(7) Modification of any exposure devices 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.

(B) Labeling Storage, and Transportation

(1) The licensee may not use a radiographic exposure device source changer or a container to store radioactive material unless the radiographic exposure device 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. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)" or "DANGER. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)."

(2) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with 105 CMR 120.770

(3) Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

(4) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(5) The licensee’s or registrant’s name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

(C) Performance Requirements. In addition to the requirements specified in 105 CMR 120.315(A) and (B), 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 routine operations or to source changers:

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(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.
(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
(4) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER -- RADIOACTIVE."

The label must 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, endcap, or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.
(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.
(9) Source 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) Leak Testing and Replacement of Sealed Sources.
(1) 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 Nuclear Regulatory Commission, or another Agreement State.
(2) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the Nuclear Regulatory Commission, or another Agreement State.
(3) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerels (0.005 Ci) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis. The license shall maintain the records of the leak tests for inspection by the Agency for five years after it is made.
(4) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.
(5) Any test conducted pursuant to 105 CMR 120.315(D)(1) and (2) which reveals the presence of 185 Bq (0.005 microcuries) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with regulations of the Agency. Within five days after obtaining results of the test, the licensee shall file a report with the Agency describing the equipment involved, the test results, and the corrective action taken.

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(6) Each exposure device using DU shielding and an "S" tube configuration shall 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 Commission or an Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal 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. Each licensee shall maintain records of leak testing of sealed sources and devices containing DU. The licensee shall retain each record for agency inspection for five years from the date of the leak test.

(7) An applicant or licensee who desires to conduct its own tests for leakage or contamination shall establish procedures to be followed when testing sealed sources for leakage or contamination and shall submit a description of such procedures to the Agency for approval. The description shall include the:

(a) Instrumentation to be used;
(b) Method of performing the tests; and
(c) Pertinent experience of the individual(s) who will perform the test.

120.316: Quarterly Inventory

(A) Each licensee or registrant shall conduct a physical inventory at intervals not to exceed three months to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license or registration.

(B) The licensee or registrant shall maintain records of the quarterly inventory in accordance with 105 CMR 120.364.

120.317: Utilization Logs

Each licensee and registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(A) A unique identification (*e.g.*, serial number) of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source;

(B) The name of the radiographer using the source of radiation;

(C) The location(s) where each source of radiation is used and dates of use; and,

(D) The date(s) each source of radiation is removed from storage and returned to storage. For fixed installations, the date(s) each source of radiation is energized or used and the number of exposures made. Utilization logs may be kept on form MRCP 120.300-2, Utilization Log, or on clear, legible records containing all the information required by 105 CMR 120.317(A) through (D). Copies of utilization logs shall be maintained for Agency inspection for five years. The records shall be kept at the location specified by the license or certificate of registration.

120.318: Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments

(A) The radiographer shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

(1) The equipment is in good working condition;
(2) The sources are adequately shielded; and,
(3) Required labeling is present.

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(B) Survey instrument operability must be performed using check sources or other appropriate means.

(C) If equipment problems are found, the equipment must be removed from service until repaired.

(D) Each licensee or registrant shall have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(E) The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(F) Records of equipment problems and of any maintenance performed under 105 CMR 120.318 must be made in accordance with 105 CMR 120.366

120.319: Permanent Radiographic Installations

(A) Permanent radiographic installations shall have high radiation area entrance controls of the type described in 105 CMR 120.227(A)(2) and (3) and (B).

(B) Each entrance that is used for personnel access to the high radiation area shall have both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

(C) The control device or alarm system shall be tested for proper operation with a source of radiation at the beginning of each day of equipment use. The test shall include a check for the visible and/or audible signals. Entrance control devices that reduce the radiation level upon entry as described in 105 CMR 120.227(A)(1) shall be tested monthly. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee or registrant implements the continuous surveillance requirements of 105 CMR 120.331, ensures that radiographic personnel use an alarming ratemeter, and complies with the requirements of 105 CMR 120.330(B). Records of these tests shall be maintained for Agency inspection for five years.

RADIATION SAFETY REQUIREMENTS

120.320: Training and Testing

(A) Radiographer Trainee Requirements. The licensee or registrant shall not permit any individual to act as a radiographer trainee until the individual

(1) has received copies of and instructions in the requirements described in 105 CMR 120.300 and the applicable sections of 105 CMR 120.100, 120.200, 120.750 , and applicable DOT regulations as referenced in 105 CMR 120.770, a copy of the license or certificate of registration issued to the licensee or registrant and copies of and instructions in the licensee's or registrant's operating and emergency procedures;

(2) has demonstrated an understanding of items in 105 CMR 120.320(A)(1) by successful completion of a written or oral examination, administered by the licensee or registrant;

(3) has been instructed in the use of the licensee's or registrant's sources of radiation, radiographic exposure devices, associated equipment, related handling tools and radiation survey instruments that may be employed in industrial radiographic assignments; and

120.320: continued

(4) has demonstrated, to the satisfaction of the licensee or registrant, an understanding of the instructions provided pursuant to 105 CMR 120.320(A)(2) and (3) as evidenced by successful completion of a written or oral test and a field examination on the subjects covered.

(B) Radiographer Requirements. The licensee or registrant shall not permit any individual to act as a radiographer until the individual:

(1) has completed a course of at least 40 hours on the applicable subjects outlined in 105 CMR 120.320(G). The course shall be one that has been accepted by the Agency, another radiation control agency or the NRC;

(2) has completed hands-on experience as a radiographer trainee under the personal supervision, as specified in 105 CMR 120.326, of one or more radiographers:

(a) Hands-on experience in addition to on the job training consisting of hands-on experience shall include at least minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines.

(b) Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of hands-on experience.

(3) has successfully completed within the last five years the appropriate agency-administerd examination as prescribed in 105 CMR 120.321. Or the appropriate examination of another certifying entity that affords the same or comparable certification standards of 105 CMR 120.320(B);

(4) Possess a current certification ID card issued in accordance with 105 CMR 120.321(H) or by another certifying entity that affords the same or comparable certification standards as those afforded by 105 CMR 120.320(B);

(5) Once an individual has completed the requirements of 105 CMR 120.320(B)(4), the licensee or registrant is not required to submit the documentation referenced in 105 CMR 120.320(B)(1) and (2).

(C) In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

(1) has received copies of and instruction in the requirements described in 105 CMR 120.300 and the applicable sections of 105 CMR 120.100, 120.200, 120.750 , and applicable DOT regulations as referenced in 105 CMR 120.770, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

(2) has demonstrated an understanding of items in 105 CMR 120.320(C)(1) by successful completion of a written or oral examination administered by the licensee or registrant;

(3) Has received training in the use and daily inspection of the registrant's radiation survey instruments, the registrant's radiation machines, or the licensee's radiographic exposure devices, associated equipment and related handling tools; and,

(4) Has demonstrated competence in the use of the equipment described in 105 CMR 120.320(C)(3) by successful completion of a practical examination administered by the licensee or registrant.

(D) The licensee or registrant 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 105 CMR 120.320(E)(4), the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer trainee to ensure that the Agency's regulations, license or registration requirements, and operating and emergency procedures are followed. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer trainee during an actual industrial radiographic operation, at intervals not to exceed six months; and,

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(2) Provide that, if a radiographer or a radiographer trainee has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 105 CMR 120.320(C)(3) and the radiographer's assistant must demonstrate knowledge of the training requirements of 105 CMR 120.320(A)(3) by a practical examination administered by the licensee or registrant before these individuals can next participate in a radiographic operation.

(3) The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

(4) In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

(F) The licensee or registrant shall maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with 105 CMR 120.367.

(G) The licensee or registrant shall include the following subjects, as applicable, that are required in 105 CMR 120 320(B)(1):

(1) Fundamentals of radiation safety including:
  (a) Characteristics of gamma and x-radiation;
  (b) Units of radiation dose and quantity of radioactivity;
  (c) Significance of dose to include: radiation protection standards, biological effects of radiation dose, and case histories of industrial radiography incidents;
  (d) Levels of radiation from sources of radiation; and,
  (e) Methods of controlling radiation dose (time, distance, and shielding);

(2) Radiation detection instruments including:
  (a) Use, operation, calibration, and limitations of radiation survey instruments;
  (b) Survey techniques; and,
  (c) Use of personnel monitoring equipment to include as a minimum, film badges, TLDs OSLs, pocket dosimeters, alarming ratemeters and electronic personal dosimeters;

(3) Equipment to be used including:
  (a) Operation and control of radiographic exposure equipment, remote handling equipment, and storage and transport containers, including pictures or models of source assemblies (pigtails);
  (b) Operation and control of radiation machines;
  (c) Storage, control, and disposal of sources of radiation; and,
  (d) Inspection and maintenance of equipment.

(4) The requirements of pertinent state and federal regulations; and,

(5) Generic written operating and emergency procedures.

120.321: Applications and Examinations

(A) Any individual applying to the Agency for certification to perform industrial radiography shall:

(1) submit a complete and legible application on forms prescribed and furnished by the Agency.

(2) pay the appropriate non-refundable fee in accordance with 105 CMR 120.321(J) .

(3) meet the examination requirements set forth in 105 CMR 120.321(D) or satisfy the requirements for certification based on reciprocity as set forth in 105 CMR 120.321(K); and,

(4) provide evidence that the requirements for the given category and class for which certification is sought have been met.

(B) Application. The appropriate fee shall accompany the application when filing with the Agency. An application shall be deemed filed on the date that it is received by the Agency or on the date that it is postmarked by the United States Postal Service.

(C) Categories of Certification.

(1) The Agency shall certify individuals to perform industrial radiography as Certified Industrial Radiographer.

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(2) Each certification issued shall include a class endorsement for the type of industrial radiography authorized. Such class endorsements are limited to:
(a) Radioactive Materials;
(b) Radiation Machines; or
(c) Radioactive Materials and Radiation Machines.

(D) Examination Requirements. An individual who seeks certification as a Certified Industrial Radiographer must have passed, prior to application for certification, a written examination appropriate to the category of certification sought in accordance with 105 CMR 120.321(E). An individual seeking certification as a Certified Industrial Radiographer must pass, within 12 months prior to application for certification, a written examination appropriate to the category and class of certification sought in accordance with 105 CMR 120.321(G).

(E) Examination. The Agency shall accept results of examinations given by certifying entities as defined in 105 CMR 120.302.

(F) Approved Training Program. Industrial radiographer training programs shall be approved by the Agency. The Agency shall recognize training programs approved by certifying entities.

(G) Experience Requirements for Certification. Applicants for certification to perform industrial radiography shall have a minimum of experience appropriate to each category and class of industrial radiography as follows:

Certified Industrial Radiographer
(1) Radioactive Materials..... 200 hrs
(2) Radiation Machines ..... 120 hrs
(3) Both Radioactive Materials and Radiation ..... 320 hrs
Machines of which not less than 200 hours shall be with radioactive materials and not less than 120 hours shall be with radiation machines.

(H) Requirements for Issuance of Certification. The Agency shall certify in a category and class of industrial radiography any individual who has satisfied the following requirements: Certified Industrial Radiographer:
(1) Submitted an application for certification on a form prescribed by the Department;
(2) Submitted the application fee specified in 105 CMR 120.321(J)(1);
(3) Passed an examination as required by 105 CMR 120.321(D) or satisfies the requirements or certification based on reciprocity as set forth in 105 CMR 120.321(K); and,
(4) Completed the required hours of experience in industrial radiography as specified in 105 CMR 120.321(G) or satisfies the requirements for certification based on reciprocity as set forth in 105 CMR 120.321(K)

(I) Duration of Certification. The duration of certification issued by the Agency shall be:
Certified Industrial Radiographer ..... five years

(J) Fees.
(1) The application fees for certification shall be non-refundable and shall be as specified for Certified Idustrial Radiographer.
(2) The appropriate fees shall accompany the application when filing with the Agency.

(K) Reciprocity.
(1) The Agency shall issue certification to an applicant who has been certified in another state or jurisdiction provided that:
(a) The applicant holds a valid certification in the appropriate category issued by another state or jurisdiction;
(b) The jurisdiction that issued the certification is a certifying entity.
(c) The applicant presents a copy of the certification document issued by the other jurisdiction to the Agency; and
(d) The applicant submits the application fee in accordance with 105 CMR 120.321(J)(1).

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(2) Individuals who are certified by reciprocity shall either:
(a) Maintain the certification upon which the reciprocal certification was issued; or
(b) Satisfy the requirements of 105 CMR 120.321(H) prior to the expiration of the certification upon which reciprocal certification was issued.

(L) Requirements for Renewal of Certification.
(1) Prerequisites:
(a) An individual shall submit an application for re-examination and renewal of certification at least six months prior to the expiration date of certification. The Agency shall waive this requirement if the applicant satisfies the requirements of 105 CMR 120.321(A). An individual may not legally perform industrial radiography without valid certification.
(b) Each applicant shall submit a complete and legible application with the fee for renewal of certification in accordance with 105 CMR 120.321(A).
(2) Re-examination. Applicants for renewal of certification shall meet the requirements of 105 CMR 120.321(H)(1) including re-examination as described in 105 CMR 120.321(L)(1).
(3) An I.D. card shall be issued to each person who successfully completes the examination prescribed in 105 CMR 120.321(E).
(4) Each person's I.D. card shall contain his/her photograph. The Agency will take the photograph at the time the examination is administered.
(5) The I.D. card remains the property of the Commonwealth of Massachusetts and may be revoked or suspended under the provisions of 105 CMR 120.322.
(6) A fee of $15.00 shall be paid to the Agency for each replacement of a lost I.D. card.

120.322: Revocation or Suspension of an I.D. Card

(A) Any radiographer who violates 105 CMR 120.000 may be required to show cause at a formal hearing why his/her I.D. card should not be revoked or suspended.

(B) When an Agency order has been issued for an industrial radiographer to cease and desist from the use of radioactive material or revoking or suspending his/her I.D. card, the industrial radiographer shall surrender the I.D. card to the Agency until such time as the order is changed or the suspension expires.

(C) The Agency may act to suspend or revoke an individual's certification for any one or a combination of the following causes:
(1) Knowingly causing a material misstatement or misrepresentation to be made in the application for initial certification or renewal of certification if such misstatement or misrepresentation would impair the Agency's ability to assess and evaluate the applicant's qualifications for certification pursuant to 105 CMR 120.321;
(2) Knowingly falsifying records of employees when such falsification would impair the Agency's ability to assess and evaluate the applicant's qualifications for certification pursuant to 105 CMR 120.321;
(3) Willfully evading the statute or regulations pertaining to certification, or willfully aiding another person in evading such statute or regulations pertaining to certification;
(4) Exhibiting significant or repeated incompetence in the performance of industrial radiography duties;
(5) Performing industrial radiography in such a manner that requirements of 105 CMR 120.300 are violated resulting in a threat to health and safety of the individual, other workers or the public;
(6) Having had a similar certification suspended or revoked if the grounds for that suspension or revocation are the same or equivalent to one or more grounds for suspension or revocation as set forth in 105 CMR 120.016(C);
(7) Failure to maintain the out-of-state certification upon which certification by reciprocity was issued;

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(D) If, based upon any of the grounds in 105 CMR 120.322(C), the Agency determines that action to suspend or revoke certification is warranted, the Agency shall notify the individual and shall provide an opportunity for a hearing in accordance with 801 CMR 1.01 *et seq*. An opportunity for a hearing shall be provided before the Agency takes action to suspend or revoke an individual's certification unless the Agency finds that an immediate suspension of certification is required to protect against immediate danger to the public health or safety, in which case the Agency shall suspend an individual's certification pending a hearing.

(E) If the Agency finds that removal of certification is warranted, the usual action shall be a suspension of certification for up to one year. The term of suspension may be reduced by the Director of the Radiation Control Program, upon the recommendation of the hearing officer, if the hearing officer finds, based upon evidence presented to him/her during a hearing, that the conditions leading to the Preliminary Order for Suspension can be cured in less than one year. However, if the Agency finds that the causes are of a serious or continuous nature, such as past actions which posed an immediate threat to occupational or public health or safety, deficiencies that cannot be cured within one year, the Agency shall revoke the individual's certification.

(F) When an individual's certification is suspended or revoked, the individual shall surrender his/her certification document to the Agency until the termination of the suspension period or until reissuance of the certification.

(G) An individual whose certification has been revoked may seek reinstatement of certification by filing with the Agency a petition for reinstatement. Such petition may be filed one year or more after the beginning of the revocation period.

120.323: Personnel Monitoring

(A) The personnel monitoring program shall meet the applicable requirements of 105 CMR 120.200.

(B) When performing industrial radiographic operations the following shall apply:

(1) The licensee or registrant shall not permit an individual to act as a radiographer, or radiographer trainee unless each individual wears, on the trunk of the body at all times during radiographic operations, a combination of a direct-reading pocket dosimeter or an electronic personal dosimeter, an alarming ratemeter, and a personnel monitoring badge that is processed and evaluated by an accredited NVLAP processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(2) Pocket dosimeters shall meet the criteria in ANSI N13.5-1972 and shall have a range of zero to two millisieverts (zero to 200 millirems).

(3) Pocket dosimeters shall be recharged at the start of each work shift.

(4) Exposure indicated by each pocket dosimeter shall be recorded at the beginning of and at the end of each work shift.

(5) If an individual's pocket dosimeter is discharged beyond its range (*i.e*., goes "off-scale"), or if an individual's electronic personal dosimeter reads greater than two millisieverts (200 mrem), industrial radiographic operations by that individual shall cease and the individual's personnel monitoring badge shall be processed immediately. The individual shall not return to work with sources of radiation until a determination of his/her radiation exposure has been made.

(6) Each personnel monitoring badge shall be assigned to and worn by only one individual.

(7) If a personnel monitoring badge is lost or damaged, the worker shall cease work immediately until a replacement personnel monitoring badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel monitoring badge.

(8) Each alarm dosimeter must:

(a) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift.

(b) Emit an alarm signal at a preset dose rate of five mSv/hr (500 mr/hr).

(c) Require special means to change the preset alarm function; and

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(d) Be tested at periods not to exceed one year for correct response to radiation. Acceptable dosimeters must alarm within plus or minus 20% of the true radiation dose rate.

(C) Records of pocket dosimeter readings of personnel exposures shall be maintained for five years by the licensee or registrant for Agency inspection. If the dosimeter readings were used to determine external radiation dose (*i.e.*, no TLD, OSL or film badge exposure records exist), the records shall be maintained until the Agency authorizes disposal.

(D) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20% of the true radiation exposure. Records of pocket dosimeter calibrations shall be maintained for five years by the licensee or registrant for Agency inspection.

(E) Processors of film badge, TLD and OSL devices must be certified by the NVLAP.

120.325: Operating and Emergency Procedures

(A) Operating and emergency procedures must include, as a minimum, instructions in the following:

(1) Appropriate handling and use of sources of radiation for industrial radiography so that no person is likely to be exposed to radiation doses in excess of the limits established in 105 CMR 120.200;
(2) Methods and occasions for conducting radiation surveys;
(3) Methods for posting and controlling access to radiographic areas;
(4) Methods and occasions for locking and securing sources of radiation;
(5) Personnel monitoring and the use of personnel monitoring equipment;
(6) Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in 105 CMR 120.770;
(7) The inspection, maintenance, and operability checks of radiographic exposure devices and associated equipment, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers and source changers;
(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;
(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by 105 CMR 120.385;
(10) The procedure for notifying proper persons in the event of an accident or incident;
(11) Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;
(12) Source recovery procedure if licensee will perform source recoveries;
(13) Maintenance of records; and,
(14) The procedures for calculating exposures as required by 105 CMR 120.323(B), when a personnel monitoring badge is lost or damaged.

(B) The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with 105 CMR120.367 and 105 CMR120.371.

120.326: Supervision of Radiographer Trainee

The radiographer's assistant shall be under the personal supervision of a radiographer when using sources of radiation, including radiation machines, radiographic exposure devices, associated equipment, or related handling tools, or while conducting radiation surveys required by 105 CMR 120.333(B) to determine that the sealed source has returned to the shielded position or the radiation machine has stopped producing radiation after an exposure. The personal supervision must include:

(A) The radiographer's physical presence at the site where the sources of radiation are being used;

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(B) The availability of the radiographer to give immediate assistance if required; and

(C) he radiographer's direct observation of the trainee's performance of the operations referred to in this section.

120.328: 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 105 CMR120.320(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 must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Agency.

(C) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(D) A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State.

120.331: Surveillance

(A) During each industrial radiographic operation, a radiographer or radiographer trainee shall maintain visual surveillance of the operation to protect against unauthorized entry into a radiation area or high radiation area, except where the high radiation area is equipped with a control device or alarm system as described in 105 CMR 120.227(A) or (B).

(B) Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal.

(C) The sealed source shall be secured and immobilized in its shielded position in the radiographic exposure device with an appropriate locking or latching mechanism each time the sealed source is returned to its shielded position.

(D) Notwithstanding the requirements of 105 CMR 120.243(A), High Radiation Area warnings may be placed at the periphery of the Radiation Area, or at the perimeter of access control.

120.332: Posting

Areas in which industrial radiography is being performed shall be posted conspicuously in accordance with 105 CMR 120.200 including:

(A) Radiation Areas. Each radiation area shall be posted conspicuously with a sign or signs displaying the radiation symbol and the words:

CAUTION (OR DANGER)

RADIATION AREA

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 one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

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(B) High Radiation Area. Each high radiation area shall be posted conspicuously with a sign or signs displaying the radiation symbol and the words:

CAUTION (OR DANGER)

HIGH RADIATION AREA

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

(C) Ropes and/or barriers shall be used as necessary to prevent unauthorized entry to radiation areas.

(D) Notwithstanding the requirements of 105 CMR 120.242(A), each radiation area may be posted in accordance with 105 CMR 120.242(B), *i.e.*, High Radiation Area warnings may be placed at the periphery of the controlled area.

120.333: Radiation Surveys and Survey Records

(A) No radiographic operation shall be conducted unless at least one calibrated and operable radiation survey meter, as described in 105 CMR 120.314, is available and used at each site where radiographic exposures are made.

(B) A survey with a radiation survey instrument shall be made 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, including the source guide tube and collimator if provided, shall be surveyed.

(C) A survey shall be made of the storage area as defined in 105 CMR 120.302 whenever a radiographic exposure device is being placed in storage.

(D) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."

(E) (1) All potential radiation areas in which industrial radiographic operations are to be performed shall be posted in accordance with 105 CMR 120.332, based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (*i.e.*, with the sealed source in the exposed position) to confirm that 105 CMR 120.332 requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 105 CMR 120.221(A). Surveys to confirm the extent of the High Radiation Area, one mSv/hr (100 mr/hr), within the Radiation Area should not be undertaken.

(2) Each time the exposure device is relocated and/or the exposed position of the sealed source is changed, the requirements of 105 CMR 120.333(E)(1) shall be met.

(3) The requirements of 105 CMR 120.333(E)(2) do not apply to pipeline industrial radiographic operations when the conditions of exposure including, but not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.

(F) A survey with a radiation survey instrument shall be made to determine that the sealed source has been returned to its shielded position any time a radiographic exposure device is placed in storage. The entire circumference of the radiographic exposure device, including the source guide tube and collimator if provided, shall be surveyed.

(G) If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 105 CMR 120.221(A) at the exterior surface of the vehicle.

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(H) Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in 105 CMR 120.221(A). These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.

(I) A survey meeting the requirements of 105 CMR 120.333(F) shall be performed on the radiographic exposure device and the source changer after every sealed source exchange.

(J) Records shall be kept of the surveys required by 105 CMR 120.333(E), (F), (G), (H), (I) and 105 CMR 120.318(A). These records shall be maintained for Agency inspection for five years after completion of the survey. If a survey was used to determine an individual's exposure due to loss of personnel monitoring data, the records of the survey shall be maintained until the Agency authorizes disposal.

120.334: Records Required at Temporary Job Sites

Each licensee and registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for Agency inspection:

(A) The appropriate license or certificate of registration or equivalent document;

(B) The appropriate operating and emergency procedures;

(C) The applicable Agency rules;

(D) The survey records required pursuant to 105 CMR 120.333 for the period of operation at the site;

(E) The daily pocket dosimeter records for the period of operation at the site; and,

(F) The most recent records of instrument and device calibration and source leak tests. Acceptable records include tags or labels which are attached to the devices or survey instruments and decay charts for sources which have been manufactured within the last six months.

120.337: Special Requirements and Exemptions for Enclosed Radiography

(A) Systems for enclosed radiography, including shielded-room radiography and cabinet x-ray systems not otherwise exempted, shall comply with all applicable requirements of 105 CMR 120.300.

(B) Systems for enclosed radiography designed to allow admittance of individuals shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of 105 CMR 120.300, 120.221(A) and 120.222. Records of these evaluations shall be maintained for Agency inspection for five years after the evaluation.

(C) Certified cabinet x-ray systems are exempt from the requirements of 105 CMR 120.300 except that:

(1) The registrant shall comply with the requirements of 105 CMR 120.020 and 120.200.

(2) Tests for proper operation of interlocks must be conducted and recorded in accordance with 105 CMR 120.319. Records of these tests shall be maintained for Agency inspection until disposal is authorized by the Agency.

(3) The registrant shall perform an evaluation to determine compliance with 21 CFR 1020.40 at intervals not to exceed one year. Records of these evaluations shall be maintained for Agency inspection for five years after the evaluation.

(D) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 and no modification may be made to the system unless prior agency approval has been granted by the Agency pursuant to 105 CMR 120.020.

120.340: Underwater and Lay-barge Radiography

(A) Underwater and/or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with 105 CMR 120.360.

(B) In addition to the other requirements of 105 CMR 120.300, the following requirements apply to the performance of lay-barge radiography:

(1) Cobalt-60 sources with activities in excess of 740 GBq (20 Ci) (nominal) and iridium-192 sources with activities in excess of 3.70 TBq (100 Ci) (nominal) shall not be used in the performance of offshore platform or lay-barge radiography.

(2) Collimators shall be used for all industrial radiographic operations performed on lay-barges.

120.350: Prohibitions

(A) Industrial radiography performed with a sealed source that is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.

(B) Retrieval of disconnected sources or sources that cannot be returned by normal means to a fully shielded position or automatically secured in the radiographic exposure device, shall not be performed unless specifically authorized by a license condition.

RECORDKEEPING REQUIREMENTS

120.360: Records for Industrial Radiography

Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license or registration.

120.361: Records of Receipt, Transfer, and Disposal of Sources of Radiation

(A) Each licensee or registrant shall maintain records showing the receipts, transfers and disposal of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for five 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 DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

120.362: Records of Radiation Survey Instruments

Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under 105 CMR 120.314 and retain each record for three years after it is made.

120.363: Records of Leak Testing of Sealed Sources and Devices Containing DU

Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (Ci). The licensee shall retain each record for five years after it is made or until the source in storage is removed.

120.364: Records of Quarterly Inventory

(A) Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by 105 CMR 120.316 and retain each record for five years.

120.364: continued

(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 sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

120.365 Utilization Logs

Each licensee and registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(A) A unique identification (*e.g.*, serial number) of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source;

(B) The name of the radiographer using the source of radiation;

(C) The location(s) where each source of radiation is used and dates of use; and,

(D) The date(s) each source of radiation is removed from storage and returned to storage. For fixed installations, the date(s) each source of radiation is energized or used and the number of exposures made. Utilization logs may be kept on form MRCP 120.300-2, Utilization Log, or on clear, legible records containing all the information required by 105 CMR 120.365(A) through (D). Copies of utilization logs shall be maintained for Agency inspection for five years. The records shall be kept at the location specified by the license or certificate of registration.

120.366: Records of Inspections and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, associated Equipment, Source Changers, and Survey Instruments

(A) Each licensee or registrant shall maintain records specified in 105 CMR 120.318 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for three years after it is made.

(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 performed.

120.367: Records of Alarm System and Entrance Control Tests at Permanent Radiographic Installations

Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by 105 CMR 120.319 and retain each record for three years after it is made.

120.368: Records of Training and Certification

Each licensee or registrant shall maintain the following records for five years:

(A) Records of training of each radiographer and each radiographer trainee. The record must include radiographer certification documents and verification of certification status, copies of written tests and the dates of oral and practical examinations administered by the licensee or registrant, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and,

(B) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

120.369: Copies of Operating and Emergency Procedures

Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license or registration. Superseded material must be retained for five years after the change is made.

120.370: Records of Personnel Monitoring

Each licensee or registrant shall maintain the following exposure records specified in 105 CMR 120.323:

(A) Direct reading dosimeter readings and yearly operability checks required by 105 CMR 120.323(B)(8) for five years after the record is made;

(B) Records of alarming ratemeter calibrations for five years after the record is made;

(C) Reports received from the personnel monitoring badge processor until the Agency terminates the license or registration; and,

(D) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel monitoring badges until the Agency terminates the license or registration.

120.371: Records of Radiation Surveys

Each licensee or registrant shall maintain a record of each survey as specified in 105 CMR 120.333(E). Each record must be maintained for five years after it is made.

120.372: Form of Records

Each record required by 105 CMR 120.360 through 120.372 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 or registrant shall maintain adequate safeguards against tampering with and loss of records.

120.373: Location of Documents and Records

(A) Each licensee or registrant shall maintain copies of records required by 105 CMR 120.300 and other applicable Parts of 120.CMR 120.000 at the location specified in 105 CMR 120.305(K).

(B) Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

(1) The license or registration authorizing the use of sources of radiation;
(2) A copy of 105 CMR120.001 105 CMR120.200, 105 CMR120.300 and 105 CMR 120.750;
(3) Utilization logs for each source of radiation dispatched from that location as required by 105 CMR120.317;
(4) Records of equipment problems identified in daily checks of equipment as required by 105 CMR120.366(A);
(5) Records of alarm system and entrance control checks required by 105 CMR120.366, if applicable;
(6) Records of dosimeter readings as required by 105 CMR120.369;
(7) Operating and emergency procedures as required by 105 CMR120.325;
(8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 105 CMR120.362;

120.373: continued

(9) Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 105 CMR120.369;
(10) Survey records as required by 105 CMR120.370, for the period of operation at the site;
(11) The shipping papers for the transportation of radioactive materials required by 105 CMR 120.770; and,
(12) When operating under reciprocity pursuant to 105 CMR120.100, a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation

120.380: Radiation Safety Officer

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 or registrant's program.

(A) The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:
(1) Completion of the training and testing requirements of 105 CMR 120.320(B);
(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 Agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate experience and knowledge with respect to the establishment and maintenance of a radiation safety protection program.

(C) The specific duties of the RSO include, but are not limited to, the following:
(1) To establish and oversee operating, emergency, and ALARA procedures as required by 105 CMR 120.200, and to review them regularly to ensure that the procedures are current and conform to Agency regulations and to the license or registration conditions;
(2) To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;
(3) To ensure that required radiation surveys and leak tests are performed and documented in accordance with 105 CMR 120.000, including any corrective measures when levels of radiation exceed established limits;
(4) To ensure 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 105 CMR 120.200;
(5) To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;
(6) To investigate and report to the Agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;
(7) To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;
(8) To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
(9) To maintain records as required by 105 CMR 120.000.
(10) To ensure the proper storing, labeling, transport, and use of exposure devices and sources of radiation;
(11) To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with 105 CMR 120.316 and 120.318; and,
(12) To ensure that personnel are complying with 105 CMR 120.000, the conditions of the license or the registration, and the operating and emergency procedures of the licensee or registrant.

120.385: Notifications

(A) The Agency shall be notified of the loss or theft of sources of radiation, overexposures, and excessive levels in accordance with 105 CMR 120.281, 120.282, 120.283, and 120.288.

(B) In addition, each licensee or registrant shall submit a written report within 30 days to the Agency whenever one of the following events occurs:

(1) A source assembly cannot be returned to the fully-shielded position and properly secured;

(2) The source assembly becomes unintentionally disconnected from the drive cable;

(3) Any component critical to safe operation of the radiographic exposure device fails to properly perform its intended function; or,

(4) An indicator on a radiation-producing machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate X-ray production.

(C) The licensee or registrant shall include the following information in each report submitted in accordance with 105 CMR 120.385(B):

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Manufacturer and model number of equipment involved in the incident;

(4) Location, time, and date of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and,

(7) Names and qualifications of personnel involved in the incident.

(D) Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 cumulative days in a calendar year, shall notify the Agency using an appropriate method listed in 105 CMR 120.013 prior to exceeding the 180 days.

120.390: Reciprocity

All reciprocal recognition of licenses and certificates of registration by the Agency will be granted in accordance with 105 CMR 120.190 and 120.033.

120.400: X-RAYS IN THE HEALING ARTS

120.401: Purpose and Scope

105 CMR 120.400 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 Commonwealth statutes to engage in the healing arts or veterinary medicine. The provisions of 105 CMR 120.400 are in addition to, and not in substitution for, other applicable provisions of 105 CMR 120.000.

120.402: Definitions

As used in 105 CMR 120.400, the following definitions apply:

Accessible Surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory Component means:

(1) A component used with diagnostic X-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of 105 CMR 120.400 but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of 105 CMR 120.400 but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all X-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Added Filtration means any filtration which is in addition to the inherent filtration.

120.402: continued

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.

Approved Provider means a post-secondary institution of higher learning, a provider approved by the American Society of Radiologic Technologists (ASRT), a provider of Category I CME approved by the American Academy of Physician Assistants (AAPA), a provider accredited by the Accreditation Council for Continuing Medical Education (ACCME) or ACCME-recognized state medical society (SMS), a provider of Category 1 CME approved by the American Medical Association (AMA), or other recognized national continuing medical education approval body approved by the Agency.

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

Attenuation Block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[1] or other materials having equivalent attenuation.

Automatic Exposure Control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

Automatic Exposure Rate Control (AERC) means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

Barrier (*See* Protective Barrier).

Beam Axis means a line from the source through the centers of the x-ray fields.

Beam-limiting Device means a device which provides a means to restrict the dimensions of the x-ray field.

Bone Densitometry System means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

C-arm Fluoroscope means a fluoroscopic x-ray system in which the image receptor and x-ray tube housing assembly are connected or coordinated. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Cantilevered Tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

Cassette Holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film [imaging] cassette during an x-ray exposure.

Cephalometric Device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

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[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00% minimum aluminum, 0.12% copper.

120.402: continued

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:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n - 1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

Computed Tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Contact Therapy System means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.

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.

Contrast Scale (CS) 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

Cooling Curve means the graphical relationship between heat units stored and cooling time.

CR means: Computed Radiography, an indirect type of imaging system. The receptor used within a CR cassette is called a photostimulable imaging plate and it absorbs the radiation exiting the patient. The exposed plate is processed in a CR reader, where the absorbed energy is extracted. The resultant latent image data is converted from an analog to a digital signal and a digital image is created.

120.402: continued

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

(a) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(b) Which is equipped with means for patient restraint; and

(c) Which is capable of rotation about its long (longitudinal) axis.

CT means computed tomography; the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

CT Condition 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 105 CMR 120.400.

CT Gantry means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

CT Number (CTN) means the number used to represent the x-ray attenuation associated with each elemental area of the CT image, that is:

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = contrast (a value of 1,000 is assigned when the Hounsefield scale of CTN is used)

μ_x = linear attenuation coefficient of the material of interest

μ_w = linear attenuation of water

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.

Detector (*See* Radiation Detector).

Diagnostic Source Assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic X-ray System means an x-ray system designed for irradiation of any part of the human (or animal) body for the purpose of diagnosis or visualization.

Diagnostic X-ray Imaging System means an assemblage of components for the generation, emission, and reception of x-ray and the transformation, storage, and visual display of the resultant x-ray image.

Direct Scattered Radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (*See* Scattered Radiation).

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

120.402: continued

DR means Direct Radiography or Digital Radiography, is a form of x-ray imaging where digital x-ray sensors are used instead of traditional photographic film.

Elemental Area means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

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).

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

Facility means the location within one building or vehicle and under the same administrative control at which one or more x-ray equipment systems are installed or located for the purpose of diagnosis or treatment.

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 Devices means separate devices, subsystems, or components that provide the display of AKR and cumulative air kerma, respectively. They include radiation detectors, if any, electronic and computer components, associated software, and data displays.

Fluoroscopic Imaging Assembly means a subsystem in which x-ray photons produce a fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic Irradiation Time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopic Procedure means the production and display of serial x-ray images for the purpose of observing real-time motion of anatomical structures.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

Focal Spot (Actual) means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General Purpose Radiographic X-ray System means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad Shield means a protective barrier for the testes or ovaries.

Half-value Layer means the thickness of specified material which attenuate the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In 105 CMR 120.402: Half-value Layer, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

120.402: continued

Hand-held X-ray Equipment means x-ray equipment that is designed to be hand-held during operation.

Healing Arts Screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized by the Commonwealth of Massachusetts to prescribe such x-ray tests for the purpose of diagnosis or treatment. to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat Unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, *i.e.*, kVp x mA x second.

HVL (*See* Half-value Layer).

Image Intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image Receptor means any device, such as a fluorescent screen, 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.

Inherent Filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Interventional Procedures means procedures that utilize imaging for guidance. Imaging includes, but is not limited to, fluoroscopy and CT.

Irradiation means the exposure of matter to ionizing radiation.

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged participles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

Kilovolts Peak (*See* Peak Tube Potential).

kV means kilovolts.

kVp (*See* Peak Tube Potential).

kWs means kilowatt second.

Last Image Hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral Fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

Lead Equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

120.402: continued

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:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, *i.e.*, ten 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.

Linear Attenuation Coefficient (μ) means the quotient of dN/N by d1 when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traveling a distance d1 in a specific material.

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.

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 = $100\ (V_n\text{-}V_l)/V_l$

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 and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Movable Tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

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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.

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.

Nurse Practitioner means a person licensed as a Registered Nurse by the Massachusetts Board in Nursing pursuant to M.G.L. c. 112, § 74, who is authorized by such Board to practice in an advanced practice nursing role as a nurse practitioner pursuant to M.G.L. c. 112, § 80B, and 244 CMR 4.00: *The Practice of Nursing in the Expanded Role*.

NVLAP means National Voluntary Laboratory Accreditation Program.

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

PBL *See* 105 CMR 120.402: Positive Beam Limitation.

Peak Tube Potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

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).

Physician Assistant means a person licensed as a physician assistant by the Massachusetts Board of Registration in Physician Assistants pursuant to M.G.L. c. 112, § 9I.

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 bean-limiting device.

Positive Beam Limitation means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

Post-secondary Institution of Higher Education means a degree granting institution duly accredited by an accrediting agency recognized by the United States Department of Education.

Practitioner of the Healing Arts means an individual licensed to practice healing arts by the Commonwealth of Massachusetts.

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;

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(2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation.

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 ½ second.

Qualified Medical Physicist means an individual is:

(1) Registered with the Agency, under the provisions of 105 CMR 120.026, as a provider of radiation services in the area of calibration and compliance surveys and,

(2) Is certified by the American Board of Radiology in:

(a) Therapeutic medical physics; or

(b) Diagnostic medical physics; or

(c) Nuclear medical physics; or

(3) Is certified by the American Board of Medical Physics; or

(4) Is certified by the Canadian College of Medical Physics; or

(5) Hold a master's or doctor's degree in physics, biophysics, radiological physics, Radiological Science, Nuclear Physics, health physics, or other catagory approved by the Agency.

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 or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

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.

Rated Line Voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated Output Current means the maximum allowable load current of the x-ray high-voltage generator.

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a retrievable form of an image resulting from x-ray photons.

Reference Plane means a plane which is displaced from and parallel to the tomographic plane.

Routine means diagnostic procedures utilizing x-ray equipment that are performed at least weekly.

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 tomogram.

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.

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Scan Time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Scattered Radiation means radiation that, during passage through matter, has been deviated in direction (*See* Direct Scattered Radiation).

Secondary 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).

Single Tomogram System means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

Solid State X-ray Imaging Device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

Source means the focal spot of the x-ray tube.

Source-image Receptor Distance means the distance from the source to the center of the input surface of the image receptor.

Source-skin Distance (SSD) means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot Film 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 the fluoroscopic image receptor for the purpose of producing a radiograph.

SSD means the distance from the source to the center of the entrant x-ray field in the plan tangent to the patient skin surface.

Stationary Tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Stationary X-ray Equipment (*See* X-ray Equipment).

Stray Radiation means the sum of leakage and scattered radiation.

Supervising Physician means a physician who holds a full license issued by the Board of Registration in Medicine and who supervises all professional activities of a physician assistant in accordance with 243 CMR 2.08 and 263 CMR 5.00. For the purposes of 105 CMR 120.405, a supervising physician shall meet the requirements of 120.405(K)(1)(a) or (b).

Technique Factors means the conditions of operation. They are specified as follows:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

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(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
(3) For CT equipment designed for pulsed operations, peaktube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and,
(5) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

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.

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Tomographic Plane means that geometric plane which is identified as corresponding to the output tomogram.

Tomographic Section means the volume of an object whose attenuation properties are imaged in a tomogram.

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.

X-ray Exposure Control means a device, switch, button, or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

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, phototimer, 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.

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X-ray Field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is ¼ of the maximum in the intersection.

X-ray High-voltage Generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high voltage switches, electrical protective devices, and other appropriate elements.

X-ray System means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray Table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or buckey), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

X-ray Tube means any electron tube which is designed to be used primarily for the production of x-rays.

120.403: General Requirements

(A) Administrative Controls.

(1) 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 105 CMR 120.403(A)(1) are met in the operation of the x-ray system(s).

(a) An x-ray system which does not meet the provisions of 105 CMR 120.400 shall not be operated for diagnostic or therapeutic purposes, unless otherwise approved by the Radiation Control Program.

(b) Individuals who shall be operating the x-ray systems shall meet the requirements of 105 CMR 125.000: *Licensing of Radiologic Technologists*.

(c) 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:

1. Patient's body size and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;
2. Type and size of the image receptor to be used;
3. Type and size of the image receptor combination to be used; if any
4. Source to image receptor distance to be used (except for dental intra-oral radiography); and
5. Type and location of placement of patient shielding (*e.g.* gonad, *etc.*) to be used.

(d) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and 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. These procedures shall be reviewed, updated, and documented annually by management.

(e) Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, and parents of pediatric patients whose presence might be required for the medical procedure or training shall be in the room or area during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

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2. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure 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. For interventional procedures, lead glasses shall be used.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

(f) Gonad shielding of not less than 0.50 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.

(g) 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 specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and

2. exposure of an individual for the purpose of healing arts screening except as authorized by 105 CMR 120.403(A)(1)(k).

(h) When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 105 CMR 120.403(A)(1)(d), shall list individual projections, specific patient conditions, or psychological development level where holding devices cannot be utilized;

2. Written safety procedures, as required by 105 CMR 120.403(A)(1)(d), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 105 CMR 120.403(A)(1)(e);

4. No individual shall be used routinely to hold film or patients;

5. 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; and,

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

(i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. An imaging system of appropriate speed consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Protective equipment including aprons, gloves, and shields shall be x-rayed annually for defects, such as holes, cracks, and tears to assure reliability and integrity. A record of this test shall be maintained for inspection by the Radiation Control Program. If such defect is found, equipment shall be replaced or removed from service until repaired or replaced.

4. Radiographic systems other than fluoroscopic, dental intra-oral, or veterinarian systems shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

5. Mammographic procedures shall only be performed on special purpose mammographic equipment.

6. Mobile or portable radiographic systems shall only be used for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

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7. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

a. Be positioned properly, *i.e.*, tube facing the right direction, and grid centered to the central ray;

b. If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

(j) All occupationally exposed individuals are subject to the requirements of 105 CMR 120.211, 120.215, 120.217 and 120.218.

(k) If the facility ceases to operate, the Registrant or Responsible person of the facility must notify the Radiation Control Program within 15 days. Included in this notification, is the name and address of the person who disposed of the x-ray unit.

(2) The registrant of the facility shall ensure that the equipment is in safe operating condition:

(a) when it is first installed and prior to use on patients;

(b) after any major changes or replacement of parts and prior to use on patients:

(c) by having physics surveys, calibrations and preventative maintenance such physics surveys and preventative maintenance shall be made annually:

1. The physics surveys shall be performed by a qualified medical physicist;

2. The preventative maintenance or calibration shall be performed by a registered service provider as specified in 105 CMR 120.026.

(d) Physics surveys shall be reviewed and signed within a reasonable time of completion of the tests but no longer than 30 days of completion of the tests by a qualified medical physicist and a responsible person at the facility or responsible physician, and any necessary corrective action shall be implemented within 30 days.

(e) Records of calibrations and preventative maintenance shall be maintained at the facility for three years.

(3) Information and Maintenance Record and Associated Information. The registrant of a facility shall maintain the following information for each x-ray system for inspection by the Radiation Control Program:

(a) Model and serial numbers of all major components, and user's manuals for those components;

(b) Records of installation, surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of 105 CMR 120.000 with the names of persons who performed such services;

(c) A copy of the service providers certificate of registration shall be maintained by the facility.

(d) A scale drawing provided by a registered service provider or qualified medical physicist of the room in which a stationary x-ray system is located with such drawing indicating the current 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:

1. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

2. The type and thickness of materials, or lead equivalency, of each protective barrier; and,

(e) A copy of all correspondence with this Radiation Control Program regarding that x-ray system.

(4) X-ray Utilization Log. Each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(5) Radiograph and Record Retention. Radiographs shall be retained for at least a minimum of five years following last visit of the patient. The written reports become a part of the patient's medical record and are to be retained for 20 years following last visit of patient.

(6) Quality Assurance Program.

(a) All registrants of diagnostic x-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

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1. Written standard operating procedures on radiation protection and the practice of radiologic technology reviewed, updated, and documented annually by management.
2. Employee review and written acknowledgement of standard operating procedures and policies on radiation protection and the practice of radiologic technology shall be documented annually.
3. Credentialling of practitioners, medical physicists, and x-ray equipment operators.
4. Film Processing equipment:
   a. Compliance with 105 CMR 120.403(C);
   b. Film processor performance to include medium density, density difference, and base + fog;
   c. Darkroom fog;
5. Radiographic equipment:
   a. Compliance with performance standards in 105 CMR 120.404 and 120.406;
   b. Entrance skin exposure rates of selected patient examinations;
   c. Image printing and viewing equipment;
   d. Measurement of low and high contrast resolution; and
   e. Radiation protection.
6. Fluoroscopic equipment:
   a. Compliance with performance standards in 105 CMR 120.405;
   b. Entrance skin exposure rates of selected patient examinations;
   c. Image printing and viewing equipment;
   d. Measurement of low and high contrast resolution; and
   e. Radiation protection.
7. Computerized tomography equipment:
   a. Compliance with performance standards in 105 CMR 120.409;
   b. CT number;
   c. Low contrast and high contrast resolution;
   d. Dosimetry of selected patient examinations to include pediatric patients if applicable;
   e. Image printing and viewing equipment; and
   f. Radiation protection.
8. Bone densitometry equipment: Compliance with requirements in 105 CMR 120.410.
9. Structural shielding for new facilities with x-ray equipment:
   a. Pre-construction shielding design and evaluation; and
   b. Post-construction radiation protection survey.
10. Structural shielding for modifying use or equipment in existing facility:
   a. Re-evaluation of shielding design; and
   b. Post-modification radiation protection survey.

(b) The registrant of a facility shall assign qualified personnel to fully implement the quality assurance program.

(c) Quality control assessments may be assigned to qualified personnel who possess the requisite training and/or experience.

(d) Quality control assessments shall be conducted by or under the direction of, a qualified medical physicist.

(e) The registrant of a facility and/or qualified medical physicist shall determine the frequency of quality control tests but shall not be less stringent than the manufacturers recommendations.

(f) The quality assurance program shall be in written form and available for review by the Agency.

(g) Equipment used for compliance with the provisions of 105 CMR 120.403(6) shall be properly calibrated and maintained in accordance with accepted professional standards.

105 CMR 120.403(A)(6) does not pertain to quality assurance for mammography equipment *see* 105 CMR 127.000.

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(7) Healing Arts Radiologic Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Radiation Control Program. When requesting such approval, that person shall submit the information outlined in 105 CMR 120.421: *Appendix B*. If any information submitted to the Radiation Control Program becomes invalid or outdated, the Radiation Control Program shall be immediately notified.

(B) Plan Review.

(1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Radiation Control Program for review and approval. The required information is denoted in 105 CMR 120.420: *Appendix A* and 105 CMR 120.422: *Appendix B*, unless specifically exempted.

(2) The Radiation Control Program may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(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 105 CMR 120.211, 120.217, 120.218 and 120.221.

(C) X-ray Film Processing Facilities and Practices.

(1) Each installation using a radiographic x-ray system and using analog image receptors (*e.g.* radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(a) Manually developed film:

1. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

2. The temperature of solutions in the tanks shall be maintained within the range of 60ºF to 80ºF (16ºC to 27ºC). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

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Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

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(b) Automatic processors and other closed processing systems:

(1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35.0	95	20
34.5	94	21
34.0	93	22
33.5	92	23
33.0	91	24
32 .0	90	25
31.5	89	26
31.0	88	27
30.5	87	28
30.0	86	29
29.5	85	30

[a/] Immersion time only, no crossover time included.

2. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

(c) Processing deviations from the requirements of 105 CMR 120.403(C)(1) shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (*e.g.*, extended processing, and special rapid chemistry). The requirements of 105 CMR 120.403(C)(1)(c) apply only to film processors routinely used in processing diagnostic x-ray images.

(d) Quality Assurance tests for the processor shall be performed on days being used.

(e) Test tools for quality assurance tests for the processor shall include the following:

1. Densitometer
2. Sensitometer
3. Thermometer
4. Film

(f) Daily film processor quality assurance tests shall include: Checking solution temperatures.

1. The developer temperature shall be as recommended by the film manufacturer.
2. Mercury thermometers are prohibited for determining solution temperatures.

(g) Determination and recording of the speed step. Maximum control limits shall not exceed ± 0.15 optical density (OD).

(h) Calculation and recording of the contrast index or density difference. Maximum control limits shall not exceed ± 0.15 optical density (OD).

(i) Measuring and plotting the Base + Fog. Maximum base plus fog density shall not exceed 0.25 optical density (OD).

(j) Chemistry replenishment rates shall be measured and recorded semi-annually.

(k) Processor sensitometric tests results including speed index, contrast index, and base plus fog shall be plotted on control charts.

(l) Operating levels and control limits for processor quality assurance tests shall be indicated on the control chart.

(m) Quality assurance records shall be maintained for a minimum of 24 months and readily available for review by representatives of the Department.

(n) Each facility shall take corrective action when Quality Assurance test do not meet the requirements in 105 CMR 120.403(C).

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(2) Other Requirements:

(a) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(b) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

1. Quality assurance tests for darkroom integrity shall be performed at least semi-annually.
2. Each facility shall use pre-exposed film for performing quality assurance tests.
3. No smoking or eating is permitted in the darkroom.
4. The darkroom shall be kept free of dust.
5. Counter tops, floors, and processing feed trays shall be cleaned daily before any films are handled or processed.

(c) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(d) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(e) Film cassettes and intensifying screens shall be kept free of artifacts and shall be cleaned regularly and replaced as necessary to best assure radiographs of good diagnostic quality.

(f) Screens shall be cleaned at intervals not to exceed one month with a screen cleaner recommended by the screen manufacturer. A copy of this requirement shall be kept in the darkroom.

(g) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

(h) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

120.404: General Requirements for All Diagnostic X-ray Systems

In addition to other requirements of 105 CMR 120.400, 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 and operating instructions 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 one meter in any direction from the source shall not exceed 100 milliroentgen (25.8 μC/kg) in one 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 two milliroentgen (0.516 μC/kg) in one hour at five 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.

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(E) Beam Quality.

(1) Half-value Layer.

(a) 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.

(b) For capacitor energy storage equipment, compliance with the requirements of 105 CMR 120.404(E) shall be determined with the system fully charged and a setting of ten mAs for each exposure.

(c) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

(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 105 CMR 120.404(E)(1) is in the useful beam for the given kVp which has been selected.

Specified Dental Systems \1\

TABLE I

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems[1]	Other X-Ray Systems[2]	Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to 105 CMR 120.404 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 105 CMR 120.404 and manufactured on or after June 10, 2006.

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(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.

(G) Mechanical Support of Tube Housing Assembly. 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 105 CMR 120.404(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) Maintaining Compliance Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

(J) Locks. All positioning locking, holding, and centering devices on x-ray systems components and systems shall function as intended.

120.405: Fluoroscopic X-ray Systems

Fluoroscopic X-ray Systems shall be installed and maintained to comply with the Federal Performance Standard for Fluoroscopic Equipment, 21 CFR 1020.32 and shall also meet the following requirements except 21 CFR 1020.32 shall prevail should there be a conflict.

(A) Limitation of Useful Beam.

(1) Primary Barrier.

(a) 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.

(b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(c) Radiation therapy simulation systems shall be exempt from 105 CMR 120.405(A) provided the systems are intended only for remote control operation.

(2) Fluoroscopic Beam Limitation.

(a) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3% of the SID. The sum of the excess length and the excess width shall be no greater than 4% of the SID.

(b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

(c) For uncertified fluoroscopic systems without a spot film device, the requirements of 120.405(A)(2)(a) apply.

1. 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;

2. 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;

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3. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;

4. 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; and,

5. For rectangular 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.

(d) For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

1. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80% of the area of the x-ray field overlaps the visible area of the image receptor; or

2. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two cm.

(3) Spot-film Beam limitation. Spot-film devices shall meet the following requirements:

(a) 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 which 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;

(b) 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% 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% of the SID;

(c) 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, five centimeters by five centimeters;

(d) 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% of the SID; and,

(e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means 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.

(4) Override. If a means exists to override any of the automatic x-ray field size adjustments required in 105 CMR 120.405(A)(2), that means:

(a) Shall be designed for use only in the event of system failure;

(b) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and,

(c) Shall be clearly and durably labeled 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 which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, 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.

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(C) Air Kerma Rates.

(1) Fluoroscopic Equipment Manufactured Before May 19, 1995.

(a) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in AKR in excess of 88 mGy per minute (ten roentgens) per minute at the point where the center of the useful beam enters the patient, except:

1. During recording of fluoroscopic images; or

2. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an AKR in excess of ten roentgens (88 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.

(b) Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in AKR in excess of 44 mGy (five roentgens) per minute at the point where the center of the useful beam enters the patient, except:

1. During recording of fluoroscopic images; or

2. When an optional high level control is activated. Special means of activation of high level controls 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.

(c) Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an AKR in excess of 88 mGy (ten roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:

1. During recording of fluoroscopic images; or

2. When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which shall result in an AKR in excess of 88 mGy (ten roentgens) per minute at the point where the center of the useful beam enters the patient, unless 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.

(2) Fluoroscopic Equipment Manufactured On or After May 19, 1995.

(a) Shall be equipped with automatic exposure rate control if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (five R/min exposure rate) at the measurement point specified in 105 CMR 120.405(C)(3). Provision for manual selection of technique factors may be provided.

(b) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (ten R/min exposure rate) at the measurement point specified in 105 CMR 120.405(C)(3).

(c) Exceptions:

1. For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

2. For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

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3. When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in 105 CMR 120.405(C)(3). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

(3) Compliance with the requirements of 105 CMR 120.405(C) shall be determined as follows:

(a) If the source is below the table, the AKR shall be measured one centimeter above the tabletop or cradle.

(b) If the source is above the table, the 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 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 beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(d) For a lateral type fluoroscope, the air kerma rate 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.

(e) In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

(4) The registrant of a facility or responsible person at the facility shall have a qualified medical physicist perform periodic measurement of AKR for both typical and maximum values as follows:

(a) Such measurements shall be made annually or after any maintenance of the system which might affect the AKR;

(b) If the fluoroscope does not display the AKR of the current patient in view of the operator when the fluoroscopy trigger is depressed, results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 105 CMR 120.403(A)(2)(b). The measurement results shall be stated in coulombs per kilogram (roentgens) 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;

(c) Conditions of periodic measurement of typical AKR are as follows:

1. The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);

2. The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use for an abdominal patient;

3. The x-ray system that incorporates automatic Exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of 105 CMR 120.405(C)(1)(e)3.; and

(d) Conditions of periodic measurement of maximum AKR are as follows:

1. The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);

2. The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum AKR;

3. The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attentuative material placed in the useful beam to produce the maximum AKR of the system.

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(D) Barrier Transmitted Radiation Rate Limits.

(1) The 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 two milliroentgen (0.516 μC/kg) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of AKR.

(2) Measuring Compliance of Barrier Transmission.

(a) The AKR due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(b) 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.

(c) 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.

(d) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(e) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of AKR and between this point and the input surface of the fluoroscopic imaging assembly.

(E) Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

(F) Source-to-skin Distance.

(1) Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in 105 CMR 120.405(D)(1), provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

(2) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in 105 CMR 120.405(F)(2), provisions may be made for operation at shorter source-skin distances but in no case less than ten cm.

(G) Fluoroscopic Timer.

(1) Fluoroscopic Equipment Manufactured Before June 10, 2006:

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(2) For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

(a) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in 105 CMR 120.405(G)(2). The following requirements apply:

1. When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds.

2. The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset.

3. Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

(b) A signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.

(H) 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:

(a) Is at least 120 centimeters from the center of the useful beam; or

(b) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 105 CMR 120.403(A)(1)(e).

(3) The Agency may grant exemptions to 105 CMR 120.405(H)(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. *See* 105 CMR 120.423: *Appendix D* for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

(I) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 105 CMR 120.405(A), (C), (D) and (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 105 CMR 120.405(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.

(J) Spot film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) modes shall meet the exposure reproducibility requirements when operating in the spot film mode.

(K) Operator Qualifications.

(1) The Registrant of a facility shall ensure that only the following health care providers shall be allowed to operate fluoroscopic x-ray systems:

(a) Licensed physicians who are board-certified in radiology;

(b) Licensed physicians who are not board-certified in radiology provided that they have been trained in the following subjects:

1. Principles and operation of the fluoroscopic x-ray system;
2. Biological effects of x-ray;
3. Principles of radiation protection;
4. Fluoroscopic outputs;
5. High level control options;
6. Dose reduction techniques for fluoroscopic x-ray systems; and
7. Application requirements of 105 CMR 120.000.

(c) Radiologic technologists who are licensed in accordance with 105 CMR 125.000 and have been trained in the safe use of fluoroscopic x-ray systems; and

(d) Physician assistants who are licensed in accordance with M.G.L. c. 112, § 9I, and 263 CMR 3.00: *Registration of Individual Physician Assistants*, and who meet the requirements of 105 CMR 120.405(K)(2).

(2) The Registrant of a facility shall ensure that a physician assistant delegated the performance of specified fluoroscopic procedures by a supervising physician has submitted documentation of the following to the facility:

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(a) Successful completion of the education and clinical training specified in 105 CMR 120.405(K)(3) offered by an approved provider;

(b) a passing score on an examination offered by the American Registry of Radiologic Technologists (ARRT) or equivalent exam approved by the Agency covering the educational and clinical requirements specified in 105 CMR 120.405(K)(3);

(c) a written and signed statement from the physician assistant's supervising physician, who meets the requirements of 105 CMR 120.405(K)(1)(a) or (b), verifying the physician assistant's competency to perform specified fluoroscopic procedures; and

(d) a written practice agreement between the physician assistant and his or her supervising physician as set forth in regulations of the Board of Registration in Medicine at 243 CMR 2.08 and of the Board of Registration of Physician Assistants in 263 CMR 5.00: *Scope of Practice and Employment of Physician Assistants*.

(3) The education and clinical training required by 105 CMR 120.405(K)(2)(a) shall consist of the following:

(a) Didactic Content

1. Digital image acquisition and display;
2. Contrast media;
3. Fluoroscopic unit operation and safety;
4. Image analysis;
5. Radiation biology;
6. Radiation production and characteristics; and
7. Radiation protection.

(b) Clinical Component

1. Clinical competency requirement: 40 clinical hours performing fluoroscopic procedures in a fluoroscopic suite under the direct supervision of a physician who meets the requirements of 105 CMR 120.405(K)(1)(a) or (b), a medical physicist, or a radiography educator. "Direct supervision," as used in 105 CMR 120.405(K)(3), means physically present where the fluoroscopic procedure is being performed and immediately available and able to provide assistance and direction throughout the procedure;

2. Fluoroscopic device orientation: safe and proper manipulation of the fluoroscopic device.

(4) The Registrant of the facility and/or responsible person at the facility shall maintain all records relating to compliance with the education and clinical training requirements for the current year and the previous four years.

(5) The facility shall establish policies and procedures for limiting the performance of fluoroscopic procedures to only those health care providers who have met the requirements of 105 CMR 120.405(K) and who have been granted privileges for the use of fluoroscopy based on their demonstrated competency in the performance of fluoroscopic procedures.

(6) The Registrant of the facility shall ensure that all physicians who are not board certified in radiology and who perform fluoroscopic procedures complete two hours of training in Radiation Safety/Radiation Protection on an annual basis, and that all physicians who are not board certified in radiology who supervise the performance of fluoroscopic procedures complete a total of four hours of Radiation Safety/Radiation Protection training on an annual basis. The facility shall maintain all records relating to compliance with this training requirement for the current year and the previous four years.

(7) The Registrant of a facility shall ensure that licensed radiologic technologists and licensed physician assistants who perform fluoroscopic procedures have satisfied all related continuing education requirements as required by their respective licensing boards, and shall maintain records documenting completion of such continuing education requirements by radiologic technologists and physician assistants for five years.

(8) In addition to any other reporting requirements, the facility shall immediately, and no later than 24 hours after discovery, report to the Agency any incident at the facility involving fluoroscopic procedures that seriously affects the health and safety of a patient or that causes serious physical injury to a patient due to radiation exposure.

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(9) Nothing in 105 CMR 120.405(K) shall prohibit nurse practitioners from practicing within their lawful scope of practice, including functioning as first assistants during cardiac catheterization procedures in accordance with 105 CMR 130.900: *Standards for Operation of Hospital-based Cardiac Catheterization Services*, and the Board of Registration in Nursing Advisory Ruling Number 0201, *Nurse Practitioner as First Assistant in Cardiac Catherization*, provided that the physician who is the primary operator, as defined in 105 CMR 130.910, is qualified to operate fluoroscopic x-ray systems pursuant to 105 CMR 120.405(K)(1)(a) or (b).

(L) Patient Dose Evaluation.

(1) Each facility performing fluoroscopically-guided interventional and CT fluoro procedures shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury as further defined in 105 CMR 120.405(L)(5).

(2) Records documenting that policies and procedures have been developed to determine that those procedures that have a potential to result in patient doses exceeding the threshold for injury have been established to reduce the probability of such exposures and that appropriate action occurs for patients receiving doses that warrant follow-up.

(3) The facility shall have a patient dose monitoring procedures in place. When the fluoroscopy unit is equipped with an Air-Kerma dose readout, the recording of this value shall suffice as a patient dose record.

(4) The facility shall document in the patient's medical record an estimate of the absorbed dose to the skin.

(5) Any cumulative absorbed dose to the skin equal to or greater than 2 Gy (200 rads) shall be noted in the patient's medical record and reviewed by the Radiation Safety Committee.

(6) Each facility that use fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name. The record shall be maintained for five years.

(M) Equipment Operation.

(1) Radiological technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or a licensed Radiological Technologist.

(2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(N) Mini-C-Arms. 105 CMR 120.405 includes Mini-C-Arms.

120.406: Diagnostic X-ray Systems

(A) Beam Limitation Except for Mammographic Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 105 CMR 120.406(G)(2) has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

(1) General Purpose Stationary and Mobile X-ray Systems, Including Veterinary Systems (Other than Portable) Installed After December 31, 1997.

(a) Only x-ray systems provided with a means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used;

(b) 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% 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;

(c) The Agency may grant an exemption on non-certified x-ray systems to 105 CMR 120.406(A)(1)(a); and,

(d) Provided the registrant makes a written application for such exemption and in that application:

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1. Demonstrates it is impractical to comply with 105 CMR 120.406(A)(1)(a) and (b); and,

2. The purpose of 105 CMR 120.406(A)(1)(a) and (b) will be met by other methods.

(2) Additional Requirements for Stationary General Purpose X-ray Systems. In addition to the requirements of 105 CMR 120.406, all stationary general purpose x-ray systems, both certified and non-certified shall meet the following requirements:

(a) 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 two percent of the SID, and to indicate the SID to within 2%;

(b) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and,

(c) Indication of field size dimensions and SID's 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% 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% 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) Radiographic Systems Other Than Those Designated in 105 CMR 120.406(A)(1) through (3).

(a) 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% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or means 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. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(c) 105 CMR 120.406(A)(4)(a) and (b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 105 CMR 120.406(A)(1) or, when alignment means are also provided, may be met with either:

1. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or,

2. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(B) Radiation Exposure Control.

(1) Timers. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

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(3) Exposure Termination. 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. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(a) Manual Exposure Control.

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:

1. Exposure of ½ second or less; or,
2. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(b) Automatic Exposure Controls. When an automatic Exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;
2. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
3. The minimum exposure time for all equipment other than that specified in 105 CMR 120.406(B)(3)(b)2. shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;
4. 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 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and,
5. A visible signal shall indicate when an exposure has been terminated at the limits required by 105 CMR 120.406(B)(3)(b)4., and manual resetting shall be required before further automatically timed exposures can be made.

(4) Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

(5) Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

(6) Operator Protection, Except Veterinary Systems.

(a) Stationary Systems. 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.

(b) Mobile and Portable Systems. Mobile and portable x-ray systems which are:

1. Used continuously for greater than one week in the same location, *i.e.*, a room or suite, shall meet the requirements of 105 CMR 120.406(B)(6)(a);
2. Used for less than one week at the same location shall be provided with either a protective barrier at least 6.5 feet (two m) high for operator protection during exposure, or means shall be provided to allow the operator to be at least nine feet (2.7 m) from the tube housing assembly during the 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.

(7) Exposure Reproducibility. When all techniques factors are held constant, including control panel selections associated with exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

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(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, except for veterinary systems.

(D) 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 two milliroentgen (0.516 μC/kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(E) Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value for kVp and 20% for time.

(F) mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated:

(1) Equipment Having Independent Selection of X-ray Tube Current (mA). The average ratios (X_i) of air kerma to the indicated milliampere-seconds product (C kg^{-1} mAs^{-1} (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

(2) Equipment Having a Combined X-ray Tube Current-exposure Time Product (mAs) Selector. The average ratios (X_i) of air kerma to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

(3) Measuring Compliance. Determination of compliance shall be based on three exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(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) Beam Limitation for Portable X-ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 105 CMR 120.406(A)(1).

(2) Field Limitation and Alignment on Stationary General Purpose X-ray Systems. For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(C):

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(a) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.

(b) The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 2% of the SID and that the sum of the length and width differences without regard to sign be no greater than 3% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

(c) The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than five by five centimeters. Return to positive beam limitation as specified in 105 CMR 120.406(F)(6)(a) and (b) shall occur upon a change in image receptor.

(d) Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not within 10° of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.

(e) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode It shall be impossible to remove the key while the positive mode is overridden.

(3) Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(4) 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 five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 C/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.

(H) Any facility that utilizes a CR or DR system shall follow the manufacturer's recommendations for Quality Assurance and Quality Control.

(1) All Quality Control tests and results shall be documented.

(2) Quality assurance and quality control records shall be maintained for a minimum of 24 months and readily available for review by representatives of the Department.

120.407: Dental Radiographic Systems

(A) General Requirements.

(1) 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, 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 0.3 second or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$T \geq 5(T_{max} - T_{min})$$

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(3) X-ray Control.

(a) 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 0.5 second or less.

(b) The exposure switch shall be of the dead-man type.

(c) Each x-ray control shall be located in such a way as to permit the operator to remain in an area of less than two millirems in any one hour during the entire exposure.

(4) 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 four Exposures are made at identical technique factors, the value of the average Exposure (E) is greater than or equal to five times the maximum Exposure (E_{max}) minus the minimum Exposure (E_{min}):

$$E \geq 5(E_{max} - E_{min})$$

(B) Additional Requirements for Dental Intraoral Systems.

(1) Source-to-skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than:

(a) 18 centimeters if operable above 50 kVp; or,

(b) ten centimeters if not operable above 50 kVp.

(2) Field Limitation.

(a) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the x-ray field, at the minimum SSD. shall be containable in a circle having a diameter of no more than seven centimeters.

(b) An open-ended beam-indicating device shall be used.

(C) Additional Requirements for Dental Extraoral System Field Limitation.

(1) Dental rotational panoramic systems shall be provided with means to limit the x-ray beam to the imaging slit in the transverse axis and shall not exceed a total of 0.5 inch larger than the imaging slit in the vertical axis.

(2) All other dental extraoral radiographic systems (*e.g.*, cephalometric) shall be provided with means to both size and align the x-ray field so that it does not exceed beyond any edge of the image receptor by more than 2% of the SID.

(D) 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 Exposure 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% 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:

$$X_1\text{-}X_2 \leq 0.10\ (X_1 + X_2)$$

where: X_1 and X_2 are the average mR/mAs values obtained at each of two 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".

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(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 105 CMR 120.404(E)(1).

(E) Additional Operation Controls for Dental Radiographic Systems.

(1) Film holding devices shall be used except in individual cases in which the practitioner has determined that such holding are contraindicated. Written safety procedures required by 105 CMR 120.400 shall state the criteria under which the exception shall apply.

(2) The tube housing support shall be constructed and adjusted so that the tube housing shall not drift from its set position during an exposure. Neither the tube housing nor the support housing shall be hand-held during an exposure.

(3) The operator shall stand at least six feet from the useful beam or behind a protective barrier. Where a protective barrier is utilized, a viewing system shall be used.

(4) Individuals who operate only dental radiographic systems are exempt from the personnel monitoring requirements of 105 CMR 120.211.

(5) Protective equipment -aprons and shields-shall be checked annually for defects, such as holes, cracks, and tears to assure reliability and integrity and documentation shall be kept for five years.

(6) Thyroid shields shall be used on all patients, when applicable.

(7) The registrant of the facility shall ensure that the equipment is in safe operating condition:

(a) when it is first installed and prior to use on patients;

(b) after any major changes or replacement of parts and prior to use on patients:

(c) by having calibrations and preventative maintenance:

1. such preventative maintenance or calibrations shall not exceed three years

2. the preventative maintenance or calibrations shall be performed by a registered service provider as specified in 105 CMR 120.026.

(d) Preventative maintenance and calibrations shall be reviewed and signed within a reasonable time of completion of the tests but no longer than 30 days of completion of the tests by the licensed dentist, and any necessary corrective action shall be implemented within 30 days.

(e) Records of the last two calibrations and preventative maintenance shall be maintained at the facility.

(F) Hand-held Intraoral Dental Radiographic Units.

(1) For all uses:

(a) Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.

(b) When operating a hand-held intraoral dental radiographic unit, operators shall wear a lead apron and thyroid collar, unless otherwise authorized by the Agency or a qualified health or medical physicist.

(c) A hand-held intraoral dental radiographic unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.

(d) Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall be used with a secondary radiation block.

(e) The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held intraoral radiographic unit.

(2) Additional requirements for operatories in permanent facilities:

(a) Hand-held intraoral dental radiographic units shall be used for patient examinations in dental operatories that meet the structural shielding requirements specified by the Agency or by a qualified health or medical physicist.

(b) Hand-held intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

(G) Cone Beam 3-D Dental Imaging Systems.

(1) Facilities shall maintain documentation of applications from the manufacturer;

(2) Operators of the unit shall be a:

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(a) Licensed Dentist or
(b) Licensed Hygienist or Certified Dental Assistant

(3) All facilities that use a Cone Beam CT unit shall follow the manufacturer's recommendations for Quality Control;

(4) All facilities shall perform calibrations and preventative maintenance annually.

(5) Preventative maintenance, surveys, and calibrations shall be reviewed and signed within a reasonable time of completion of the tests but no longer than 30 days of completion of the tests by a qualified medical physicist and the licensed dentist and any necessary corrective action shall be implemented within 30 days.

120.408: Veterinary X-ray Systems

(A) Equipment.

(1) Technique and Exposure Indicators.

(a) 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.

(b) The requirements of 105 CMR 120.408(A)(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.

(c) The x-ray control shall provide visual indication of the production of x-rays observable at or from the operator's protected position whenever x-rays are produced.

(2) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgen in one hour when the x-ray tube is operated at its leakage technique factors. Measurement is averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(3) The useful beam shall be restricted to the area of clinical interest and no larger than the size of the image receptor.

(4) Collimating devices shall be provided and shall limit the beam to the area of the image receptor to within 2% of the SID, and shall provide the same degree of protection as is required of the housing.

(5) The half-value layer of the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters and 70 kVp, and two millimeters aluminum equivalent for machines operating above 70 kVp.

(6) A device shall be provided to terminate the exposure after a preset time or Exposure.

(7) A dead-man type of exposure switch shall be provided, together with an exposure cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures.

(8) 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 (E) is greater than or equal to five times the maximum Exposure (E_{max}) minus the minimum Exposure (E_{min}):

$$E \geq 5 (E_{max} - E_{min})$$

(9) The primary beam shall be aligned with the film by using specified techniques in the facility's operating procedures.

(10) Fluoroscopic, CT, and therapy systems used in veterinary facilities shall meet the requirements of 105 CMR 120.405, 120.409 and 120.410 respectively, except the aural communications of 105 CMR 120.400, 120.422: *Appendix C*, 120.409(B)(1) and 120.410(B)(1).

(11) Portable machines shall be used in a manner which complies with 105 CMR 120.000.

(B) Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 105 CMR 120.211, 120.221 and 120.222.

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(C) Additional Operational Controls for Veterinary Facilities.

(1) All exams and retakes shall be ordered by the veterinarian.

(2) The x-ray tube shall not be held by any individual during radiographic exposures.

(3) Unless required to restrain an animal, the operator shall stand at least six feet away from the useful beam and the animal during radiographic exposures.

(4) No individual, other than the operator, shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.

(5) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used when technique permits.

(6) A pregnant female shall not hold or restrain an animal.

120.409: Computed Tomography (CT) X-ray Systems

Any facility offering CT services after April 30, 2011 shall have ACR accreditation.

Definitions. In addition to the definitions provided in 105 CMR 120.402, the following definitions shall be applicable

Computed Tomography Dose Index (CTDI) means the integral 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:

$$\overline{CTDI} = \frac{1}{n\,T}\int_{-\frac{nT}{2}}^{+\frac{nT}{2}} D(z)\,dz$$

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.

Computed Tomography Dose Index (CTDI) 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.

CT Dosimetry Phantom means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. Any effect 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.

Dose Profile means the dose as a function of position along a line.

Modulation Transfer Function means the modulus of the Fourier transform of the impulse response of the system.

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Noise means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (Sn) is calculated using the following expression:

$$S_n = \frac{100 \bullet \overline{CS} \bullet s}{\mu_w}$$

where:

$\overline{CS}$ = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

Picture Element means an elemental area of a tomogram.

Remanufacturing means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in 105 CMR 120.408 to manufacture, manufacturer, or manufacturing includes remanufacture, remanufacturing, respectively.

Sensitivity Profile means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

Single Tomogram System means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

(A) Equipment Requirements.

(1) Tomographic Plane Indication and Alignment.

(a) 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.

(b) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

(c) If a device using a light source is used to satisfy 105 CMR 120.409(A)(1)(a) or (b), 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

(2) 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 are 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.

(3) Initiation of Operation.

(a) The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(b) Means shall be provided to require operator initiation of each individual scan or series of scans.

(c) All emergency buttons/switches shall be clearly labeled as to their functions.

(4) Termination of Exposure.

(a) 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% of its preset value through the use of either a backup timer or devices which monitor equipment function.

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(b) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 105 CMR 120.409(A)(4)(a).

(c) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

(5) Extraneous Radiation. The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by 105 CMR 120.404(C).

(6) Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured after September 3, 1985.

(a) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.

(b) If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 seconds. 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.

(c) The deviation of indicated scan increment versus actual increment shall not exceed to within one millimeter with any mass from zero 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 can be taken anywhere along this travel.

(B) 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 System.

(a) 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.

(b) 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.

(C) Dose Measurements, Spot Checks, Surveys, and Calibrations.

(1) Dose Measurements.

(a) Dose measurements of the radiation output of the CT x-ray system shall be performed by a qualified medical physicist.

(b) Dose measurements of a CT x-ray system shall be performed at intervals specified by a qualified medical physicist and after any change or replacement of components which, in the opinion of a qualified medical physicist, could cause a change in the radiation output.

(c) Measurements of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated or inter compared with a calibrated chamber within the preceding two years. The calibration of such system shall be traceable to a national standard.

(d) Calibration procedures shall be in writing. Records of calibration performed shall be maintained for inspection by the Radiation Control Program.

(2) Spot Checks.

(a) Spot check procedures shall be in writing and developed by a qualified medical physicist.

(b) All spot checks shall be included in the calibration required by 105 CMR 120.409(C)(1), and otherwise at time intervals and system conditions specified by a qualified medical physicist.

(c) Spot checks shall include acquisition of images obtained with the phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by 105 CMR 120.409(C)(1). The images shall be retained until a new dose measurement is performed in two forms as follow:

120.409: continued

1. Photographic copies of the images obtained from the image display device; and
2. Images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.

(d) 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.

(e) Written records of the spot checks performed shall be maintained for inspection by the Agency.

(3) Surveys .

(a) All CT x-ray systems installed after March 3, 2012 and those systems not previously surveyed shall have a survey made by a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(b) The registrant of the facility [licensee] shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the Agency upon request.

(4) Physics Evaluations.

(a) The physics evaluation of the radiation output of the CT x-ray system shall be performed by a qualified medical physicist.

(b) The physics evaluation of a CT x-ray system shall be performed after initial installation and before use on human patients, annually or at intervals specified by a qualified medical physicist, and after any change or replacement of components which, in the opinion of the qualified medical physicist, could cause a change in the radiation output.

(c) The physics evaluation of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The physics evaluation of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

(d) 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:

1. 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;
2. 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;
3. 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;
4. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(e) The physics evaluation shall be required for each type of head, body, or whole-body scan performed at the facility.

(f) Physics evaluation shall meet the following requirements:

1. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant 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;

120.409: continued

2. The CTDi[2] along the two axes specified in 105 CMR 120.409(C)(4)(d)2. 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 of operation shall correspond to typical values used by the registrant.

3. The spot checks specified in 105 CMR 120.409(C)(2) shall be made.

(D) Additional Operational Controls for CT X-Ray Systems.

(1) The CT x-ray system shall only be operated by an individual who has been specifically trained in its operation and who holds a valid Massachusetts license in radiologic technology.

(2) Information shall be available at the control panel or in a specified location regarding the operation and calibration of the system. The information shall contain:

(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) The results of at least the most recent checks conducted on the system; and,

(c) The distance, in millimeters, between the tomographic plane and the reference plane, if a reference plane is utilized.

(3) 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 medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist.

(4) Quarterly reviews shall be conducted of dose protocols being used at the facility.

(5) Dose indicators shall be included in the patient's medical record.

(E) Mini CT Units.

(1) All facilities that use a Mini CT unit shall follow the manufacturer's recommendations for Quality Control.

(2) Operators of Mini CT units shall be:

(a) Licensed physician; or

(b) Licensed as a Radiologic Technologist.

(3) Each facility shall maintain the records of applications from the manufacturer.

120.410: Bone Densitometry

(A) Bone Densitometry Systems shall be:

(1) Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C – Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act.;

(2) Registered in accordance with 105 CMR 120.020;

(3) Maintained and operated in accordance with the manufacturer's specifications.

(B) Equipment Requirements. Systems with stepless collimators 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 2% of the SID.

(C) Operators of Bone Densitometry Systems shall be:

(1) Licensed as a radiologic technologist [by the Agency]; or

(2) A licensed physician; or

(3) International Society For Clinical Densitometry certified as a bone densitometry technologist; or

(4) ARRT certified in Bone Density

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[2] For the purpose of determining the CTDI, the manufacturer's statment as to the nominal tomographic section thickness for that particular system may be utilized.

120.410: continued

(D) During the Operation of any Bone Densitometry System:
(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.
(2) The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

(E) The Manufacturer's Quality Assurance and Quality Control programs shall be followed.

(F) The registrant of the facility shall keep maintenance records for bone densitometry systems. These records shall be maintained for inspection by the Agency for three years.

(G) Bone Densitometry on Human Patients Shall be Conducted Only:
(1) Under a prescription of a licensed practitioner of the healing arts; or
(2) Under a screening program approved by the Agency.

(H) Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in 105 CMR 120.421: *Appendix B* and include the name and address of the individual who will interpret the screening results.

(I) 105 CMR 120.010 includes CT units that are designed for bone density.

120.420: Appendix A -- Radiation Shielding and Safety Requirements

In order for the Radiation Control Program to provide an evaluation, and official approval on shielding requirements for a radiation installation, the following must be submitted. The plans shall show as a minimum the following:

(A) The normal location of the x-ray system's radiation port, the port's travel and transverse limits, general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth and the location of the x-ray control panel.

(B) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor and ceiling of the room(s) concerned.

(C) The dimensions of the room(s) concerned.

(D) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is any exterior wall, show distance to the closest area(s) where it is likely that individuals will be present.

(E) The make and model of the x-ray equipment.

(F) The typical type of examination(s) and treatment(s) which will be performed with the equipment.

(G) Information on the anticipated workload of the x-ray system(s).

(H) An interlock and/or warning light shall be installed at all egresses. For diagnostic x-ray installations, the warning light shall be wired to the rotor of the x-ray system.

(I) All basic assumptions used to determine the shielding requirements in developing these plans shall be submitted with these plans.

120.421: Appendix B -- Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

120.421: continued

(A) Name and address of the applicant and, where applicable, the names and addresses of agents within this Commonwealth.

(B) Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

(C) A detailed description of the x-ray examinations proposed in the screening program.

(D) Description of the population to be examined in the screening program, *i.e.*, age, sex, physical condition, and other appropriate information.

(E) An evaluation of any known alternate methods not involving ionizing radiation, which would achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.

(F) An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of 105 CMR 120.000.

(G) A description of the diagnostic film quality control program.

(H) A copy of the technique charts for the x-ray examination procedures to be used.

(I) The qualifications of each individual who will be operating the x-ray system(s).

(J) The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

(K) The name and address of the individual who will interpret the radiograph(s).

(L) Procedures to be used in advising the individuals screened and their practitioner of the healing arts or healthcare provider of the results of the screening procedure and any further medical needs indicated.

(M) The duration of the screening program.

120.422: Appendix C -- Design Requirements for an Operator's Booth

(A) Space Requirements

(1) The operator shall be allotted not less than 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth.

(2) The operator's booth may be any geometric configuration with no dimension of less than two feet (0.61 m).

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

(4) The booth shall be located or constructed such that unattenuated direct scatter radiation originating in the examination table or at the wall cassette shall not reach the operator's station in the booth.

(B) Structural Requirements

(1) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high.

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

(3) Shielding shall be provided to maintain exposure inside the booth equal to or less than two mR per week.

(C) X-ray Control Placement. The x-ray exposure switch for the system shall be fixed within the booth and;

(1) Shall be at least 40 inches (1.02 m) from any open edge of the booth and;

(2) Shall allow the operator to use the majority of the available viewing windows.

120.422: continued

(D) Viewing System Requirements.

(1) Each booth shall have at least one viewing device which will:

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

(b) The device should 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 that allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure, which will prevent the exposure if the door is not closed.

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

(a) The viewing area shall be at least one square foot (0.0929 m^2).

(b) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457m) from the edge of the booth.

(c) The material constituting the window shall have at least the same lead equivalence as that required in the booth's walls in which it is mounted.

(3) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 105 CMR 120.422: *Appendix C*(A)(4).

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

(a) The camera shall be so located as to accomplish the general requirements of 105 CMR 120.421: *Appendix C*(A)(4); and,

(b) There shall be an alternate viewing system as a backup for the primary system.

(c) Means shall be provided for the operator to be able to orally communicate with the patient at all times.

NON-TEXT PAGE

120.423: Appendix D – Exemptions from Shielding for Certain Fluoroscopic Procedures

(A) Angiograms

(B) Arthrograms

(C) Biliary drainage procedures

(D) Fluoroscopic biopsy procedures

(E) Myelograms

(F) Percutaneous cholangiograms

(G) Percutaneous nephrostomies

(H) Sinograms or fistulograms

(I) T-tube cholangiograms

120.430: THERAPEUTIC RADIATION MACHINES IN THE HEALING ARTS

120.431: Purpose and Scope

(A) 105 CMR 120.430 establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of 105 CMR 120.430 are in addition to, and not in substitution for, other applicable provisions of 105 CMR 120.000.

(B) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by 105 CMR 120.433(C).

120.432: Definitions

As used in 105 CMR 120.430, the following definitions apply:

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

Absorbed Dose Rate means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible Surface means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

Added Filtration means any filtration which is in addition to the inherent filtration.

120.432: continued

Air Kerma (K) means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

Barrier (*See* Protective Barrier in 105 CMR 120.005).

Beam Axis means the axis of rotation of the beam limiting device.

Beam-limiting Device means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

Beam Monitoring System means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Beam Scattering Foil means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Bent Beam Linear Accelerator means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Certified Health Physicist means and individual certified by the American Board of Health Physics as a health physicist.

Changeable Filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

Contact Therapy System means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

Conventional Simulator means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

Detector (*See* Radiation Detector in 105 CMR 120.402).

Dose Monitor Unit (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

Dosimetry System means a device which can measure radiation dose.

Electronic Brachytherapy means a method of radiation therapy using an electrically generated source of ionizing radiation 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.

External Beam Radiation Therapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening Filter means a filter used to flatten the absorbed dose rate over the radiation field.

120.432: continued

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 105 CMR 120.436.

Gantry means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

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

Intensity Modulated Radiation Therapy (IMRT) means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

Interlock means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Interruption of Irradiation means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Isocenter means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

Leakage Radiation means radiation emanating from the radiation therapy system except for the useful beam.

Light Field means the area illuminated by light, simulating the radiation field.

mA means milliampere.

Megavolt (MV) [Mega Electron Volt (MeV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note: current convention is to use MV for photons and MeV for electrons.]

Mobile Electronic Brachytherapy Service means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

Monitor Unit (MU) (*See* Dose Monitor Unit).

Moving Beam Radiation Therapy means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

Nominal Treatment Distance means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

Peak Tube Potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Periodic Quality Assurance Check means a procedure which is performed to ensure that a previous calibration continues to be valid.

Prescribed Dose means the total dose and dose per fraction as documented in the written directive.

420.432: continued

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 delivered.

Primary Protective Barrier (*See* 105 CMR 120.005: Protective Barrier).

Qualified Medical Physicist means an individual qualified in accordance with 105 CMR 120.433(D).

Radiation Field (*See* Useful Beam)

Radiation Head means the structure from which the useful beam emerges.

Redundant Beam Monitoring System means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

Secondary Dose Monitoring System means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Secondary Protective Barrier (*See* Protective Barrier in 105 CMR 120.005).

Simulator (Radiation Therapy Simulation System) means any x ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. (*See*: Conventional Simulator and Virtual Simulator.)

Source means the region and/or material from which the radiation emanates.

Source-skin Distance (SSD) (*See* Target-skin Distance).

Stationary Beam Radiation Therapy means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray Radiation means the sum of leakage and scattered radiation.

Target means that part of an x-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

Target-skin Distance (TSD) means the distance measured along the beam axis from the target to the surface of the irradiated object or patient.

Tenth-value Layer (TVL) means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

Termination of Irradiation means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Therapeutic Radiation Machine means x-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of 105 CMR 120.000, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

Tube means an x-ray tube, unless otherwise specified.

Tube Housing Assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

120.432: continued

Useful Beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

Virtual Simulator means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

Virtual Source means a point from which radiation appears to originate.

Wedge Filter means a filter which effects continuous change in transmission over all or a part of the useful beam.

Written Directive means an order, such as a physician's prescription, in writing, by an authorized user for the administration of radiation to a specific patient or human research subject, as specified in 105 CMR 120.435(A).

X-ray Tube means any electron tube which is designed to be used primarily for the production of x-rays.

120.433: General Administrative Requirements for Facilities Using Therapeutic Radiation Machines

(A) Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of 105 CMR 120.430 are met in the operation of the therapeutic radiation machine(s).

(B) Prohibition A therapeutic radiation machine which does not meet the provisions of 105 CMR 120.000 shall not be used for irradiation of patients.

(C) Training for Therapeutic Radiation Machine Authorized Users The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall require the authorized user to be a physician who:

(1) Is certified in:

(a) Radiology or therapeutic radiology by the American Board of Radiology; or

(b) Radiation oncology by the American Osteopathic Board of Radiology; or

(c) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.

(2) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(a) To satisfy the requirement for instruction in 105 CMR 120.433(C)(2), the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of ionization radiation; and
4. Radiation biology.

(b) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

1. Review of the full calibration measurements and periodic quality assurance checks;
2. Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
3. Using administrative controls to prevent misadministrations;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and,
5. Checking and using radiation survey meters.

120.433: continued

(c) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional year years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/ contraindications;
2. Selecting proper dose and how it is to be administered;
3. Calculating thetherapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and,
4. Post administration follow up and review of case histories.

(d) Notwithstanding the requirements of 105 CMR 120.433(C)(1) and (2), the registrant for any therapeutic radiation machine subject to 105 CMR 120.436 may also submit the training of the prospective authorized user physician for Agency review on a case by case basis.

(e) A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.

(D) Training for Qualified Medical Physicist for Radiation Therapy. The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall require the Qualified Medical Physicist to:

(1) Be registered with the Agency, under the provisions of 105 CMR 120.026, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and,

(2) Be certified by the American Board of Radiology in:

(a) Therapeutic radiological physics; or
(b) Roentgen-ray and gamma-ray physics; or
(c) X-ray and radium physics; or
(d) Radiological physics; or,

(3) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or,

(4) Be certified by the Canadian College of Medical Physics.

(E) Qualifications of Operators.

(1) Individuals who will be operating a therapeutic radiation machine for medical use shall possess a valid Massachusetts License as a Radiologic Technologists in Radiation Therapy.

(2) The names and the respective 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 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(F) Written safety procedures and rules shall be developed by a Qualified Medical Physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(G) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by an authorized user meeting the requirements of 105 CMR 120.433(C) who is specifically identified on the Certificate of Registration. 105 CMR 120.433(G) specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

120.433: continued

(H) Visiting Authorized User. Notwithstanding the provisions of 105 CMR 120.433(G), a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

(1) The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee; and

(2) The visiting authorized user meets the requirements established for authorized user(s) in 105 CMR 120.433(C)(1) and (2); and

(3) The registrant maintains copies of all records specified by 105 CMR 120.433(H) for five years from the date of the last visit.

(I) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's written directive program. In addition to the requirements of 105 CMR 120.430, these individuals are also subject to the requirements of 105 CMR 120.201 and 120.205.

(J) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

(1) Report of acceptance testing;

(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 105 CMR 120.430, as well as the name(s) of person(s) who performed such activities;

(3) Records of maintenance and/or modifications performed on the therapeutic radiation machine after July 9, 1999, as well as the name(s) of person(s) who performed such services;

(4) Signature of the Radiation therapy Physicist or Authorized User authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(K) Records Retention. All records required by 105 CMR 120.430 shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in 105 CMR 120.430. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

120.434 General Technical Requirements for Facilities Using Therapeutic Radiation Machines

(A) Protection Surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with 105 CMR 120.438. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation. The following standards must be met and recorded:

(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 105 CMR 120.211(A); and,

(b) Radiation levels in unrestricted areas do not exceed the limits specified in 105 CMR 120.221(A) and (B).

(2) In addition to the requirements of 105 CMR 120.434(A)(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

(a) After making any structural or composite modifications to the treatment room shielding;

(b) After making any changes in the location of the therapeutic radiation machine within the treatment room;

(c) After relocating the therapeutic radiation machine; or

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(d) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or a Certified Health Physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey;

(4) If the results of the surveys required by 105 CMR 120.434(A)(1) or (2) indicate any radiation levels in excess of the respective limit specified in 105 CMR 120.434(A)(1), the registrant shall lock the control in the "OFF" position and not use the unit:

(a) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(b) Until the registrant has received a specific exemption from the Agency.

(B) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by 105 CMR 120.434(A) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 105 CMR 120.221(A) and (B), before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 105 CMR 120.221(A) and (B);

(2) Perform the survey required by 105 CMR 120.434(A) again; and,

(3) Include in the report required by 105 CMR 120.434(D) the results of the initial survey, a description of the modification made to comply with 105 CMR 120.434(B)(1), and the results of the second survey; or,

(4) Request and receive a registration amendment under 105 CMR 120.221(C). that authorizes radiation levels in unrestricted areas greater than those permitted by 105 CMR 120.221(A) and (B).

(C) Dosimetry Equipment.

(1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

(a) For beams with energies greater than one MV (one MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(b) For beams with energies equal to or less than one MV (one MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 105 CMR 120.434(C)(1) This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 105 CMR 120.434(C)(1);

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 105 CMR 120.434(C)(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Qualified Medical Physicist.

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(D) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall furnish a copy of the records required in 105 CMR 120.434(A) and (B) to the Agency within 30 days following completion of the action that initiated the record requirement.

120.435: Written Directives

(A) A written directive, as defined in 105 CMR 120.432, must be dated and signed by an authorized user prior to the administration of radiation.

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 will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment target volume, and number of fractions.

(C)(1) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The registrant shall retain a copy of the written directive for three years.

(D) Procedures for Administrations of Doses of Radiation. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

(1) Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) Therapeutic radiation machine approved isodose plan and related calculations are in accordance with the respective written directives by:

(a) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive approved by the authorized user and reviewed by the qualified medical physicist; and

(b) 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.

(E) Reports and Notification of Medical Events.

(1) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of radiation from a radiation therapy machine results in:

(a) A dose that differs from the prescribed dose by more than 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

1. The total dose delivered differs from the prescribed dose by 20% or more;

2. The calculated weekly administered dose differs from the weekly prescribed dose by 30% or more; or

3. For a planned treatment course of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose; or

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4. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

(b) A dose that exceeds 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

1. An administration of a dose or dosage to the wrong individual or human research subject; or
2. An administration of a dose delivered by the wrong mode of treatment;

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% of the dose expected from the administration defined in the written directive.

(2) A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

(3) The registrant shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The registrant shall submit a written report to the Agency within 15 days after discovery of the medical event.

(a) The written report must include:

1. The registrant's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the administration;
6. Actions, if any, that have been taken, or are planned, to prevent recurrence;
7. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The registrant shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in 105 CMR 120.435 affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.435(E). A copy of the record required under 105 CMR 120.435(E) shall be provided to the referring physician if other than the registrant, within 15 days after discovery of the medical event.

(F) Records of Medical Events. A registrant shall retain a record of medical events reported in accordance with 105 CMR 120.435(E) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

120.436: Therapeutic Radiation Machines of Less than 500 kV

(A) Leakage Radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(1) 5-50 kV Systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one mGy (100 mrad) in any one hour.

(2) >50 and <500 kV Systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one cGy (one rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

(3) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 105 CMR 120.436(A)(1) and (2) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

(B) Permanent Beam Limiting Devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(C) Adjustable or Removable Beam Limiting Devices.

(1) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5% of the useful beam for the most penetrating beam used;

(2) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(D) Filter System. The filter system shall be so designed that:

(1) Filters can not be accidentally displaced at any possible tube orientation;

(2) For equipment installed after July 9, 1999, an interlock system prevents irradiation if the proper filter is not in place;

(3) The air kerma rate at a distance of one meter from the filter shall not exceed one cGy (one rad) per hour under any operating conditions; and,

(4) Each filter shall be marked as to its material of construction and its thickness.

(E) Tube Immobilization.

(1) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

(2) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(F) Source Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

(G) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(H) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(1) 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 or time remaining indicator;

(2) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(3) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(4) The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

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(5) The timer shall not permit an exposure if set at zero;
(6) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and,
(7) The timer and back-up timer if present shall be accurate to within 1% of the selected value or one second, whichever is greater.

(I) Control Panel Functions. The control panel, in addition to the displays required by other provisions in 105 CMR 120.436, shall have:
(1) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
(2) An indication of whether x-rays are being produced;
(3) Means for indicating x-ray tube potential and current;
(4) The means for terminating an exposure at any time;
(5) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
(6) For therapeutic radiation machines manufactured after July 9, 1999, a positive display of specific filter(s) in the beam.

(J) Multiple Tubes. When a control panel is capable of energizing more than one x-ray tube:
(1) It shall only be allowable to activate one X-ray tube at any time;
(2) There shall be an indication at the control panel identifying which x-ray tube is activated; and
(3) There shall be an indication at the tube housing assembly when that tube is energized.

(K) Target-to-skin Distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(L) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(M) Low-filtration X-ray Tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(N) Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 105 CMR 120.439, the treatment room shall meet the following design requirements:
(1) Aural Communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;
(2) Viewing Systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(O) Additional Requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:
(1) All protective barriers shall be fixed except for entrance doors or beam interceptors;
(2) The control panel shall be located outside the treatment room or inside the treatment room within a totally enclosed booth with protective barrier walls, door(s), ceiling and floor;
(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall 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; and

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(4) When any door referred to in 105 CMR 120.436(O)(3) is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

(P) Full Calibration Measurements.

(1) Full calibration of a therapeutic radiation machine subject to 105 CMR 120.436 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist:

(a) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(b) At intervals not exceeding one year; and

(c) Before medical use under the following conditions:

1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled; and

2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(d) Notwithstanding the requirements of 105 CMR 120.436(P)(1)(c):

1. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and

2. If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 105 CMR 120.436(P)(1)(c)1.

(2) To satisfy the requirement of 105 CMR 120.436(P)(1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Qualified Medical Physicist responsible for performing the calibration.

(Q) Periodic Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to 105 CMR 120.436, which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 105 CMR 120.436(Q)(1), quality assurance checks shall meet the following requirements:

(a) The registrant shall perform quality assurance checks in accordance with written procedures established by the Qualified Medical Physicist; and

(b) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 105 CMR 120.436(P)(1). They shall also state the acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 105 CMR 120.436(P)(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the Qualified Medical Physicist shall be investigated and corrected before the system is used for patient irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in 105 CMR 120.436(P)(1);

(5) The registrant shall use the dosimetry system described in 105 CMR 120.434(C)(2) to make the quality assurance check required in 105 CMR 120.436(Q)(2);

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(6) The registrant shall have the Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within 30 days of the date that the check was performed;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 105 CMR 120.436 are performed at intervals not to exceed 30 days;

(8) Notwithstanding the requirements of 105 CMR 120.436(Q)(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 105 CMR 120.436(Q)(6) and (7) have been performed within one month period immediately prior to said administration;

(9) To satisfy the requirement of 105 CMR 120.436(Q)(7), safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance;

(b) Proper operation of the "BEAM-ON" and termination switches;

(c) Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

(d) Viewing systems;

(e) If applicable, electrically operated treatment room doors activated from inside and outside the treatment room;

(10) The registrant shall maintain a record of each quality assurance check required by 105 CMR 120.436(Q)(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

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(R) Operating Procedures.

(1) The therapeutic radiation machine shall not be used for irradiation of patients unless and until the requirements of 105 CMR 120.436(P) and (Q) have been met;

(2) Therapeutic radiation machines shall not be left unattended unless secured pursuant to 105 CMR 120.436(I)(5);

(3) Mechanical supporting or restraining devices shall be used when a patient must be held in position for radiation therapy;

(4) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(6) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 105 CMR 120.211.

(S) Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 105 CMR 120.436 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten μSv (one mrem) per hour to ten mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 105 CMR 120.438.

120.437: Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)

(A) Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 105 CMR 120.437 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten Sv (one mrem) per hour to ten mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 105 CMR 120.438.

(B) Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(1) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (*i.e.* patient plane), shall not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

(2) Except for the area defined in 105 CMR 120.437(B)(1), the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

(3) For equipment manufactured after July 9, 1999, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 105 CMR 120.437(B)(1) through (B)(3) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

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(C) Leakage Radiation Through Beam Limiting Devices.

(1) Photon Radiation. The secondary collimators shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2% (averaged over a one cm squared area) of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm^2 radiation field, or maximum available field size if less than 100 cm^2;

(2) Electron Radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(a) A maximum of 2% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(b) A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of Leakage Radiation.

(a) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;

(b) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

(D) Filters/Wedges.

(1) Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

(2) If the absorbed dose rate information required by 105 CMR 120.437(I) relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

(3) For equipment manufactured after the effective date of these regulations which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

(a) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

(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 wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

(d) An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

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(E) X-ray/Neutron Contamination of the Useful Beam. For equipment manufactured after the effective date of these regulations, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

(F) Beam Monitors. All therapeutic radiation machines subject to 105 CMR 120.437 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(1) Equipment manufactured after the effective date of these regulations shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

(2) Equipment manufactured on or before the effective date of these regulations shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;

(3) 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, if movable, shall be interlocked to prevent incorrect positioning;

(b) Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

(c) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(d) For equipment manufactured after the effective date of these regulations, the design of the beam monitoring systems shall ensure that the:

1. Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

2. Failure of either system shall terminate irradiation or prevent the initiation of radiation.

(e) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these regulations, each display shall:

1. Maintain a reading until intentionally reset;

2. Have only one scale and no electrical or mechanical scale multiplying factors;

3. Utilize a design such that increasing dose is displayed by increasing numbers; and

4. In the event of power failure, the beam monitoring information required in 105 CMR 120.437(F)(3)(e)3. 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.

(G) Beam Symmetry.

(1) Bent-beam linear accelerators subject to 105 CMR 120.437 shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in 105 CMR 120.437(G)(1) shall be able to detect field asymmetry greater than 10%; and

(3) The device(s) referenced in 105 CMR 120.437(G)(1) shall be configured to terminate irradiation if the specifications in 105 CMR 120.437(G)(2) can not be maintained.

(H) Selection and Display of Dose Monitor Units.

(1) Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

(2) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

(3) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(4) For equipment manufactured after the effective date of these regulations, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

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(I) Air Kerma Rate/Absorbed Dose Rate. For equipment manufactured after October 6, 2006, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. [The radiation detectors specified in 105 CMR 120.437(F) may form part of this system.] In addition:

(1) The dose monitor unit rate shall be displayed at the treatment control panel;

(2) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(3) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four Gy (400 rad); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 105 CMR 120.437(I)(2) and (I)(3) for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Agency.

(J) Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

(1) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

(2) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(3) For equipment manufactured after July 9, 1999, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(K) Termination of Irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(L) Interruption of Irradiation. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from 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 pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(M) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(1) A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

(2) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(3) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(N) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

(2) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

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(3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation modality which has been selected;
(4) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;
(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
(6) 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.

(O) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
(1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
(2) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;
(3) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and
(4) For equipment manufactured after July 9, 1999, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

(P) Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:
(1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
(2) The mode of operation shall be displayed at the treatment control panel;
(3) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;
(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
(5) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1999:
(a) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10° of rotation or one cm of linear motion differs by more than 20% from the selected value;
(b) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5% from the dose monitor unit value selected;
(c) An interlock shall be provided to prevent motion of more than 5° or one cm beyond the selected limits during moving beam radiation therapy;
(d) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.
(e) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.
(6) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 105 CMR 120.437(J); and
(7) For equipment manufactured after July 9, 1999, an interlock system shall be provided to terminate irradiation if movement:
(a) Occurs during stationary beam radiation therapy; or
(b) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

120.437: continued

(Q) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of 105 CMR 120.439, the following design requirements are made:

(1) Protective Barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

(2) Control Panel. In addition to other requirements specified in 105 CMR 120.430, the control panel shall also:

(a) Be located outside the treatment room;

(b) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(c) Provide an indication of whether radiation is being produced; and

(d) Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine;

(3) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(4) Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(5) Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

(6) Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

(7) Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 105 CMR 120.221(A) and (B), interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

(8) Sliding Shielding Doors. Registrants with treatment rooms which utilize sliding shielding doors or other doors so massive that they may become jammed in the case of catastrophe will have in place an emergency plan to address such failure. In addition:

(a) Each door to a treatment room installed after July 9, 1999 will be equipped with an independent means of opening operable by a single able individual;

(b) Each sliding door installed after July 91, 1999 will be equipped with an electronic sensor which will immediately stop and disable the door closer (or reverse its motion) in the event of an imminent collision between the door and a person or object in its path.

(9) Emergency Cutoff Switches. At least three emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 105 CMR 120.437(K). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

(10) Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

(11) Surveys for Residual Radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(R) Qualified Medical Physicist Support.

(1) The services of a Qualified Medical Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Qualified Medical Physicist shall be responsible for:

120.437: continued

(a) Full calibration(s) required by 105 CMR 120.437(T) and protection surveys required by 105 CMR 120.434(A);
(b) Supervision and review of dosimetry;
(c) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
(d) Quality assurance, including quality assurance check review required by 105 CMR 120.437(U)(5);
(e) Consultation with the authorized user in treatment planning, as needed; and
(f) Perform calculations/assessments regarding medical events.

(2) Radiation therapy facilities shall have a minimum of one half-time qualified medical physicist available on a regular, on going, basis. In addition, radiation therapy facilities will have a minimum of one full time equivalent qualified medical physicist for every 500 total patients per year.

(3) If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by 105 CMR 120.437(S) shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

(S) Operating Procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 105 CMR 120.434(A), 120.437(T) and (U) have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

(T) Acceptance Testing, Commissioning and Full Calibration Measurements.

(1) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 105 CMR 120.437 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist.

(2) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" or most current AAPM recommendation or most current AAPM published recommendations and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

(3) Full calibration shall include measurement of all parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" or most current AAPM recommendation or the most current AAPM published recommendations. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.

(4) The Qualified Medical Physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

(a) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and

(b) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 105 CMR 120.437(T)(4)(a).

(5) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Qualified Medical Physicist responsible for performing the calibration.

(U) Periodic Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 105 CMR 120.437 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations;

(2) To satisfy the requirement of 105 CMR 120.437(U)(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations. Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been inter-compared within the previous 12 months with the dosimetry system described in 105 CMR 120.434(C)(1) to make the periodic quality assurance checks required in 105 CMR 120.437(U)(2);

(4) The registrant shall perform periodic quality assurance checks required by 105 CMR 120.437(U)(1) in accordance with procedures established by the Qualified Medical Physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(a) The authorized user and Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

(b) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or Qualified Medical Physicist within three treatment days; and

(c) The Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

(6) Therapeutic radiation machines subject to 105 CMR 120.437 shall have safety quality assurance checks listed in the most currently published recommendations of reports of the AAPM Radiation Therapy Committee Task Group 40 at intervals not to exceed the frequencies recommended therein;

(7) To satisfy the requirement of 105 CMR 120.437(U)(6), safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance;

(b) Proper operation of the "BEAM-ON", interrupt and termination switches;

(c) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(d) Viewing systems;

(e) Electrically operated treatment room door(s) from inside and outside the treatment room;

(f) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

120.437: continued

(8) The registrant shall promptly repair any system identified in 105 CMR 120.437(U)(7) that is not operating properly; and

(9) The registrant shall maintain a record of each quality assurance check required by 105 CMR 120.437(U)(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

(V) Quality Assurance Checks for IMRT shall:

(1) Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans [Note: IMRT is a rapidly evolving modality and the QA program shall also evolve to handle new issues that arise.]; and

(2) Be performed in accordance with "Dosimetry Tools and Techniques for IMRT - The report of AAPM Task Group 120" (2010), or current AAPM Recommendation"; and

(3) Be performed in accordance with the manufacturer's contractual specifications.

120.438: Calibration of Survey Instruments

(A) The registrant shall ensure that the survey instruments used to show compliance with 105 CMR 120.430 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(B) To satisfy the requirements of 105 CMR 120.438(A), the registrant shall:

(1) Calibrate all required scale readings up to ten mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately ⅓ and ⅔ of full-scale; and

(3) Calibrate automatically ranging digital display survey instruments at no less than one point on each decade and at no less than two points on one of these decades. These points should be at approximately ⅓ and ⅔ of the decade.

(C) To satisfy the requirements of 105 CMR 120.438(B), the registrant shall:

(1) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and,

(2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20% if a correction factor or graph is conspicuously attached to the instrument.

(D) The registrant shall retain a record of each calibration required in 105 CMR 120.438(A) for three 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.

(E) The registrant 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 105 CMR 120.438(D) shall be maintained by the registrant.

120.439: Shielding and Safety Design Requirements

(A) Each therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 105 CMR 120.211 and 120.221.

120.439: continued

(B) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for Agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in 105 CMR 120.440: *Appendix A*.

(C) Quality Assurance For Radiation Therapy Simulation Systems.

(1) Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance; and

(2) Be performed in accordance with "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No.40: AAPM Report No. 46" for a conventional simulator; or

(3) Be performed in accordance with "Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83" for a virtual simulator.

120.440: Appendix A: Information on Radiation Shielding Required for Plan Reviews

I. ALL THERAPEUTIC RADIATION MACHINES

A. Basic facility information including: name, telephone number and Agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. THERAPEUTIC RADIATION MACHINES UP TO 150 kV (PHOTONS ONLY)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at one meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale [0.25 inch = one foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 105 CMR 120.211.

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

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

(1) If commercial software is used to generate shielding requirements, please also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

NON-TEXT PAGE

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III. THERAPEUTIC RADIATION MACHINES OVER 150 kV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [*ie*: photon, electron]. The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at one meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = one foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [*ie*: room may be designed for six MV unit although only a four MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [*ie*: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. NEUTRON SHIELDING

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above ten MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [*ie*: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility.

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(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. REFERENCES

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

120.500: USE OF RADIONUCLIDES IN THE HEALING ARTS

GENERAL INFORMATION

120.501: Purpose and Scope

105 CMR 120.500 establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of 105 CMR 120.500 are in addition to, and not in substitution for, others in 105 CMR 120.000. The requirements and provisions of 105 CMR 120.000 apply to applicants and licensees subject to 105 CMR 120.500, unless specifically exempted. (*See* exemption in 105 CMR 120.104(C)(4)).

120.502: Definitions

As used in 105 CMR 120.500, the following definitions apply:

Address of Use means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

Area of Use means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

Associate Radiation Safety Officer means an individual who:

(1) Meets the requirements in 105 CMR 120.524 and 105 CMR 120.529; 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:

(a) A specific medical use license issued by the Agency, Nuclear Regulatory Commission or an Agreement State; or

(b) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Authorized Medical Physicist means an individual who:

(1) Meets the requirements in 105 CMR 120.525(A) and 120.529; or

(2) Is identified as a medical physicist or teletherapy physicist on:

(a) A specific medical use license or equivalent permit issued by the Agency, Nuclear Regulatory Commission or Agreement State;

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(b) A permit issued by the Agency, Nuclear Regulatory Commission or Agreement State medical use license of broad scope that is authorized to permit the use of radioactive material;
(c) A medical use permit issued by a NRC master material licensee; or
(d) A permit issued by a NRC master material license broad scope medical use permittee.

Authorized Nuclear Pharmacist means a pharmacist as defined in 105 CMR 120 005 who:
(1) Meets the requirements in 105 CMR 120.526(A) and 120.529; or
(2) Is identified as an authorized nuclear pharmacist on:
(a) A specific license issued by NRC or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
(b) A permit issued by a NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
(c) A permit issued by a NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
(d) A permit issued by a 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 105 CMR 120.128(J)(2)(d).

Authorized User means a physician, dentist, or podiatrist who:
(1) Meets the requirements in 105 CMR 120.529 and 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.569(A), or 120.587(A); or
(2) Identified as an authorized user on:
(a) A NRC or Agreement State license that authorizes the medical use of byproduct material;
(b) A permit issued by a NRC master material licensee that is authorized to permit the medical use of byproduct material;
(c) A permit issued by a NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or
(d) A permit issued by a NRC master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

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

Brachytherapy Source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's Address means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with 105 CMR 120.541.

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.

Dentist means an individual licensed by the Commonwealth to practice dentistry.

Diagnostic Clinical Procedures Manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

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High Dose-rate Remote Afterloader (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Low Dose-rate Remote Afterloader (LDR) means a device that remotely delivers a dose rate of less than or equal to two gray (200 rads) per hour at the treatment site.

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 therapy in which brachytherapy sources are manually applied or inserted.

Medical Institution means an organization in which several medical disciplines are practiced.

Medical Use means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

Medium Dose-rate Remote Afterloader (MDR) means a device that remotely delivers a dose rate of greater than two gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

Mobile Medical Service means the transportation of radioactive material and its medical use at the client's address.

Ophthalmic Physicist means an individual who:

(1) Meets the requirements in 105 CMR 120.564A(A)(2) and 105 CMR 120.529; and

(2) Is identified as an ophthalmic physicist on a:

(a) Specific medical use license issued by the Agency, Nuclear Regulatory Commission or an Agreement State;

(b) Permit issued by the Agency, Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

(c) Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

(d) Permit issued by a Nuclear Regulatory Commission master material 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 brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient Intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Preceptor means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

Prescribed Dosage means the quantity of a radiopharmaceutical activity as documented:

(1) In a written directive as specified in 105 CMR 120.521; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to 105 CMR 120.544, 120.547 and 120.552.

Prescribed Dose means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

120.502: continued

(3) For manual brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed Dose-rate Remote Afterloader (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who:

(1) Meets the requirements in 105 CMR 120.524(A) or (C)(1) and 120.529; or

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

(a) A specific medical use license issued by NRC or Agreement State; or

(b) A medical use permit issued by NRC master material license.

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

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic Radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a tissue volume.

Structured Educational Program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy as used in 105 CMR 120.500, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary Jobsite means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic Dosage means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic Dose means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment Site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of Use means use of radioactive material as specified under 105 CMR 120.544, 120.547, 120.552, 120.559, 120.569, 120.570 or 120.589.

Unit Dosage means a dosage that:

(1) Is obtained or prepared in accordance with 105 CMR 120.544, 120.547, 120.552; and

(2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Visiting Authorized User means an authorized user who is not identified on the license of the licensee being visited.

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Written Directive means 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 105 CMR 120.521.

120.503: Maintenance of Records

Each record required by 105 CMR 120.500 must be legible throughout the retention period specified by each Agency regulation. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and 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.

120.504: Provisions for Research Involving Human Subjects

A licensee may conduct research involving human subjects using radioactive material provided:

(A) That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(B) The research involving human subjects authorized in 105 CMR 120.504(A) shall be conducted using radioactive material authorized for medical use in the license; and

(C) Nothing in 105 CMR 120.504 relieves licensees from complying with the other requirements in 105 CMR 120.500.

(D) FDA, Other Federal, and State Requirements. Nothing in 105 CMR 120.500 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

120.505: Implementation

(A) A licensee shall implement the provisions in 105 CMR 120.500 on October 6, 2006.

(B) When a requirement in 105 CMR 120.500 differs from the requirement in an existing license condition, the requirement in 105 CMR 120.500 shall govern.

(C) Any existing license condition that is not affected by a requirement in 105 CMR 120.500 remains in effect until there is a license amendment or license renewal.

(D) If a license condition exempted a licensee from a provision of 105 CMR 120.500 on October 6, 2006, it will continue to exempt a licensee from the corresponding provision in 105 CMR 120.500.

(E) If a license condition cites provisions in 105 CMR 120.500 that will be deleted on October 6, 2006, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(F) Licensees shall continue to comply with any license condition that requires it to implement procedures required by 105 CMR 120.573, 120.579, 120.580 and 120.581 until there is a license amendment or renewal that modifies the license condition.

120.506: License Required

(A) A person shall only manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in 105 CMR 120.506(B)(1) or (2)

(B) (1) Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with 105 CMR 120.500 under the supervision of an authorized user as provided in 105 CMR 120.519.
(2) Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with 105 CMR 120.500 under the supervision of an authorized nuclear pharmacist or an authorized user as provided in 105 CMR 120.519.

120.507: Application for License, Amendments, or Renewal

(A) An application must be signed by the applicant's or licensee's management.

(B) An application for a license for medical use of radioactive material as described in 105 CMR 120.544, 120.547, 120.552, 120.559, 120.568, 120.570 or 120.589 must be made by:
(1) Filing an original and one copy of Agency application form MRCP 120.100- 4 that includes the facility diagram, equipment, and training, experience and qualifications of the Radiation safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and
(2) Submitting procedures required by 105 CMR 120.573, 120.579, 120.580 and 120.581, as applicable.

(C) A request for a license amendment or renewal must be made by:
(1) Submitting an original of either:
(a) Agency form MRCP 120.100- 4; or
(b) a letter containing all information required by Agency form MRCP 120.100- 4; and
(2) Submitting procedures required by 105 CMR 120.573, 120.579, 120.580 and 120.581, as applicable.

(D) In addition to the requirements in 105 CMR 120.507(B) and (C), an application for a license or amendment for medical use of radioactive material as described in 105 CMR 120.589 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in, or differ from, 105 CMR 120.501 through 120.543 and 105 CMR 120.590 through 120.594, identification of and commitment to follow the applicable radiation safety program requirements in 105 CMR 120.547 through 120.587 that are appropriate for the specific 105 CMR 120.589 medical use, as well as any specific information on:
(1) Radiation safety precautions and instructions;
(2) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
(3) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(E) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

(F) An applicant that satisfies the requirements specified in 105 CMR 120.127(B) may apply for a Type A specific license of broad scope.

120.508: License Amendments

A licensee shall apply for and must receive a license amendment:

(A) Before it receives, prepares or uses radioactive material for a type of use that is permitted under 105 CMR 120.500, but that is not authorized on the licensee's current license issued pursuant to 105 CMR 120.500;

120.508: continued

(B) Before it permits anyone to work as an authorized user, a visiting authorized medical physicist, a visiting ophthalmic physicist, or visiting authorized nuclear pharmacist to work under the license except:

(1) for an authorized user, an individual who meets the requirements in 105 CMR 120.529 and 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.569(A), and 120.587(A);

(2) for an authorized nuclear pharmacist, an individual who meets the requirements in 105 CMR 120.526(A) and 120.529;

(3) for an authorized medical physicist, an individual who meets the requirements in 105 CMR 120.525(A) and 120.529;

(4) An individual who is identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist or ophthalmic physicist on an Agency, or the U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

(5) An individual who is identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist or ophthalmic physicist on a permit issued by the Agency, or the U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or the practice of nuclear pharmacy, respectively.

(C) Before changing a Radiation Safety Officer, except as provided in 105 CMR 120.515(C);

(D) Before permitting 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;

(E) Before receiving radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(F) Before adding to or changing the areas of use identified in the application or on the license, except as specified in 105 CMR 120.509;

(G) Before changing the address(es) of use identified in the application or on the license;

(H) Before changing statements, representations, and procedures which are incorporated into the license;

(I) Before releasing licensed facilities for unrestricted use; and

(J) Before receiving 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.

120.509: Notifications

(A) A licensee shall provide to the Agency no later than 30 days after the date that the licensee permits an individual to work as an authorized user, authorized medical physicist, ophthalmic physicist or an authorized nuclear pharmacist pursuant to 105 CMR 120.508(B):

(1) A copy of the board certification and, as appropriate, verification of completion of:

(a) Training for the authorized medical physicist under 105 CMR 120.525(C);

(b) Any additional case experience required in 105 CMR 120.556(B)(1)(b)6. for an authorized user under 105 CMR 120.552; or

(c) Device specific training in 105 CMR 120.587(C) for the authorized user under 105 CMR 120.570; or

(2) A copy of the Agency, Nuclear Regulatory Commission or Agreement State license, the permit issued by a Nuclear Regulatory Commission master material licensee, the permit issued by the Agency, Nuclear Regulatory Commission or Agreement State licensee of broad scope, or the permit issued by a Nuclear Regulatory Commission master material license broad scope permittee.

120.509: continued

(B) A licensee shall notify the Agency by letter no later than 30 days after:
(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an ophthalmic physicist or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
(2) The licensee permits an authorized user or an individual qualified to be a Radiation Safety Officer, under 105 CMR 120.524 and 105 CMR 120.529, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with 105 CMR 120.515(C);
(3) The licensee's mailing address changes;
(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 105 CMR 120.131(B);
(5) The licensee has added to or changed the areas where radioactive material is used in accordance with 105 CMR 120.544 and 120.547; or
(6) 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 105 CMR 120.508(J). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

120.510: Exemptions Regarding Type A Specific Licenses of Broad Scope

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(A) The provisions of 105 CMR 120.507(D) regarding the need to file an amendment to the license for medical use of radioactive material as described in 105 CMR 120.589;

(B) The provisions of 105 CMR 120.508(B);

(C) The provisions of 105 CMR 120.508(F) regarding additions to or changes in the areas of use at the addresses specified in the license;

(D) The provisions of 105 CMR 120.509(A);

(E) The provisions of 105 CMR 120.509(B)(1) for an authorized user, an authorized nuclear pharmacist, an ophthalmic physicist or an authorized medical physicist;

(F) The provisions of 105 CMR 120.509(B)(5); and

(G) The provisions of 105 CMR 120.523(A) regarding suppliers for sealed sources.

120.511: License Issuance

(A) The Agency shall issue a license for the medical use of radioactive material if:
(1) The applicant has filed Agency application form MRCP 120.100- 4 in accordance with the instructions in 105 CMR 120.507;
(2) The applicant has paid any applicable fee;
(3) The applicant meets the requirements of 105 CMR 120.100; and
(4) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

(B) The Agency shall issue a license for mobile services if the applicant:
(1) Meets the requirements in 105 CMR 120.511(A); and,
(2) Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with 105 CMR 120.540.

120.513: Specific Exemptions

The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in 105 CMR 120.500 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

GENERAL ADMINISTRATIVE REQUIREMENTS

120.515: Authority and Responsibilities for the Radiation Protection Program

(A) In addition to the radiation protection program requirements of 105 CMR 120.210, a licensee's management must approve in writing:

(1) Requests for license application, renewal, or amendments before submittal to the Agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under 105 CMR 120.517.

(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 individual qualified to be a Radiation Safety Officer, under 105 CMR 120.534 and 120.529, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 105 CMR 120.515(E), provided the licensee takes the actions required in 105 CMR 120.515(B), (D), (E) and (H) and notifies the Agency in accordance with 105 CMR 120.509(B).

(D) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with 105 CMR 120.515(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) 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.

(G) Licensees that are authorized for two or more different types of radioactive material use under 105 CMR 120.552, 120.559, 120.570, and 120.589, or two or more types of units under 105 CMR 120.570 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

120.515: continued

(H) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each meeting in accordance with 105 CMR 120.590(A).

(I) A licensee shall retain a record of actions taken pursuant to 105 CMR 120.515(A), (B) and (E) in accordance with 105 CMR 120.590(A).

120.517: Radiation Protection Program Changes

(A) A licensee may revise its radiation protection program without Agency approval if:
(1) The revision does not require an amendment under 105 CMR 120.508;
(2) The revision is in compliance with the regulations and the license;
(3) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
(4) The affected individuals are instructed on the revised program before the changes are implemented.

(B) A licensee shall retain a record of each change in accordance with 105 CMR 120.590(B).

120.518: Duties of Authorized User and Authorized Medical Physicist

120.519: Supervision

(A) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 105 CMR 120.506(B)(1) shall:
(1) In addition to the requirements in 105 CMR 120.753, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures in 105 CMR 120.500, and license conditions with respect to the use of radioactive material;
(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 105 CMR 120.500, and license conditions with respect to the medical use of radioactive material; and
(3) Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.

(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 105 CMR 120.506(B)(2), 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, the written radiation protection procedures in 105 CMR 120.500, and license conditions.

(C) Unless physical presence as described in other sections of 105 CMR 120.500 is required, a licensee that permits supervised activities under 105 CMR 120.519(A) and (B) shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification; and

(D) A licensee that permits supervised activities under 105 CMR 120.519(A) and (B) is responsible for the acts and omissions of the supervised individual.

120.520: Visiting Authorized User, Visiting Authorized Nuclear Pharmacist, Visiting Ophthalmic Physicist or Visiting Medical Physicist

(A) A licensee may permit any visiting authorized user, visiting authorized nuclear pharmacist, visiting ophthalmic physicist or visiting authorized medical physicist to work as an authorized user, authorized nuclear pharmacist, ophthalmic physicist or medical physicist, respectively, under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user, the visiting authorized nuclear pharmacist, the visiting ophthalmic physicist or the visiting authorized medical physicist has the prior written permission of the licensee's management and, if the work is performed on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user, the visiting authorized nuclear pharmacist, the visiting ophthalmic physicist or the visiting authorized medical physicist by name as an authorized user for medical use, as an authorized nuclear pharmacist, as an ophthalmic physicist, or as an authorized medical physicist respectively; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license are performed by that individual.

(B) A licensee need not apply for a license amendment in order to permit a visiting authorized user, a visiting authorized nuclear pharmacist, a visiting ophthalmic physicist or a visiting authorized medical physicist to use licensed material as described in 105 CMR 120.520(A).

(C) A licensee shall retain copies of the records specified in 105 CMR 120.520(A) for three years from the date of the last visit.

120.521: Written Directives

(A) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 μCi), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

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 will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name and the following:

(1) For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

(2) For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

(3) For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

(4) For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(5) For permanent implant brachytherapy:

(a) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(b) 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

(6) For all other brachytherapy including LDR, MDR, and PDR:

(a) Prior to implantation: treatment site, the radionuclide, and dose; and,

(b) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose) and date.

120.521: continued

(C) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(D) The licensee shall retain the written directive in accordance with 105 CMR 120.590(C).

120.522: 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) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(B) The procedures required by 105 CMR 120.522(A) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations;

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 105 CMR 120.570 or 120.589;

(5) Determining if a medical event, as defined in 105 CMR 120.594(A), 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.

120.523: Suppliers for Sealed Sources or Devices Containing Sealed Sources for Medical Use

For medical use, a licensee may only use:

(A) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 105 CMR 120.100 and 120.128(L) or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(B) Sealed sources or devices non-commercially transferred from a 10 CFR Part 35 licensee or an Agreement State medical use licensee.

(C) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 105 CMR 120.100 or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State.

120.524: Training for Radiation Safety Officer and Associate Radiation Safety Officer

Except as provided in 105 CMR 120.528, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in 105 CMR 120.515 to be an individual who:

120.524: continued

(A) Is certified by a speciality board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.524(D). The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are 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) (a) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(b) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(c) Pass an examination administered by 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) (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and/or supervised experience in medical physics.

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, Nuclear Regulatory Commission or an Agreement State; or

2. In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 105 CMR 120.528, 120.551 or 120.556; and

3. 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) (1) Has completed a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and
5. Radiation dosimetry; and

(b) One year of full time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, or Nuclear Regulatory Commission license or permit issued by a Nuclear Regulatory Commission 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 an Agency, Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full time radiation safety experience must involve the following:

1. Shipping, receiving and performing related radiation surveys;
2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
3. Securing and controlling radioactive material;
4. Using administrative controls to avoid mistakes in the administration of radioactive material;
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
6. Using emergency procedures to control radioactive material; and
7. Disposing of radioactive material; and

120.524: continued

(2) 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 byproduct 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 105 CMR 120.524(B)(1) and 120.524(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 the Agency, Nuclear Regulatory Commission or an Agreement State under 105 CMR 120.525(A), has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and who meets the requirements in 105 CMR 120.524(D); or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an Agency, Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in 105 CMR 120.524(D); or

(3) Has experience with the radiation safety aspects of the types of use of byproduct 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. The individual must also meet the requirements in 105 CMR 120.524(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.

120.525: Training for Authorized Medical Physicist

Except as provided in 105 CMR 120.528, the licensee shall require the authorized medical physicist to be an individual who:

(A) Is certified by a speciality board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.525(C). The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are 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) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of full-time practical training and/or supervised experience in medical physics;

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State; or

(b) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 105 CMR 120.528, 120.566 or 120.587; and

120.525: continued

(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 one year of full-time training in medical physics and an additional year of fulltime 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 one million electron volts) and brachytherapy services and must include:

(a) Performing sealed source leak tests and inventories;

(b) Performing decay corrections;

(c) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(d) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.525(B)(1) and 120.525(C), and is able to independently fulfill the radiation safety-related duties 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 105 CMR 120.525, 120.528, or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

(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.

120.526: Training for an Authorized Nuclear Pharmacist

Except as provided in 105 CMR 120.528, 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 Agency, Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are 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) 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

120.526: continued

(B) (1) Has completed 700 hours in a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and
5. Chemistry of radioactive material for medical use; and

(b) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
4. Using administrative controls to avoid medical events in the administration of radioactive material; and
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 105 CMR 120.526(B)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

120.528: 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 on an Agency, Nuclear Regulatory Commission or Agreement State license or a permit issued by an Agency, Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019 need not comply with the training requirements of 105 CMR 120.524, 120.525, or 120.526, respectively, except the Radiation Safety Officers and authorized medical physicists identified in 105 CMR 120.528(A)(1) must meet the training requirements in 105 CMR 120.524(D) or 120.525(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 105 CMR 120.524 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an Agency, Nuclear Regulatory Commission or Agreement State license or Nuclear Regulatory Commission 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 105 CMR 120.525, for those materials and uses that these individuals performed on or before October 24, 2005.

120.528: continued

(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 Federal 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 105 CMR 120.524, 120.525 or 120.526, 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 105 CMR 120.528(A)(4), 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 105 CMR 120.500.

(B) (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Agency, Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by the Agency, Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556, 120.557, 120.558, 120.558A, 120.566, 120.567, 120.569 and 120.587.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Agency, Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by the Agency, Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556, 120.557, 120.558, 120.558A, 120.566, 120.567, 120.569 and 120.587 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(a) For uses authorized under 105 CMR 120.544 or 120.547, 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;

(b) For uses authorized under 105 CMR 120.552, 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;

(c) For uses authorized under 105 CMR 120.559 or 120.570, 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

(d) For uses authorized under 105 CMR 120.568, 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.

120.528: continued

(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 105 CMR 120.546, 120.551, 120.556, 120.557, 120.558, 120.558A, 120.566, 120.567, 120.569 and 120.587 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 105 CMR 120.528(B)(3), qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of 105 CMR 120.500.

(C) Individuals who need not comply with training requirements as described in 105 CMR 120.528 may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

120.529: Recentness of Training

The training and experience specified in 105 CMR 120.500 must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

GENERAL TECHNICAL REQUIREMENTS

120.531: Quality Control of Diagnostic Equipment

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

120.532: Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material

(A) For direct measurements performed in accordance with 105 CMR 120.534, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(B) A licensee shall calibrate the instrumentation required in 105 CMR 120.532(A) in accordance with nationally recognized standards or the manufacturer's instructions.

(C) A licensee shall retain a record of each instrument calibration required by 105 CMR 120.532 in accordance with 105 CMR 120.590(F).

120.533: Calibration of Survey Instruments

(A) A licensee shall ensure that the survey instruments used to show compliance with 105 CMR 120.200 and 120.500 have been calibrated before first use, annually, and following repair.

(B) To satisfy the requirements of 105 CMR 120.533(A), the licensee shall:

(1) Calibrate all required scale readings up to ten millisieverts (1000 mrem) per hour with a radiation source;

(2) Have each radiation survey instrument calibrated:

(a) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(b) For linear scale instruments, at two points located approximately ⅓ and ⅔ 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 three points between 0.02 and ten millisieverts (two and 1000 mrem) per hour; and

120.533: continued

(c) For dose rate instruments, so that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.

(3) Conspicuously note on the instrument the date of calibration.

(C) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20%.

(D) The licensee shall retain a record of each survey instrument calibration in accordance with 105 CMR 120.590(G).

120.534: Determination of Dosages of Unsealed Radioactive Material for Medical Use

(A) A licensee shall determine and record the activity of each dosage prior to medical use.

(B) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, or an Agreement State.

(C) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, or an Agreement State.

(D) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20%.

(E) A licensee shall retain a record of the dosage determination required by 105 CMR 120.534 in accordance with 105 CMR 120.590(H).

120.535: Authorization for Calibration, Transmission and Reference Sources

(A) Any person authorized by 105 CMR 120.506 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under 105 CMR 120.128(L) or equivalent Nuclear Regulatory Commission or Agreement State regulations;

(2) 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 105 CMR 120.128(L) or equivalent Nuclear Regulatory Commission 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;

(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);

(4) Any byproduct 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 105 CMR 120.297: *Appendix C*; or

(5) Technetium-99m in amounts as needed.

(B) Byproduct material in sealed sources authorized by 105 CMR 120.535 shall not be:

(1) Used for medical use as defined in 105 CMR 120.502 except in accordance with the requirements in 105 CMR 120.568; or

(2) Combined (*i.e.*, bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under 105 CMR 120.535.

120.535: continued

(C) A licensee using calibration, transmission, and reference sources in accordance with the requirements in 105 CMR 120.535(A) and (B) need not list these sources on a specific medical use license.

120.536: 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 or equivalent instructions approved by the Agency.

(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 six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(C) To satisfy the leak test requirements of 105 CMR 120.536(B), the licensee shall measure the sample so that the leak test can detect the presence of 185 becquerels (0.005 μCi) of radioactive material in the sample. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of 105 CMR 120.100 and 120.200; and,

(2) File a report with the Agency within five days of receiving the leak test results with the Agency describing the equipment involved, the test results, and the action taken.

(D) A licensee shall retain leak test records in accordance with 105 CMR 120.590(I)(1).

(E) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with 105 CMR 120.590(I)(2).

120.537: Labeling of Vials and Syringes

Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled, unless the label on the syringe or vial is visible when shielded.

120.539: Surveys for Ambient Radiation Dose Rate and Contamination

(A) In addition to the surveys required by 105 CMR 120.200, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

(B) A licensee does not need to perform the surveys required in 105 CMR 120.539(A) in area(s) where patients or human research subjects are confined when they can not be released pursuant to 105 CMR 120.540.

(C) A licensee shall retain a record of each survey in accordance with 105 CMR 120.590(J).

120.540: 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 five millisievert (0.5 rem). [NOTE: NRC Regulatory Guide, NUREG-1566, 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 five millisieverts (0.5 rem).]

(B) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(C) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 105 CMR 120.590(K)(1).

(D) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 105 CMR 120.590(K)(2).

(E) The licensee shall immediately notify the Agency in accordance with 105 CMR 120.594(D) if a patient departs prior to an authorized release.

120.541: Provision of Mobile Medical Service

The Agency may license mobile medical services and/or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(A) A licensee providing mobile medical service shall:

(1) Obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use and clearly delineates the authority and responsibility of the licensee and the client. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile medical service;

(2) 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 check for proper function required by 105 CMR 120.541(A)(2) must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 105 CMR 120.200.

(B) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(C) A mobile medical service shall inform the client's management who is on-site at each client's address of use at the time that radioactive material is being administered.

120.541: continued

(D) A mobile medical service licensee shall maintain all records required by 105 CMR 120.200 and 120.500 at a location within the Agency's jurisdiction that is:

(1) A single address:

(a) identified as the records retention location; and

(b) staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or

(2) When no address is identified on the license for records retention, the mobile unit:

(a) identified in the license; and

(b) whose current client's address schedule and location schedule is reported to the Agency.

(E) A licensee providing mobile medical services shall:

(1) Retain the letter required in 105 CMR 120.541(A)(1) in accordance with 105 CMR 120.590(L); and

(2) Retain a record of each survey required by 105 CMR 120.541(A)(4) in accordance with 105 CMR 120.590(L).

(F) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards.

120.542: Storage of Volatiles and Gases

(A) A licensee shall store volatile radiopharmaceuticals and radioactive gases in a radiation shield and container.

(B) A licensee shall store and use a multidose container in a properly functioning fume hood.

(C) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in 105 CMR 120.200.

(D) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(E) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for three years.

120.543: Decay-in-storage

(A) A licensee may hold radioactive material with a physical half-life of less than 120 days (or longer, if the Agency has approved it) for decay-in-storage before disposal without regard to its radioactivity if the licensee:

(1) Monitors radioactive material at the surface and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(2) Removes or obliterates all radiation labels except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

(3) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(B) For radioactive material disposed in accordance with 105 CMR 120.543(A), the licensee shall retain a record of each disposal in accordance with 105 CMR 120.590(M).

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, OR EXCRETION STUDIES

120.544: Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for Which a Written Directive Is Not Required

A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion:

(A)(1) Obtained from a manufacturer or preparer licensed pursuant to 105 CMR 120 128(J) or equivalent regulations of another Agreement State, or the Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(B) Excluding production PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551, or 120.556 and 120.551(C)(1)(b)7.; or

(3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.544(B)(1) or the physician who is an authorized user in 105 CMR 120.544(B)(2); or

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, 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

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

120.545: Possession of Survey Instrument

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour. The instrument shall be operable and calibrated in accordance with 105 CMR 120.533.

120.546: Training for Uptake, Dilution, and Excretion Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 105 CMR 120.544 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are 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 byproduct material for uptake, dilution, and excretion studies as described in 105 CMR 120.546(C)(1)(a) through (b)6.; 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 105 CMR 120.551 or 120.556, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

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(C) (1) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements 105 CMR 120.528, 120.546,120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects;

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.546(C)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 105 CMR 120.544. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.546, 120.551, or 120.556, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) 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 105 CMR 120.528, 120.546, 120.551, or 120.556, or equivalent Nuclear Regulatory Commission 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 105 CMR 120.546(C)(1).

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL WRITTEN DIRECTIVE NOT REQUIRED

120.547: Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required

A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 105 CMR 120.521 that is:

(A) Obtained from:

(1) A manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent regulations of another Agreement State, or the Nuclear Regulatory Commission;

(2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

120.547: continued

(B) Excluding production PET radionuclides prepared by:
(1) An authorized nuclear pharmacist;
(2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556 and 120.551(C)(1)(b)7.; or
(3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.547(B)(1) or the physician who is an authorized user in 105 CMR 120.547(B)(2); or

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, 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

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(E) Provided the conditions of 105 CMR 120.542 are met, a licensee may use radioactive aerosols or gases if specific application is made to and approved by the Agency.

120.548: Radionuclide Contaminants

(A) A licensee shall not administer to humans a radiopharmaceutical containing**:**
(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m); or
(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride); or
(3) More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

(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 105 CMR 120.548(A).

(C) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 105 CMR 120.548(A).

(D) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 105 CMR 120.590(N).

(E) The licensee shall report any measurement that exceeds the limits in 105 CMR 120.548(A) at the time of generator elution, in accordance with 105 CMR 120.594(F).

120.551: Training for Imaging and Localization Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 105 CMR 120.547 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are 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 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in105 CMR 120.551(C)(1)(a) through (b)7.; and

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(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 105 CMR 120.556 and meets the requirements of 105 CMR 120.551(C)(1)(b)7., or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies; the training and experience must include, at a minimum:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements of 105 CMR 120.528, 120.551, or 120.556 and 120.551(C)(1)(b)7., or equivalent Agreement State, or Nuclear Regulatory Commission requirements. An authorized nuclear pharmacist who meets the requirements in 105 CMR 120.526 or 120.528 may provide the supervised work experience for 105 CMR 120.551(C)(1)(b)7. Work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects; and
7. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic 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 105 CMR 120.551(C)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 105 CMR 120.544 and 120.547. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.551, or 120.556 and 120.551(C)(1)(b)7., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) 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 105 CMR 120.528, 120.551, or 120.556 and 120.551(C)(1)(b)7., or equivalent Nuclear Regulatory Commission 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 105 CMR 120.551(C)(1).

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL WRITTEN DIRECTIVE REQUIRED

120.552: Use of Unsealed Byproduct Material for Which a Written Directive Is Required

A licensee may use any unsealed radioactive material identified in 105 CMR 120.556(B)(1)(b)6. prepared for medical use and for which a written directive is required that is:

(A) Obtained from a manufacturer or preparer licensed in accordance with 105 CMR 120.128(J) or a PET radioactive drug producer licensed in accordance with 105 CMR 120.128(A), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(B) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, or a physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556, or an individual under the supervision of either as specified in 105 CMR 120.519; or

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

120.553: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who have received therapy with with a radioactive drug, and cannot be released in accordance with 105 CMR 120.540. To satisfy the requirement in 105 CMR 120.553(A), the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control to include the following:

(a) Routine visitation to hospitalized individuals in accordance with 105 CMR 120.221(A)(1) and (C);

(b) Contamination control;

(c) Waste control; and

(d) Notification of the RSO, or his or her designee, and the 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 105 CMR 120.590(P).

120.554: Safety Precautions

(A) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 105 CMR 120.540, a licensee shall:

(1) Quarter the patient or the human research subject either in:

(a) A private room with a private sanitary facility; or

(b) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with 105 CMR 120.540; and

(2) Visibly post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

120.554: continued

(3) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination 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 these materials and items as radioactive waste.

(B) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.556: Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of radioactive material for the uses authorized under 105 CMR 120.552 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.556(B)(1)(b)6. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission 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 105 CMR 120.556(B)(1)(a) through (b)5. 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 Committee on Post-graduate 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 byproduct 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 byproduct material requiring a written directive. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of byproduct material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in 105 CMR 120.556(B), must also have experience in administering dosages in the same dosage category or categories (*i.e.*,105 CMR 120.556(B)(1)(b)6.) as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

120.556: continued

6. Administering dosages of radioactive drugs to patients or human research subjects from the three categories in 105 CMR 120.556(B)(1)(b)6. Radioactive drugs containing radionuclides in categories not included in 105 CMR 120.556(B)(1)(b) 6. are regulated under 105 CMR 120.589. 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:

a. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

b. Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 [Note: *Experience with at least three cases in category (b) also satisfies the requirement in category (a)]*;

c. Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.556(B)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 105 CMR 120.552 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, or equivalent Nuclear Regulatory Commission 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

(b) 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 105 CMR 120.528, 120.556, or equivalent Nuclear Regulatory Commission 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 105 CMR 120.556(B)(1).

120.557: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabequerels (33 millicurie) for Which a Written Directive Is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.557(C)(1) and (2) and whose certification process has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)6.a. or b., 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

120.557: continued

(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Chemistry of radioactive material for medical use; and
(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B) must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)6.a. or b. The work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(c) Calculating, measuring, and safely preparing patient or human research subject dosages;
(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
(e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.557(C)(1) and (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 105 CMR 120.552. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)6.a. or b.; or
(b) 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 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)6.a. or b., 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 105 CMR 120.557(C)(1) and (2).

120.558: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabequerels (33 millicurie) for Which a Written Directive Is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.558(C)(1) and (2) and whose certification has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses License Toolkit Web page; or

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)6.b. or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or

120.558: continued

(C)(1) Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Chemistry of radioactive material for medical use; and,
(e) Radiation biology; and,

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, or 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)6.b.; the work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(c) Calculating, measuring, and safely preparing patient or human research subject dosages;
(d) Using administrative controls to prevent a medical event involving the use of byproduct material;
(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration 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 105 CMR 120.558(C)(1) and (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 105 CMR 120.552. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)6.b.; or
(b) 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 105 CMR 120.528, 120.556, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)6.b., 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 105 CMR 120.558(C)(1) and (2).

120.558A: Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

(A) Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under 105 CMR 120.556 for uses listed in 105 CMR 120.556(B)(1)(b)6.c., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(2) Is an authorized user under 105 CMR 120.566, 120.587, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and who meets the requirements in 105 CMR 120.558A(B); or

120.558A: continued

(3) Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State under 105 CMR 120.566 or 120.587, and who meets the requirements in 105 CMR 120.558A(B).

(B) The physician:

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in 105 CMR 120.556(B)(1)(b)6.c. The training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of byproduct material for medical use; and

(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in 105 CMR 120.556(B)(1)(b)6.c. A supervising authorized user who meets the requirements in 105 CMR 120.556, 120.558A, or equivalent Nuclear Regulatory Commission 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:

(a) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(e) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(f) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in 105 CMR 120.556(B)(1)(b)6.c.; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.558A(B)(1) and (2), 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:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in 105 CMR 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(b) 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 105 CMR 120.528, 120.556, 120.558A, or equivalent Nuclear Regulatory Commission 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 105 CMR 120.558A(B)(1) and (2).

MANUAL BRACHYTHERAPY

120.559: Use of Sealed Sources for Manual Brachytherapy

A licensee must use only brachytherapy sources:

(A) 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 U.S. Food and Drug Administration, provided the requirements of 105 CMR 120.523(A) are met.

120.560: Surveys After Source Implant and Removal

(A) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform 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 in accordance with 105 CMR 120.590(Q).

120.561: Brachytherapy Sources Accountability

(A) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(B) Promptly 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 105 CMR 120.592(A).

120.562: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subject that are undergoing brachytherapy and cannot be released in accordance with 105 CMR 120 540. Instruction must be commensurate with the duties of the personnel and shall include the following:

(1) Size and appearance of the brachytherapy sources;
(2) Safe handling and shielding instructions;
(3) Patient or human research subject control;
(4) Visitor control, including both;
  (a) Routine visitation of hospitalized individuals in accordance with 105 CMR 120.221(A)(1);
  (b) Visitation authorized in accordance with 105 CMR 120.221(C); and
(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or human research subject dies or has a medical emergency.
(6) A licensee shall retain a record of individuals receiving instruction in accordance with 105 CMR 120.590(P).

120.563: Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy

(A) For each patient or human research subject receiving brachytherapy and cannot be released in accordance with 105 CMR 120.540, a licensee shall:

120.563: continued

(1) Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy; and

(2) Visibly post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(B) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

(1) Dislodged from the patient; or

(2) Lodged within the patient following removal of the source applicators.

(C) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.564: Calibration Measurement of Brachytherapy Sealed Sources

(A) Prior to the first medical use of a brachytherapy sealed source on or after October 6, 2006, a licensee shall perform the following:

(1) Determine the source output or activity using a dosimetry system that meets the requirements of 105 CMR 120.575(A);

(2) Determine source positioning accuracy within applicators; and

(3) Use published protocols accepted by nationally recognized bodies to meet the requirements of 105 CMR 120.564(A)(1) and (2).

(B) A licensee may use measurements provided by the source manufacturer [or by a calibration laboratory accredited by the American Association of Physicists in Medicine] that are made in accordance with 105 CMR 120.564(A).

(C) A licensee shall mathematically correct the outputs or activities determined in 105 CMR 120.564(A) for physical decay at intervals consistent with 1.0% physical decay.

(D) An authorized medical physicist shall perform or review the calculation measurements made pursuant to 105 CMR 120.564(A), (B), or (C).

(E) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(B).

120.564A: Strontium-90 Sources for Ophthalmic Treatments

(A) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 105 CMR 120.564A(B) are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(a) is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, Nuclear Regulatory Commission or an Agreement State; permit issued by the Agency, Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

(b) 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

(c) has successfully completed one 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

(d) Has documented training in:

1. The creation, modification, and completion of written directives;

2. Procedures for administrations requiring a written directive; and

120.564A: continued

3. Performing the calibration measurements of brachytherapy sources as detailed in 105 CMR 120.564.

(B) The individuals who are identified in 105 CMR 120.564A(A) 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 105 CMR 120.564; 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 105 CMR 120.564A(A) 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) Licensees must retain a record of the activity of each strontium-90 source in accordance with 105 CMR 592(C).

120.565: Therapy-related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(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. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.

(C) The accuracy of isodose plots and graphic displays; and

(D) The accuracy of the software used to determine radioactive source positions from radiographic images.

120.566: Training for Use of Manual Brachytherapy Sources

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are 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 three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by 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:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;

120.566: continued

3. Mathematics pertaining to the use and measurement of radioactivity; and,
4. Radiation biology; and

(b) 500 hours work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical facility authorized to use byproduct materials under 105 CMR 120.559, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing brachytherapy sources;
4. Maintaining running inventories of material on hand;
5. Using administrative controls to prevent a medical event involving the use of byproduct material;
6. Using emergency procedures to control byproduct material; and

(2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.566(B)(1)(b); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.566(B)(1) and (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 105 CMR 120.528. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.566, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) 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 105 CMR 120.528, 120.566, or equivalent Nuclear Regulatory Commission 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 105 CMR 120.566(B)(1) and (2).

120.567: Training for Ophthalmic Use of Strontium-90

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is an authorized user under 105 CMR 120.566 or equivalent Agreement State or Nuclear Regulatory Commission 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:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity; and
(d) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user who meets the requirements in 105 CMR 120.566 or 120.567, and that includes the use of strontium-90 for ophthalmic treatment of five individuals that includes:

120.567: continued

(a) Examination of each individual to be treated;
(b) Calculation of the dose to be administered;
(c) Administration of the dose; and
(d) Follow-up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.566, 120.567 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.567(B)(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

SEALED SOURCES FOR DIAGNOSIS

120.568: Use of Sealed Sources and Medical Devices 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 105 CMR 120.523(A) are met.

120.569: Training for Use of Sealed Sources and Medical Devices for Diagnosis

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a diagnostic sealed source or a device authorized under 105 CMR 120.568 to be a physician, dentist, or podiatrist who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.569(C) and (D) and whose certification has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

(B) Is an authorized user for uses listed in 105 CMR 120.547 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(C) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:
(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.

PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

120.570: Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

(A) A licensee must only use sealed sources:

(1) Approved and as provided for 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 provided the requirements of 105 CMR 120.523(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 105 CMR 120.523(A) are met.

120.571: Surveys of Patients and Human Research Subjects Treated with 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.

(B) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.590(Q).

120.572: Installation, Maintenance, Adjustment, and Repair

(A) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, 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) drive 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 Agency, an Agreement State, or the Nuclear Regulatory Commission 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 Agency, an Agreement State, or the Nuclear Regulatory Commission, 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 done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 105 CMR 120.592(D).

120.573: 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 is unattended;

(2) Permit only individuals approved by 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. This procedure must include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(c) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(B) A copy of the procedures required by 105 CMR 120 573(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 105 CMR 120 573(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:

(a) The procedures identified in 105 CMR 120.573(A)(4); and

(b) 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 105 CMR 120.573(D), in accordance with 105 CMR 120.590(P).

(G) A licensee shall retain a copy of the procedures required by 105 CMR 120.573(A)(4) and (D)(2)(b) in accordance with 105 CMR 120.590(O).

120.574: 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;

120.574: continued

(2) Cause the source(s) to be shielded promptly when an entrance door is opened; and
(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(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 105 CMR 120.574(A) through (E), a licensee shall:
(1) For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:
(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and,
(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
(2) For high dose-rate remote afterloader units, require:
(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
(b) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
(4) Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(G) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:
(1) Remains in the unshielded position; or
(2) Lodges within the patient following completion of the treatment.

120.575: 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 two years and after any servicing that may have affected system calibration; or

120.575: continued

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee 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 available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 105 CMR 120.575(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 105 CMR 120.575(A).

(C) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with 105 CMR 120.592(E).

120.576: 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:

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(B) To satisfy the requirement of 105 CMR 120.576(A), full calibration measurements shall include determination of:

(1) The output within 3% for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy;

(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 105 CMR 120.575(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.576(B)(1) may then be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.576(A) in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall correct mathematically the outputs determined in 105 CMR 120.576(B)(1) for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137, or at intervals consistent with 1% decay for all other nuclides.

120.576: continued

(F) Full calibration measurements required by 105 CMR 120.576(A) and physical decay corrections required by 105 CMR 120.576(E) shall be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.577: 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; and

(2) Before medical use under the following conditions:

(a) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(b) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding one year for low dose-rate remote afterloader units.

(B) To satisfy the requirement of 105 CMR 120.577(A), full calibration measurements shall include, as applicable, determination of:

(1) the output within +/- 5%;

(2) Source position 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 applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(C) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 105 CMR 120.577(B), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(D) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output.

(E) A licensee shall make full calibration measurements required by 105 CMR 120.577(A) in accordance with published protocols accepted by nationally recognized bodies.

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 105 CMR 120.577(A) through (E).

(G) A licensee shall mathematically correct the outputs determined in 105 CMR 120.577(B)(1) for physical decay at intervals consistent with 1% physical decay.

(H) Full calibration measurements required by 105 CMR 120.577(A) and physical decay corrections required by 105 CMR 120.577(G) must be performed by the authorized medical physicist.

(I) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.578: 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; and

(2) Before medical use under the following conditions:

120.578: continued

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(c) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(B) To satisfy the requirement of 105 CMR 120.578(A), full calibration measurements shall include determination of:

(1) The output within ± 3%;
(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 microswitchs;
(9) Emergency timing circuits; and
(10) Stereotactic frames and localizing devices (trunnions).

(C) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.578(B)(1) may be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.578(A) in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall mathematically correct the outputs determined in 105 CMR 120.578(B)(1) at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1% physical decay for all other radionuclides.

(F) Full calibration measurements required by 105 CMR 120.578(A) and physical decay corrections required by 105 CMR 120.578(E) must be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.579: 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 105 CMR 120.575(B); and
(6) The difference between the measurement made in 105 CMR 120.579(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).

120.579: continued

(B) A licensee shall perform measurements required by 105 CMR 120.579(A) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the output spot-check measurements.

(C) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output 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 105 CMR 120.579(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 spot-check required by 105 CMR 120.579(A) and (D), in accordance with 105 CMR 120.592(G).

120.580: Periodic Spot-checks for Remote Afterloader Units

(A) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks on each remote afterloader facility and on each unit:

(1) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
(2) Prior to each patient treatment with a low dose-rate remote afterloader unit; and
(3) After each source installation.

(B) A licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in 105 CMR 120.580(A). The authorized medical physicist need not actually perform the spot-check measurements.

(C) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(D) To satisfy the requirement of 105 CMR 120.580(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.

120.580: continued

(E) If the results of the checks required in 105 CMR 120.580(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 spot-check required by 105 CMR 120.580(D), in accordance with 105 CMR 120.592(H).

120.581: 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 on each gamma stereotactic radiosurgery facility and on each unit:
(1) Monthly;
(2) At the beginning of each day of use; and
(3) After each source installation.

(B) A licensee shall have the authorized medical physicist:
(1) Establish written procedures for performing the spot-checks required in 105 CMR 120.581(A); and
(2) Review the results of each spot-check required by 105 CMR 120.581(A)(1) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

(C) To satisfy the requirement of 105 CMR 120.581(A)(1), spot-checks must, at a minimum:
(1) Assure proper operation of:
(a) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
(b) Helmet microswitchs;
(c) Emergency timing circuits; and
(d) Stereotactic frames and localizing devices (trunnions).
(2) Determine:
(a) The output for one typical set of operating conditions measured with the dosimetry system described in 105 CMR 120.575(B);
(b) The difference between the measurement made in 105 CMR 120.581(C)(2)(a) 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);
(c) Source output against computer calculation;
(d) Timer accuracy and linearity over the range of use;
(e) On-off error; and
(f) Trunnion centricity.

(D) To satisfy the requirements of 105 CMR 120.581(A)(2) and (3), spot-checks must assure proper operation of:
(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance
(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
(3) Viewing and intercom systems;
(4) Timer termination;
(5) Radiation monitors used to indicate room exposure; and
(6) Emergency off buttons.

(E) A licensee shall arrange for prompt repair of any system identified in 105 CMR 120.581(C) that is not operating properly.

(F) If the results of the checks required in 105 CMR 120.581(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 105 CMR 120.581(C) and (D) in accordance with 105 CMR 120.592(I).

120.582: Additional Technical Requirements for Mobile Remote Afterloader Units

(A) A licensee providing mobile remote afterloader service shall:
(1) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
(2) Account for all sources before departure from a client's address of use.

(B) In addition to the periodic spot-checks required by 105 CMR 120.580, 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 105 CMR 120.582(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 105 CMR 120.582(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 105 CMR 120.582(B) in accordance with 105 CMR 120.592(J).

120.583: Radiation Surveys

(A) In addition to the survey requirements in 105 CMR 120.225, a person licensed pursuant to 105 CMR 120.500 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 does not exceed the levels stated in the Sealed Source and Device Registry.

(B) The licensee shall make the survey required by 105 CMR 120.583(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 in 105 CMR 120.583(A) in accordance with 105 CMR 120.592(K).

120.584: Full Inspection Servicing 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 each 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 five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

(B) This inspection and servicing may 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 maintain a record of the inspection and servicing in accordance with 105 CMR 120.592(L).

120.585: Therapy-related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(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. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine radioactive 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.

120.587: Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a sealed source for a use authorized under 105 CMR 120.570 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in 105 CMR 120.587(C). The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission 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 three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by 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:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical facility that is authorized to use byproduct materials in 105 CMR 120.570, involving:

1. Reviewing full calibration measurements and periodic spot checks;
2. Preparing treatment plans and calculating treatment doses and times;
3. Using administrative controls to prevent a medical event involving the use of radioactive material;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
5. Checking and using survey meters; and
6. Selecting the proper dose and how it is to be administered; and

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(2) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.587(B)(1)(b); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.587(B)(1) and (2) and (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:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.587, or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(b) 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 105 CMR 120.528, 120.587, or equivalent Nuclear Regulatory Commission 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 105 CMR 120.587(B)(1) and (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.

OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

120.589: 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 that is not specifically addressed in 105 CMR 120.500 if:

(A) The applicant or licensee has submitted the information required by 105 CMR 120.507(B) through (D); and

(B) The applicant or licensee has received written approval from the Agency in a license and uses the material in accordance with 105 CMR 120.000 and specific conditions the agency considers necessary for the medical use of the material.

RECORDS

120.590: Requirements for Recordkeeping

(A) Records of Authority and Responsibilities for Radiation Protection Programs.

(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with 105 CMR 120.515(A) for five years. The record must include a summary of the actions taken and a signature of licensee management.

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(2) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 105 CMR 120.515(E), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 105 CMR 120.515(B). The record must include the signature of the Radiation Safety Officer and licensee management.

(3) For each Associate Radiation Safety Officer appointed under 105 CMR 120.515(B), the licensee shall retain, for five 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.

(B) Records of Radiation Protection Program Safety Changes. A licensee shall retain a record of each radiation protection program change made in accordance with 105 CMR 120.517(A) for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(C) Records of Written Directives. A licensee shall retain a copy of each written directive as required by 105 CMR 120.521 for three years.

(D) Records of Medical Events. A licensee shall retain a record of medical events reported in accordance with 105 CMR 120.594(A) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(E) Record of a Dose to an Embryo/Fetus or a Nursing Child. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 105 CMR 120.594(B) for three years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned of the embryo/fetus or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(F) 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 105 CMR 120.532 for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(G) Records of Survey Instrument Calibrations. A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.533 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(H) Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by 105 CMR 120.534 for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

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(I) Records of Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee shall retain a record of the leak test required by 105 CMR 120.536(B) for three years. The record must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source 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.

(2) A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 105 CMR 120.536(E) for three years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(J) Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by 105 CMR 120.539 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(K) Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.

(1) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered;

(b) Using an occupancy factor less than 0.25 at one meter;

(c) Using the biological or effective half-life; or

(d) Considering the shielding by tissue.

(2) A licensee shall retain a record, for three years after the date of release, that the instructions required by 105 CMR 120.540(B) were provided to a breast-feeding woman [if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five mSv (0.5 rem)].

(L) Records of Administrative and Technical Requirements That Apply to the Provision of Mobile Services.

(1) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by 105 CMR 120.541(A)(1), for three years after the last provision of service.

(2) A licensee shall retain the record of each survey required by 105 CMR 120.541(A)(4) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(M) Records of Decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by 105 CMR 120.543, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(N) Records of Radionuclide Purity. A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 105 CMR 120.548(B) and (C) for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide, or microcuries of contaminant per millicurie of desired radionuclide, the time and date of the measurement, and the name of the individual who made the measurement.

(O) Records of Safety Procedures. A licensee shall retain a copy of the procedures required by 105 CMR 120.573(A)(4) and (D)(2)(b) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

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(P) Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by 105 CMR 120.553, 120.562 and the operational and safety instructions required by 120.573 for three years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(Q) Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by 105 CMR 120.560 and 120.571 for three 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.

120.592: Requirements for Recordkeeping Pertaining to the Use of Sealed Sources

(A) Records of Brachytherapy Source Inventory.

(1) A licensee shall maintain a record of brachytherapy source accountability required by 105 CMR 120.561 for three years.

(2) For temporary implants, the record must include:

(a) 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

(b) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them from storage.

(3) For permanent implants, the record must include:

(a) 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;

(b) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(c) The number and activity of sources permanently implanted in the patient or human research subject.

(B) Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by 105 CMR 120.564 for three years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(C) Records of Decay of Strontium-90 Sources for Opthalmic Treatments. A licensee shall maintain a record of the activity of a strontium-90 source required by 105 CMR 120.564A for the life of the source. The record must include the date and initial activity of the source as determined under 105 CMR 120.564, and for each decay calculation, the date and the source activity as determined by 105 CMR 120.564A.

(D) Records of Installation, Maintenance, Adjustment, and Repair. 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 105 CMR 120.572 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(E) Records of Dosimetry Equipment.

(1) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 105 CMR 120.575 for the duration of the license.

(2) For each calibration, intercomparison, or comparison, the record must include:

(a) The date;

(b) The manufacturer’s name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 105 CMR 120.575(A) and (B);

(c) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

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(d) The names of the individuals who performed the calibration, intercomparison, or comparison.

(F) Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

(1) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 105 CMR 120.576, 120.577 and 120.578 for three years.

(2) The record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

(c) The results and assessments of the full calibrations;

(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) The signature of the authorized medical physicist who performed the full calibration.

(G) Records of Periodic Spot-checks for Teletherapy Units.

(1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 105 CMR 120.579 for three years.

(2) The record must include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(c) An assessment of timer linearity and constancy;

(d) The calculated on-off error;

(e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(f) The determined accuracy of each distance measuring and localization device;

(g) The difference between the anticipated output and the measured output;

(h) 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

(i) 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.

(H) Records of Periodic Spot-checks for Remote Afterloader Units.

(1) A licensee shall retain a record of each spot-check for remote afterloader units required by 105 CMR 120.580 for three years.

(2) The record must include, as applicable:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(c) An assessment of timer accuracy;

(d) 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

(e) 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.

(I) Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 105 CMR 120.581 for three years.

(2) The record must include:

(a) The date of the spot-check;

(b) 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;

(c) An assessment of timer linearity and accuracy;

(d) The calculated on-off error;

(e) A determination of trunnion centricity;

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(f) The difference between the anticipated output and the measured output;
(g) An assessment of source output against computer calculations;
(h) Notations indicating the operability of radiation monitors, helmet microswitchs, 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
(i) 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.

(J) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.
(1) A licensee shall retain a record of each check for mobile remote afterloader units required by 105 CMR 120.582 for three years.
(2) The record must include:
(a) The date of the check;
(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;
(c) Notations accounting for all sources before the licensee departs from a facility;
(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
(e) The signature of the individual who performed the check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(K) Records of Surveys of Therapeutic Treatment Units.
(1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 105 CMR 120.583 for the duration of use of the unit.
(2) The record must include:
(a) The date of the measurements;
(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
(d) The signature of the individual who performed the test.

(L) Records of Full Inspection Servicing for Teletherapy and Gamma Stereotactic Surgery Units.
(1) A licensee shall maintain a record of the full inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by 105 CMR 120.584 for the duration of use of the unit.
(2) The record must contain:
(a) The inspector's radioactive materials license number;
(b) The date of inspection;
(c) The manufacturer's name and model number and serial number of both the treatment unit and source;
(d) A list of components inspected and serviced, and the type of service; and
(f) The signature of the inspector.

REPORTS

120.594: Reports and Notifications

(A) Report and Notification of a Medical Event.
(1) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:
(a) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:
1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

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a. The total dose delivered differs from the prescribed dose by 20% or more;

b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

c. The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50% or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

a. An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

b. An administration of a radioactive drug containing byproduct material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment; or

e. A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

a. 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

b. 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(b) 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% 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% 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 discontiguous 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.

(2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

(a) The written report must include:

1. The licensee's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the individual(s) who received the administration;

6. Actions, if any, that have been taken, or are planned, to prevent recurrence; and

7. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

120.594: continued

(5) The licensee shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of 105 CMR 120.594(A)(5), the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in 105 CMR 120.594 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.590(D). A copy of the record required under 105 CMR 120.590(D) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.

(B) Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than five mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

(a) Is greater than five mSv (500 mrem) total effective dose equivalent; or

(b) 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 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(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 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

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(a) The written report must include:
1. The licensee's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect 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.

(b) 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 notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under 105 CMR 120.594(B)(1) or (2), 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 event because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. 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 event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with 105 CMR 120.590(E). A copy of the record required under 105 CMR 120.590(E) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(C) Reports of Leaking Sources. A licensee shall file a report with the Agency within five days if a leakage test required by 105 CMR 120.536 reveals the presence of 185 Becquerel (0.005 Ci) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(D) Reports of Patient Departure Prior to Authorized Release.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 105 CMR 120.540(A).

(2) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

(a) The licensee's name;

(b) The date and time of the unauthorized departure;

(c) The projected date and time when release would have occurred;

(d) The general location address of the patient's or human research subject's home or anticipated destination following departure;

(e) The radionuclide, chemical and physical form and calculated activity at time of release;

(f) The apparent reason(s) for the departure prior to authorized release; and

(g) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(E) Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 105 CMR 120.221 as a result of the deceased's body.

150.594: continued

(2) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 105 CMR 120.594(E)(1) has died. The written report must include:

(a) The licensee's name;

(b) The date of death;

(c) The radionuclide, chemical and physical form and calculated activity at time of death; and

(d) The names (or titles) and address(es) of known individuals who might have received exposures exceeding five mSv (500 mrem).

(F) Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

(1) The licensee shall notify by telephone the Agency and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 105 CMR 120.548(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.

(2) By an appropriate method listed in 105 CMR 120.013, the licensee shall submit a written report to the Agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. 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 105 CMR 120.594(F)(1).

120.600: RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

120.601: Purpose and Scope

105 CMR 120.600 provides special requirements for analytical X-ray equipment. The requirements of 105 CMR 120.600 are in addition to, and not in substitution for, applicable requirements in other Sections of 105 CMR 120.000.

120.602: Definitions

As used in 105 CMR 120.600, 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-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

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.

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.

120.602: continued

Open-beam Configuration means an analytical x-ray system in which an individual could accidently place some part of his body in the primary beam path during normal operation.

Primary Beam means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

120.603: 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:

(a) X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or,

(b) Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of 105 CMR 120.600, 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 105 CMR 120.237 and 120.238 if the radiation source is a radionuclide.

(E) Shutters. On open-beam configurations installed after the effective date of 105 CMR 120.600, 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) Warning Lights.

(1) An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

(a) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or,

(b) 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.

(2) On equipment installed after the effective date of 105 CMR 120.600, warning lights shall have fail-safe characteristics.

(G) Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

120.603: continued

(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.
(2) 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 five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.

(H) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five 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.

120.604: 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 105 CMR 120.221. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(B) Surveys.
(1) Radiation surveys, as required by 105 CMR 120.222, of all analytical x-ray systems sufficient to show compliance with 105 CMR 120.604(A) shall be performed:
(a) Upon installation of the equipment, and at least once every 12 months thereafter;
(b) Following any change in the initial arrangement, number, or type of local components in the system;
(c) Following any maintenance requiring the disassembly or removal of a local component in the system;
(d) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
(e) Any time a visual inspection of the local components in the system reveals an abnormal condition; and,
(f) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 105 CMR 120.211.
(2) Radiation survey measurements shall not be required if a registrant [or licensee] can demonstrate compliance with 105 CMR 120.604(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 105 CMR 120.238.

120.605: 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 105 CMR 120.605(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.

120.605: continued

(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.

120.606: 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:
(a) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and,
(b) Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.
(2) Reported dose values shall not be used for the purpose of determining compliance with 105 CMR 120.200 unless evaluated by a qualified expert.

120.620: LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

120.621: Purpose and Scope

(A) 105 CMR 120.620 contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. 105 CMR 120.620 also contains radiation safety requirements for operating irradiators. The requirements of 105 CMR 120.620 are in addition to other requirements of 105 CMR 120.000. In particular, the provisions of 105 CMR 120.001, 120.100, 120.200, 120.750 and 120.770 apply to applications and licenses subject to 105 CMR 120.620. Nothing in 105 CMR 120.620 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) 105 CMR 120.620 applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed five grays (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by 105 CMR 120.620.

(C) 105 CMR 120.620 does not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

120.622: Definitions

Annually means either:

(1) at intervals not to exceed one year; or
(2) once per year, at about the same time each year (plus or minus one month).

120.622: continued

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 doses rates exceeding five grays (500 rads) per hour exist at one 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 105 CMR 120.671 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 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.

Sealed Source means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Seismic Area means any area where the probability of horizontal acceleration in rock more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the U.S. Geological Survey.

Underwater Irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

120.631: Application for a Specific License

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

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

(C) Each application shall be signed by the applicant or licensee, or a person duly authorized to act for and on the applicant's or licensee's behalf.

(D) An application for a license may include a request for a license authorizing one or more activities. The Agency may require the issuance of separate specific licenses for those activities.

120.631: continued

(E) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection in accordance with 105 CMR 120.010. The Agency may also request additional information after the license has been issued to enable the Agency to determine whether the license should be modified or revoked.

(F) Each application for a specific license, unless otherwise exempted by the Agency, shall be accompanied by the fee prescribed by the Executive Office for Administration and Finance.

120.633: Specific Licenses for Irradiators

The Agency will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in 105 CMR 120.633.

(A) The applicant shall satisfy the general requirements specified in 105 CMR 120.100 and the requirements contained in 105 CMR 120.620.

(B) The application must describe the training provided to irradiator operators including:
(1) Classroom training;
(2) On-the-job or simulator training;
(3) Safety reviews;
(4) Means employed by the applicant to test each operator's understanding of the Agency's regulations and licensing requirements and the irradiator operating, safety, and emergency procedures; and
(5) Minimum training and experience of personnel who may provide training.

(C) The application must include an outline of the written operating, safety, and emergency procedures listed in 105 CMR 120.673 that describes the radiation safety aspects of the procedures.

(D) 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.

(E) The application must include a description of the access control systems required by 105 CMR 120.643, the radiation monitors required by 105 CMR 120.649, the method of detecting leaking sources required by 105 CMR 120.679, including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(F) 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:
(1) instruments to be used;
(2) methods of performing the analysis; and,
(3) pertinent experience of the individual who analyzes the samples.

(G) 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, the Commission, an Agreement State, or a Licensing State to load or unload irradiator sources.

(H) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by 105 CMR 120.681.

120.635: Commencement of Construction

Commencement of construction of a new irradiator may not occur prior to the submission to the Agency of both an application for a license for the irradiator and the prescribed fee. As used in 105 CMR 120.620 through 120.693, the terms "commencement of construction" and "construction" are defined in 105 CMR 120.102. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P, rules, regulations, and orders issued under M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P.

120.637: Applications for Exemptions

Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

120.639: Request for Written Statements

Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Agency's request, submit written statement to enable the Agency to determine whether the license should be modified, suspended, or revoked.

120.641: Performance Criteria for Sealed Sources

(A) Requirements for sealed sources installed after July 1, 1993:

(1) Must have been registered in accordance with 105 CMR 120.128(N);

(2) Must be doubly encapsulated;

(3) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and,

(5) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in 105 CMR 120.641(B) through (G).

(B) Temperature: The test source must be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to 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 five minutes to an external pressure (absolute) of two million newtons per square meter.

(D) Impact: A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of one meter onto the test source.

(E) Vibration: The test source must be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(F) Puncture: A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of one meter onto the test source.

(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 ten times the minimum cross-sectional dimension of the source.

120.643: 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 shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to the 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 radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in 105 CMR 120.643(B). The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(D) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(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 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 be posted as required by 105 CMR 120.238. Radiation postings for panoramic irradiators must comply with the posting requirements of 105 CMR 120.238, except that signs 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. The 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.

120.645: Shielding

(A) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (two 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 centimeters. Areas where the radiation dose rate exceeds 0.02 millisievert (two 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 millisievert (two millirems) per hour when the sources are in the fully shielded position.

(C) The radiation dose rate a one meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (two millirems) per hour and at five centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

120.647: 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.

120.649: 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 105 CMR 120.649(A).

(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.

120.651: 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 shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

(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 shielded position.

(D) Each control for a panoramic irradiator must be clearly marked as to its function.

120.653: Irradiator Pools

(A) For licenses initially issued after July 1, 1993, irradiator pools must either:
(1) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
(2) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(B) For licenses initially issued after July 1, 1993, 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 20 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 0.02 millisievert (two millirems) per hour.

120.655: 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 carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

120.657: Power Failures

(A) If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

(B) The lock on the door of the radiation room of a panoramic irradiator must remain locked in the event of 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.

120.659: Design Requirements

Irradiators whose construction began after July 1, 1993, must meet the design requirements of 105 CMR 120.659.

(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 105 CMR 120.645. If the irradiator will use more than five million curies (2×10^{17} becquerels) 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.

120.659: continued

(C) Pool Integrity: For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 105 CMR 120.653(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 105 CMR 120.653(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 105 CMR 120.649(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 105 CMR 120.679(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 105 CMR 120.643.

(H) Fire Protection: For panoramic irradiators, the licensee shall verify that the number, locations, 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 ten 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.

120.661: Construction Monitoring and Acceptance Testing

The requirements of 105 CMR 120.661 must be met for irradiators whose construction began after July 1, 1993. The requirements must be met prior to loading sources.

120.661: continued

(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 for verify that their construction meets design specifications.

(C) Pool Integrity: For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of 105 CMR 120.653(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 105 CMR 120.649(A). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet 105 CMR 120.679(B). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 105 CMR 120.649(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 105 CMR 120.655 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 that 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.

120.671: 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);

120.671: continued

(2) The requirements of 105 CMR 120.620 and 120.750 that are relevant to the irradiator;
(3) The operation of the irradiator;
(4) Those operating, safety, and emergency procedures listed in 105 CMR 120.673 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, safety, 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, safety, 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 brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
(1) Changes in operating, safety, and emergency procedures since the last review, if any;
(2) Changes in rules 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, safety, 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 105 CMR 120.673 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 105 CMR 120.643(B) and (I), 105 CMR 120.647(A), 120.649(A) and (B), and 120.679(B) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

120.673: Operating, Safety, 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 105 CMR 120.681;
(7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and,
(8) Inspection of movable shielding required by 105 CMR 120.643(H), if applicable.

120.673: continued

(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.

(C) The licensee may revise operating, safety, and emergency procedures without Agency approval only if all of the following conditions are met:

(1) The revisions do not reduce the safety of the facility;
(2) The revisions are consistent with the outline or summary of procedures submitted with the license application;
(3) The revisions have been reviewed and approved by the radiation safety officer; and
(4) The users or operators are instructed and tested on the revised procedures before they are put into use.

120.675: Personnel Monitoring

(A) Irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges) *see* 105 CMR 120.225(C)). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly.

(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, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of 105 CMR 120 675(B), a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ±30% of the true radiation dose.

120.677: 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 three 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 105 CMR 120.645 are exceeded, the facility must be modified to comply with the requirements in 105 CMR 120.645.

120.677: continued

(C) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(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 105 CMR 120.296: *Appendix B*, Table II, Column 2 or Table III, *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 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

120.679: Detection of Leaking Sources

(A) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Agency, the Commission, an Agreement State, or a Licensing State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Agency, the Commission, an Agreement State, or a Licensing State 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 six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear 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 Agency, Commission, Agreement State, or Licensing State 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 Agency, Commission, Agreement State, or Licensing State 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 105 CMR 120.296: *Appendix B*, Table II, Column 2. (*See* 105 CMR 120.282 for reporting requirements.)

120.681: 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 105 CMR 120.643.

(2) Functioning of the source position indicator required by 105 CMR 120.651(B).

(3) Operability of the radiation monitor for radioactive contamination in pool water required by 105 CMR 120.679(B) using a radiation check source, if applicable.

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by 105 CMR 120.649(B).

(5) Operability of the product exit monitor required by 105 CMR 120.649(A).

(6) Operability of the emergency source return control required by 105 CMR 120.651(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 105 CMR 120.647 (but without turning extinguishers on).

(9) Operability of the means of pool water replenishment required by 105 CMR 120.653(C).

(10) Operability of the indicators of high and low pool water levels required by 105 CMR 120.653(D).

(11) Operability of the intrusion alarm required by 105 CMR 120.643(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 105 CMR 120.655.

(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 105 CMR 120.683(B).

(B) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

120.683: Pool Water Purity

(A) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee 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 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

120.685: 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 105 CMR 120.671(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 105 CMR 120.671(F) and (G). Static irradiations may be performed without a person present at the facility.

120.687: 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 no one else is in it; and

(2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(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 105 CMR 120.649(B) is operating with backup power.

120.689: 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.

120.691 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 105 CMR 120.671(A), (B), (C), (D), (F), and (G) until three years after the individual terminates work.

(C) Records of the annual evaluations of the safety performance of irradiator operators required by 105 CMR 120.671(E) for three years after the evaluation.

(D) A copy of the current operating, safety, and emergency procedures required by 105 CMR 120.673 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 105 CMR 120.673(C)(3) retained for three years from the date of the change.

(E) Evaluations of personnel dosimeters required by 105 CMR 120.675 until the Agency terminates the license.

(F) Records of radiation surveys required by 105 CMR 120.677 for three years from the date of the survey.

(G) Records of radiation survey meter calibrations required by 105 CMR 120.677 and pool water conductivity meter calibrations required by 105 CMR 120.683(B) until three years from the date of calibration.

120.691: continued

(H) Records of the results of leak tests required by 105 CMR 120.679(A) and the results of contamination checks required by 105 CMR 120.679(B) for five years from the date of each test.

(I) Records of inspection and maintenance checks required by 105 CMR 120.681 for three years.

(J) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

(K) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by 105 CMR 120.009 and 120.140.

(L) Records on the design checks required by 105 CMR 120.659 and the construction control checks as required by 105 CMR 120.661 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 105 CMR 120.125(C)(1)(g).

120.693: Reports

(A) In addition to the reporting requirements in other parts of 105 CMR 120.000, the licensee shall report the following events if not reported under other parts of 105 CMR 120.000:

(1) Source stuck in an unshielded position.
(2) Any fire or explosion in a radiation room.
(3) Damage to the source racks.
(4) Failure of the cable or drive mechanism used to move the source racks.
(5) Inoperability of the access control system.
(6) Detection of radiation source by the product exit monitor.
(7) Detection of radioactive contamination attributable to licensed radioactive material.
(8) Structural damage to the pool liner or walls.
(9) Abnormal water loss or leakage from the source storage pool.
(10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(B) The report must include a telephone report within 24 hours as described in 105 CMR 120.142(C)(1), and a written report within 30 days as described in 105 CMR 120.142(C)(2).

120.700: RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

120.701: Purpose and Scope

(A) 105 CMR 120.700 establishes procedures for the registration and the use of particle accelerators.

(B) In addition to the requirements of 105 CMR 120.700, all registrants are subject to the requirements of 105 CMR 120.001, 120.020, 120.750, 120.100 and 120.200. Registrants engaged in industrial radiographic operations are subject to the requirements of 105 CMR 120.300, and registrants engaged in the healing arts are subject to the requirements of 105 CMR 120.430 and/or 105 CMR 120.500, and registrants engaged in wireline operations are subject to 105 CMR 120.900. Registrants whose operations result in the production of radioactive material are subject to the requirements of 105 CMR 120.100.

120.702: Registration Requirements

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to 105 CMR 120.020 or 120.100.

120.703: General Requirements for the Issuance of a Registration for Particle Accelerators

In addition to the requirements of 105 CMR 120.020 or 120.100, 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 in question for the purpose requested in accordance with 105 CMR 120.700, 120.200 and 120.750 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 105 CMR 120.704;

(D) The applicant has appointed a radiation safety officer;

(E) The applicant and/or the applicant's staff has 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 to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Agency; and,

(G) The applicant has an adequate training program for operators of particle accelerators.

120.704: Human Use of Particle Accelerators

In addition to the requirements of 105 CMR 120.020, a registration for use of a particle accelerator in the healing arts will be issued only if the applicant or registrant meets the requirements of 105 CMR 120.430 “THERAPEUTIC RADIATION MACHINES”.

120.705: 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 105 CMR 120.700 and the applicable requirements of 105 CMR 120.200 and 120.750, 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 or 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.

120.706: 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/or secondary barriers as are necessary to assure compliance with 105 CMR 120.211 and 120.221.

120.707: Particle Accelerator Controls and Interlock Systems

(A) Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

120.707: continued

(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.

120.708: Warning Devices

(A) Each location designated as high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(B) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of prompt radiation. Such warning device shall be clearly discernible in all high radiation areas.

(C) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 105 CMR 120.227 and 120.247.

120.709: 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 three 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 and/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.

120.710: Radiation Monitoring Requirements

(A) There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation before use or once every three months, whichever is the lesser.

(B) 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.

(C) 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.

(D) All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

(E) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

(F) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

(G) 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.

(H) Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the Agency.

120.711: 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 120.296: *Appendix B*, Table I.

(B) A registrant, as required by 105 CMR 120.221, shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in 105 CMR 120.296: *Appendix B*, Table II, except as authorized pursuant to 105 CMR 120.221(A)(3) or 120.222(C). For purposes of 105 CMR 120.711(B), concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

120.750: NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

120.751: Purpose and Scope

105 CMR 120.750 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 M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P and regulations, orders, and licenses issued thereunder regarding radiological working conditions. 105 CMR 120.750 applies to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the Agency pursuant to 105 CMR 120.020 and 105 CMR 120.100.

120.752: Posting of Notices to Workers

(A) Each licensee or registrant shall post current copies of the following documents:
(1) 105 CMR 120.750 and in 105 CMR 120.200;

120.752: continued

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
(3) The operating procedures applicable to activities under the license or registration; and,
(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 105 CMR 120.001, and any response from the licensee or registrant.

(B) If posting of a document specified in 105 CMR 120.752(A)(1), (2), or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(C) Form MRCP 120.750-1 "Notice to Employees" shall be posted by each licensee or registrant as required by 105 CMR 120.000.

(D) Agency documents posted pursuant to 105 CMR 120.752(A)(4) shall be posted within five working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(E) Documents, notices, or forms posted pursuant to 105 CMR 120.752 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.

120.753: Instructions to Workers

(A) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of one mSv (100 mrem)
(1) shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;
(2) shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
(3) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of 105 CMR 120.000 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, 105 CMR 120.000, 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 shall be furnished pursuant to 105 CMR 120.754.

(B) In determining those individuals subject to the requirements of 105 CMR 120.753(A), licensees 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 facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

120.754: 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 105 CMR 120.750. The information reported shall include data and results obtained pursuant to 105 CMR 120.000, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 105 CMR 120.267.

120.754: continued

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 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 105 CMR 120.750. You should preserve this report for future reference."

(B) Each licensee or registrant shall furnish to each worker annually a written report of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 105 CMR 120.267. The licensee shall provide an annual report to each individual monitored under 105 CMR 120.226 of the dose received in that monitoring year if:

(1) The individual's occupational dose exceeds one mSv (100 mrem) TEDE or one mSv (100 mrem) to any individual organ or tissue; or

(2) The individual requests his or her annual dose report.

(C) Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly 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 105 CMR 120.226. Such report shall be furnished within 30 days from the date of the request, 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 105 CMR 120.282, 120.283 or 120.284 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included in the report to the Agency. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

(E) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

120.755: Presence of Representatives of Licensees or Registrants and Workers During Inspection

(A) Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to 105 CMR 120.000.

(B) During an inspection, Agency inspectors may consult privately with workers as specified in 105 CMR 120.756. The licensee or registrant may accompany Agency inspectors 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 worker’s representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 105 CMR 120.753.

120.755: continued

(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 during the inspection of physical working conditions.

(G) Notwithstanding the other provisions of 105 CMR 120.755, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. 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.

120.756: Consultation with Workers During Inspections

(A) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of 105 CMR 120.000 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 inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of M.G.L. c. 111, §§, 5N, and 5P, 105 CMR 120.000, 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 105 CMR 120.757(A).

(C) The provisions of 105 CMR 120.756(B) shall not be interpreted as authorization to disregard instructions pursuant to 105 CMR 120.753.

120.757: Requests by Workers for Inspections

(A) Any worker or representative of workers believing that a violation of the Act, 105 CMR 120.000, 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, his 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 105 CMR 120.757(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 105 CMR 120.757 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 105 CMR 120.000 or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by 105 CMR 120.750.

120.758: Inspections not Warranted; Informal Review

(A) (1) If the Agency determines, with respect to a complaint under 105 CMR 120.757, 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 Department. The Department 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 Department. The Department will provide the complainant with a copy of such statement by certified mail.

(2) Upon the request of the complainant, the Department 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 Department 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 105 CMR 120.757(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 105 CMR 120.757(A).

120.760: Emergency Plans

The user should formulate suitable emergency plans as may be indicated to protect his employees and the public against potential hazards due to his specific source(s), and should make known the details and existence of such plans to the Agency and such other public agencies having a concern; including, but not limited to, boards of health, fire departments and police departments.

120.770: TRANSPORTATION OF RADIOACTIVE MATERIAL

120.771: Purpose and Scope

(A) 105 CMR 120.770 establishes requirements for packaging, preparation for shipment, and transportation of licensed material.

(B) The packaging and transport of licensed material are also subject to other sections of 105 CMR 120.000 and to the regulations of other agencies (such as the United States Department of Transportation, the United States Postal Service and the United States Nuclear Regulatory Commission) having jurisdiction over means of transport. The requirements of 105 CMR 120.770 are in addition to, and not in substitution for, other requirements

(C) 105 CMR 120.770 applies to any licensee authorized by specific or general license issued by the Agency to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Agency license, or transports that material on public highways. No provision of 105 CMR 120.770 authorizes possession of licensed material.

(D) Exemptions from the requirement for license in 105 CMR 120.773 are specified in 105 CMR 120.775. General licenses for which no NRC package approval is required are issued in 105 CMR 120.780 through 120.782. The general license in 105 CMR 120.777 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license. The transport of licensed material or delivery of licensed material to a carrier for transport is subject to the operating control and procedures requirements of 105 CMR 120.784 through 120.790, to the quality assurance requirements of 105 CMR 120.791 through 120.797, and to the general provisions of 105 CMR 120.771 through 120.774, including referenced United States Department of Transportation regulations.

120.771: continued

(E) 105 CMR 120.770 applies to any person required to obtaina certificate of compliance or an approved compliance plan from the NRC pursuant to 10 CFR 76 if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.

120.772: Definitions

The following terms are as defined here for the purpose of 105 CMR 120.770. 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 105 CMR 120.770, either unit may be used.

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in 105 CMR 120.798: *Appendix A*, Table A-1, or may be derived in accordance with the procedures prescribed in 105 CMR 120.798: *Appendix A*.

A_2 means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in 105 CMR 120.798: *Appendix A*, Table A-1, or may be derived in accordance with the procedures prescribed in 105 CMR 120.798: *Appendix A*.

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 Commission.

Certificate of Compliance (CoC) means the certificate issued by the Commission under 10 CFR 71 Subpart D 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 (1 x 10^{-5} $\mu Ci/cm^2$) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 (1 x 10^{-6} $\mu Ci/cm^2$) 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 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 105 CMR 120.781 and 120.782, 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.

120.772: continued

Deuterium means, for the purposes of 10 CFR 71.15 and 71.22, 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 uranium-233, uranium-235, plutonium-239, and plutonium-241, 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 105 CMR 120.772: Fissile Material.[1] Certain exclusions from fissile material controls are provided in 105 CMR 120.775.

Graphite means, for the purposes of 105 CMR 120.775 and 120.781, graphite with a boron equivalent content less than five 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 105 CMR 120.775(D), and which satisfies the descriptions and limits set forth in 105 CMR 120.772: Low Specific Activity (LSA) Material(1) through (3). 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.

(a) 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;

(b) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;

(c) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(d) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 105 CMR 120.798: *Appendix A*.

(2) LSA-II.

(a) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(b) 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:

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[1] Agency jurisdiction extends only to "special nuclear material in quantities not sufficient to form a critical mass" as defined in 105 CMR 120.005.

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(a) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, *etc.*);
(b) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, will not exceed 0.1 A_2; and
(c) The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2 x 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 alpha emitters with a half-life of less than ten days.

Maximun Normal Operating Pressure means the maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

Natural Thorium means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

Normal Form Radioactive Material means radioactive material which has not been demonstrated to qualify as special form radioactive material.

Nuclear Waste means a quantity of source, byproduct or special nuclear material required to be in US Nuclear Regulatory Commission-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

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 NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs./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 71.19.

Packaging means the assembly of components necessary to ensure compliance with the packaging requirements of 49 CFR Part 173. 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.

Regulations of the U.S. Department of Transportation (DOT) means the regulations in 49 CFR Parts 100 through 189 and Parts 390 through 397.

Regulations of the U.S. Nuclear Regulatory Commission (NRC) means the regulations in 10 CFR 71 for purposes of 105 CMR 120.770.

120.772: continued

Specific Activity of a radionuclide means the activity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the activity per unit mass of the material.

Surface Contaminated Object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(1) SCO-I: A solid object on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed four 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;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ 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

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (one 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.

(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} 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;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters; and

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters.

Transport Index means the dimensionless number (rounded up to the next tenth) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft.) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one 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 105 CMR 120.798: *Appendix A* or may be determined by procedures described in 105 CMR 120.798: *Appendix A*.

Type B Quantity means a quantity of radioactive material greater than a Type A quantity.

Unirradiated Uranium means uranium containing not more than 2×10^3 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium-235.

Uranium - Natural, Depleted, Enriched.

(1) Natural Uranium means uranium (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).

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(2) Depleted Uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.
(3) Enriched Uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

GENERAL REGULATORY PROVISIONS

120.773: Requirement for License

Except as authorized in a general license or a specific license issued by the Agency, or as exempted in 105 CMR 120.775, no licensee may:

(A) Deliver licensed material to a carrier for transport; or

(B) Transport licensed material.

120.774: Transportation of Licensed Material

(A) Each licensee who transports licensed material outside the site of usage, as specified in the 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 U.S. Department of Transportation 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:
(a) Packaging - 49 CFR Part 173: Subparts A and B and I.
(b) Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.441, and Subpart E.
(c) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.
(d) Accident reporting - 49 CFR Part 171: §§ 171.15 and 171.16.
(e) Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.
(f) Hazardous material employee training - 49 CFR Part 172: Subpart H.
(g) Security plans - 49 CFR Part 172: Subpart I.
(h) 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:
(a) Rail - 49 CFR Part 174: Subparts A through D, and K.
(b) Air - 49 CFR Part 175.
(c) Vessel - 49 CFR Part 176: Subparts A through F and M.
(d) Public Highway - 49 CFR Part 177 and Parts 390 through 397.

(3) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 105 CMR 120.242(E).

(B) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 107, 171 through 180 and 390 through 397 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Radiation Control Program.

120.775: Exemptions

(A) Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from 105 CMR 120.774 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under 105 CMR 120.775 must be licensed under 10 CFR Part 35 or the equivalent Agreement State regulations.

120.775: continued

(B) Common and contract carriers, freight forwarders, and warehouse workers who are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), and the U.S. Postal Service are exempt from the requirements of 105 CMR 120.770 to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 105 CMR 120.773 and other applicable requirements of 105 CMR 120.000.

(C) A licensee is exempt from all requirements of 105 CMR 120.770, 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 ten times the applicable radionuclide activity concentration values specified in 105 CMR 120.798: *Appendix A*, Table A-2, or *Table A-3*.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in 105 CMR 120.798: *Appendix A*, Table A-2, or *Table A-3*, or for which the consignment activity is not greater than the limit for an exempt consignment found in 105 CMR 120.798: *Appendix A*, Table A-2, or *Table A-3*.

(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 105 CMR 120.772.

(D) Fissile materials meeting one of the following requirements are exempt from the classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 10 CFR 71.59, but are subject to all other requirements of 10 CFR 71, except as noted.

(1) Individual package containing two grams or less fissile material.

(2) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

(3) (a) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

1. There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and
2. There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

(b) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of 1% by weight, and with total plutonium and uranium-233 content of up to 1% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5% of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2% by mass, with a total plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of two. The material must be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20% by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

120.776: General Licenses for Carriers

(A) A general license is hereby issued to any common or contract carrier not exempt under 105 CMR 120.775 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(B) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(C) Persons who transport radioactive material pursuant to the general licenses in 105 CMR 120.776(A) or (B) are exempt from the requirements of 105 CMR 120.200 and 120.750 to the extent that they transport radioactive material.

120.777: General License: Nuclear Regulatory Commission - Approved Packages

(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, or other approval has been issued by the Nuclear Regulatory Commission.

(B) This general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(C) Each licensee issued a general license under 105 CMR 120.777(A) shall:

(1) Maintain a copy of the NRC issued certificate of compliance, or other approval by the Nuclear Regulatory Commission 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 prior to shipment;

(2) Comply with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of 105 CMR 120.016(L), 105 CMR 120.771 through 120.774 and 105 CMR 120.784 through 120.797; and

(3) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

(D) The general license in 105 CMR 120.777(A) 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 the Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

120.779: General License: U.S. Department of Transportation Specification Container

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(B) This general license applies only to a licensee who:

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[3] Notification of an incident shall be filed with, or made to, the Agency as prescribed in 49 CFR, regardless of, and in addition to, notification made to U.S. Department of Transportation or other agencies.

120.779: continued

(1) Has a copy of the specification;
(2) Complies with the terms and conditions of the specification and the applicable requirements of 105 CMR 120.770; and
(3) Has a quality assurance program as required by 105 CMR 120.791.

(C) This general license in 105 CMR 120.779(A) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

(D) The general license specified in 105 CMR 120.779 expires on October 1, 2008.

120.780: 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 which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.23.

(B) This general license applies only to shipments made to or from locations outside the United States.

(C) Except as otherwise provided in 105 CMR 120.780, the general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the applicable provisions of 105 CMR 120.791 through 120.797.

(D) Each licensee issued a general license under 105 CMR 120.780(A) 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 105 CMR 120.016(L), 105 CMR 120.771 through 120.774 and 105 CMR 120.784 through 120.797.

120.781: General License: Fissile Material, Limited Quantity per Package

(A) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with 105 CMR 120.781. The fissile material need not be contained in a package which meets the standards of 10 CFR 71 Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(C) The general license applies only when a package's contents:
(1) Contain less than a Type A quantity of fissile material; and
(2) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(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 105 CMR 120.781(E);
(2) Has a value less than or equal to ten; 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).

120.781: continued

(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 I or II, as appropriate;

(4) If Table II 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 I values for X, Y, and Z must be used to determine the CSI if:

(a) Uranium-233 is present in the package;

(b) The mass of plutonium exceeds 1% of the mass of uranium-235;

(c) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(d) 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 I – Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per 105 CMR 120.781(E)

Fissile Materials	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[a] (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

[a] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15% of the moderating substance has an average hydrogen density greater than H2O.

120.781: continued

Table II – Mass Limits for General License Packages Containing Uranium-235
of Known Enrichment per 105 CMR 120.781(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

120.782: General License: Plutonium Beryllium Special Form Material

(A) A general license is issued to any licensee 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 105 CMR 120.782. This material need not be contained in a package which meets the standards of subparts E and F of 10 CFR 71; 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 Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(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 105 CMR 120.782(E);
(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:

$$CSI = 10\left[\frac{\text{grams of } {}^{239}Pu + \text{grams of } {}^{241}Pu}{24}\right];$$

(2) The calculated CSI must be rounded up to the first decimal place.

PACKAGE APPROVAL STANDARDS

120.783: External Radiation Standards for All Packages

(A) Except as provided in 105 CMR 120.783(B), 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/hr (200 mrem/hr) at any point on the external surface of the package, and the transport index does not exceed ten.

(B) A package that exceeds the radiation level limits specified in 105 CMR 120.783(A) 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):
(a) The shipment is made in a closed transport vehicle;
(b) The package is secured within the vehicle so that its position remains fixed during transportation; and,
(c) There are no loading or unloading operations between the beginning and end of the transportation;
(2) 2 mSv/h (200 mrem/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 two 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 two meters (6.6 ft.) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

120.783: continued

(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 105 CMR 120.226.

(C) For shipments made under the provisions of 105 CMR 120.783(B), 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.

OPERATING CONTROLS AND PROCEDURES

120.784: Assumptions as to Unknown Properties of Fissile Material

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

120.785: Preliminary Determinations

Prior to 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.

120.786: Routine Determinations

Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies applicable requirements of 10 CFR 71 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 which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

(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 10 CFR 71.47 at any time during transportation; and

120.786: continued

(K) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

120.787: Air Transport of Plutonium

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in 105 CMR 120.770 or included indirectly by citation of the U.S. Department of Transportation regulations, 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:

(A) The plutonium is contained in a medical device designed for individual human application;

(B) The plutonium is contained in a material in which the specific activity is not greater than or equal to the activity concentration values for plutonium specified in 105 CMR 120.798: *Appendix A*, Table A-2, and in which the radioactivity is essentially uniformly distributed;

(C) 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 105 CMR 120.774;

(D) The plutonium is shipped in a package specifically authorized (in the Certificate of Compliance issued by the Nuclear Regulatory Commission for that package) for the shipment of plutonium by air; or

(E) For a shipment of plutonium by air which is subject to105 CMR 120.787(D), the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

(F) Nothing in 105 CMR 120.787 is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

120.788: 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 105 CMR 120.242(E).

120.789: Records

(A) Each licensee shall maintain, for a period of three years after shipment, a record of each shipment of licensed material not exempt under 105 CMR 120.775(C), 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:
  (a) Identification by model number and serial number;
  (b) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and
  (c) 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 105 CMR 120.786 and by the conditions of the package approval.

120.789: continued

(B) The licensee shall make available to the Agency for inspection, upon reasonable notice, all records required by 105 CMR 120.770 through 120.798. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(C) 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 105 CMR 120.785; 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 three years after the life of the packaging to which they apply.

120.790: Advance Notification of Shipment of Nuclear Waste

(A)(1) As specified in 105 CMR 120.790(B) through (D), 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 105 CMR 120.790(B) through (D) each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in 105 CMR 120.790(C)(3)(c), 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 105 CMR 120.790 for shipment of licensed material meeting the following three conditions:

(1) The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;

(2) The licensed material is being transported into, within, or through a state 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:

(a) 3000 times the A_1 value of the radionuclides as specified in 105 CMR 120.798: *Appendix A*, Table A-1 for special form radioactive material;

(b) 3000 times the A_2 value of the radionuclides as specified in 105 CMR 120.798: *Appendix A*, Table A-1 for normal form radioactive material; or

(c) 1000 TBq (27,000 Ci).

(C) Procedures for Submitting Advance Notification.

(1) The notification must be made in writing to the office of each appropriate governor or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, and to the Director of the Agency.

(2) A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(a) 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).

(b) Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf.

120.790: continued

(c) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of 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 three years.

(D) Information to Be Furnished in Advance Notification of Shipment. Each advance notification of shipment of nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the nuclear waste shipment;

(2) A description of the 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 seven-day period during which departure of the shipment is estimated to occur;

(4) The seven-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact, with a telephone number, for current shipment information.

(E) Revision Notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with 105 CMR 120.790, 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 three years.

(F) Cancellation Notice.

(1) Each licensee who cancels a 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 to the Director of the Agency.

(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 three years.

QUALITY ASSURANCE

120.791: Quality Assurance Requirements

(A) Purpose. 105 CMR 120.791 through 120.797 describes 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 105 CMR 120.791 through 120.797, "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 the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to 105 CMR 120.791 through 120.797.

(B) Establishment of Program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 105 CMR 120.791 through 120.797 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.

120.791: continued

(C) Approval of Program. Before the use of any package for the shipment of licensed material subject to 105 CMR 120.791 through 120.797, each licensee shall obtain Agency approval of its quality assurance program. Using an appropriate method listed in 105 CMR 120.013, each licensee shall file a description of its quality assurance program, including a discussion of which requirements of 105 CMR 120.791 through 120.797 are applicable and how they will be satisfied, by submitting the description to the Agency.

(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 10 CFR 34.31(b) or equivalent Agreement State requirement, is deemed to satisfy the requirements of 105 CMR 120.777(B) and 120.791(B).

120.792: 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 functions that are important to safety have been correctly performed.

120.793: 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 105 CMR 120.791 through 120.797. 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 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.

(C) 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 they are executing.

120.794: Changes to Quality Assurance Program

(A) Each quality assurance program approval holder shall submit, in accordance with 105 CMR 120.013, 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. 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 105 CMR 120.791 through 120.797.

(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 105 CMR 120.013. 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 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.

120.795: 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.

120.796: 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 105 CMR 120.794. The records must include the instructions or procedures that 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 three years beyond the date when the licensee last engaged 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 three years after it is superseded.

120.797: 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.

120.798: 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 105 CMR 120.000 are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. 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 in Appendix AII(a) and II(b), to the Agency, in accordance with 105 CMR 120.013.

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 nuclide has a half-life either longer than ten days, or longer than that of the parent nuclide, 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 nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i 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.

Appendix A: continued

(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 for radioactivity for radionuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for radioradionuclide 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 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.

Appendix A: continued

(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

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(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)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	$2.7X10^{0}$	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	$2X10^{0}$	$5.4X10^{1}$	$2X10^{0}$	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
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		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	$2.7X10^{0}$	$1.0X10^{-1}$	$2.7X10^{0}$	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	$3.4X10^{0}$
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		$5.0X10^{0}$	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{0}$	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		$1.0X10^{0}$	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$5.8X10^{4}$	$1.6X10^{6}$
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)	$7.0X10^{0}$	$1.9X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195	Gold (79)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{0}$	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
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)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Ba-133		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$9.4X10^{0}$	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.9X10^{0}$	$5.2X10^{1}$
Bi-210		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
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)	$8.0X10^{0}$	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	$1.0X10^{0}$
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	$8.1X10^{0}$	$6.1X10^{1}$	$1.6X10^{3}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.6X10^{-1}$	$4.5X10^{0}$
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.3X10^{0}$	$2.2X10^{2}$
Cd-115 (a)		$3.0X10^{0}$	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	$7.0X10^{0}$	$1.9X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
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)		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		$3.0X10^{0}$	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	$4.1X10^{0}$
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$4.0X10^{0}$	$1.1X10^{2}$
Cf-251		$7.0X10^{0}$	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	$1.6X10^{0}$
Cf-252		$1.0X10^{-1}$	$2.7X10^{0}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	$1.1X10^{0}$	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		$9.0X10^{0}$	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$3.0X10^{0}$	$8.1X10^{1}$
Cm-245		$9.0X10^{0}$	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		$9.0X10^{0}$	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		$3.0X10^{0}$	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
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		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
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)	$4.0X10^{0}$	$1.1X10^{2}$	$4.0X10^{0}$	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
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		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{0}$	$8.7X10^{1}$
Cu-64	Copper (29)	$6.0X10^{0}$	$1.6X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
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)		$2.0X10^{0}$	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long-lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.5X10^{0}$	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.8X10^{0}$	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.7X10^{5}$	$7.3X10^{6}$
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)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	$5.4X10^{0}$	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	$7.0X10^{0}$	$1.9X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
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		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$1.2X10^{0}$	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	$9.0X10^{0}$	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
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		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		$2.0X10^{0}$	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.3X10^{-1}$	$3.5X10^{0}$
Hg-195m (a)		$3.0X10^{0}$	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
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		$5.0X10^{0}$	$1.4X10^{2}$	1	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	$1.8X10^{0}$
I-123	Iodine (53)	$6.0X10^{0}$	$1.6X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		$3.0X10^{0}$	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
I-134		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$9.9X10^{5}$	$2.7X10^{7}$
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)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		$7.0X10^{0}$	$1.9X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
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]$1.0X10^{0}$	[c]$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-79	Krypton (36)	$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
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		$8.0X10^{0}$	$2.2X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	$6.0X10^{0}$	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
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		$8.0X10^{0}$	$2.2X10^{2}$	$8.0X10^{0}$	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		$9.0X10^{0}$	$2.4X10^{2}$	$9.0X10^{0}$	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
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)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	$1.1X10^{0}$
Mo-99 (a) (h)		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
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		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$8.8X10^{0}$	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	$6.0X10^{0}$	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.1X10^{0}$	$5.7X10^{1}$
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)		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
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		$7.0X10^{0}$	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Os-185	Osmium (76)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	$2.0X10^{0}$	$5.4X10^{1}$	$7.0X10^{-2}$	$1.9X10^{0}$	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		$4.0X10^{0}$	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		$5.0X10^{0}$	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		$4.0X10^{0}$	$1.1X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		$1.0X10^{0}$	$2.7X10^{1}$	$5.0X10^{-2}$	$1.4X10^{0}$	$2.8X10^{0}$	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	$5.4X10^{0}$	$5.1X10^{4}$	$1.4X10^{6}$
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		$2.0X10^{0}$	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$5.2X10^{0}$	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
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		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	$1.0X10^{0}$	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		$4.0X10^{0}$	$1.1X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.4X10^{0}$	$3.7X10^{1}$
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)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	$1.6X10^{0}$	$3.8X10^{0}$	$1.0X10^{2}$
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)		$2.0X10^{-1}$	$5.4X10^{0}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	$5.4X10^{0}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	$1.0X10^{0}$
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Rb-81	Rubidium (37)	$2.0X10^{0}$	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
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)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		$3.0X10^{0}$	$8.1X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
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)		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$0.0X10^{0}$	$2.4X10^{-8}$
Rh-99	Rhodium (45)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		$4.0X10^{0}$	$1.1X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
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)	$3.0X10^{-1}$	$8.1X10^{0}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	$5.0X10^{0}$	$1.4X10^{2}$	$5.0X10^{0}$	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
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		$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
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		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.9X10^{0}$	$1.1X10^{2}$
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		$9.0X10^{0}$	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		$7.0X10^{0}$	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$
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)	$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$2.3X10^{3}$	$6.2X10^{4}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Sr-85		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		$5.0X10^{0}$	$1.4X10^{2}$	$5.0X10^{0}$	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$5.1X10^{0}$	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		$1.0X10^{0}$	$2.7X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$4.7X10^{5}$	$1.3X10^{7}$
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)	$1.0X10^{0}$	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
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		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
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		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
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		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{0}$	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		$5.0X10^{0}$	$1.4X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		$8.0X10^{0}$	$2.2X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
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		$5.0X10^{0}$	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231	Thorium (90)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.4X10^{0}$	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{0}$	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	$7.0X10^{0}$	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	$2.7X10^{0}$	$1.0X10^{3}$	$2.7X10^{4}$
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)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	$2.4X10^{0}$	$3.6X10^{-4}$	$9.7X10^{-3}$
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)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	$2.4X10^{0}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a), (d), (e), (f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d), (e), (f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less)(g)		Unlimited	Unlimited	Unlimited	Unlimited	N/A	N/A
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	$0.0X10^{0}$	*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)	$9.0X10^{0}$	$2.4X10^{2}$	$5.0X10^{0}$	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
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		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$3.7X10^{2}$	$1.0X10^{4}$
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		$2.0X10^{0}$	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		$3.0X10^{0}$	$8.1X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (79)	$4.0X10^{0}$	$1.1X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Zn-69m (a)		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$
Zr-95 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
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 ten 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
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-103	Rh-103m
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

Appendix A: continued

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* 105 CMR 120.798: *Appendix A – Determination of A_1 and A_2, subsection 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.

Appendix A: continued

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)	$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
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)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
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	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

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)
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	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
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	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
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		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166 (a)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

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)
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long-lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152 m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

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-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
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	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
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 (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

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)
Pa-230 (a)	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	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	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
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		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

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)
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
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		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Tb-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		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
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	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
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)	Uranium (92)	$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

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-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)	Uranium (92)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
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)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less)(g)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
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 (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a] [Reserved]

Appendix A: continued

[b] Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
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-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-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.

Appendix A: continued

Table A-3: General Values for A_1 and A_2)

Contents	A_1		A_2		Activity concentration for exempt material	Activity concentration for exempt material	Activity limits for exempt consignments	Activity limits for exempt consignments
	(TBq)	(Ci)	(TBq)	(Ci)	(Bq/g)	(Ci/g)	(Bq)	(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 radionuclides, 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 radio-nuclides are known to be present or no relevant data is 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 radionuclides 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}

120.800: LICENSING AND OPERATIONAL REQUIREMENTS FOR LOW-LEVEL RADIOACTIVE WASTE FACILITIES

120.801: Purpose and Scope

(A) 105 CMR 120.800 establishes procedures, performance objectives, criteria, terms and conditions governing the issuance of licenses for the treatment, storage or disposal of low-level radioactive wastes received from other persons, as well as the development, operation, closure, post-closure observation and maintenance, and institutional control of a low-level radioactive waste treatment, storage or disposal facility. The requirements of 105 CMR 120.800 are in addition to, and not in substitution for, other applicable requirements of 105 CMR 120.000.

(B) 105 CMR 120.800 is applicable to any low-level radioactive waste facility for treatment, storage, or disposal of all classes of waste, which are not exempt from regulation pursuant to 105 CMR 120.200 as well as any wastes that the Board has required to be treated, stored or disposed of at a low-level radioactive waste facility.

120.801: continued

(C) 105 CMR 120.800 is applicable to any method of treatment, storage or disposal except shallow land burial, as defined in 105 CMR 120.803. Shallow land burial is prohibited.

(D) Class A, B, C, as defined in 105 CMR 120.200, and mixed waste may be accepted for storage, treatment or disposal at a facility, if the Board so determines. Waste received at a facility shall be handled in accordance with the operational requirements of 105 CMR 120.800.

120.801: continued

(E) Any facility licensed pursuant to 105 CMR 120.800 may also accept NARM waste if the Board so determines. The limits of the quantities and concentrations of such NARM waste that may be accepted shall be specified as part of the waste acceptance criteria to be determined by the Board.

(F) No waste shall be acceptable for storage, treatment or disposal at a facility if either the Operator or the Department has reason to believe that the waste, as originally generated, was not radioactive. Acceptance of such waste shall be subject to penalty.

(G) No waste shall be accepted from an electric-power-generating facility if such waste requires regulations more stringent than the most stringent management required for any waste that may be accepted at the facility from another generator.

(H) In addition to the requirements of 105 CMR 120.800 all facility operations are subject to the requirements of 105 CMR 120.001, 120.100, 120.200 and 120.750. If a conflict in 105 CMR 120.000 exists, the more stringent provision shall apply.

(I) 105 CMR 120.800 does not authorize the treatment, storage or disposal of byproduct material as defined in 105 CMR 120.005: *Byproduct Material* in quantities greater than 10,000 kilograms containing more than five millicuries of radium-226. Nor do they apply to the disposal of radioactive material as provided for in 105 CMR 120.200.

120.802: Regulatory Authority

The authority for the Department of Public Health to promulgate 105 CMR 120.800 is found in: M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P; M.G.L. c. 111H, §§ 1, 7, 8, 11, 13, 16 and 31.

120.803: Definitions

As used in 105 CMR 120.800 the following definitions apply:

Accident means any event arising from the storage, treatment, recycling or disposal of waste that causes a discharge or dispersal of waste or elements contained in the waste from its intended place of confinement.

Active Maintenance means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in 105 CMR 120.811 and 120.812 are met. The term includes major remedial action such as replacement of disposal unit barrier. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit barriers, and general disposal site upkeep such as mowing grass.

Adverse Effect means an injurious impact which is significant in relation to the public health, safety, or environmental interest being protected.

Affected Community means a community, other than a site community, which is identified in an environmental impact report prepared pursuant to M.G.L. c. 111H, § 30, and can be expected to experience significant impacts as a result of the location, development, operation, closure, post-closure observation and maintenance or institutional control of a facility.

ALARA [acronym for "as low as reasonably achievable"] means making every reasonable effort to maintain exposures to radiation as far below the dose limits in 105 CMR 120.200 as is practical consistent with the purpose for which the licensed 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 materials in the public interest.

120.803: continued

Board means the Low-Level Radioactive Waste Management Board established in M.G.L. c. 111H, § 2.

Buffer Zone means a parcel of land which is an integral part of a facility that is controlled by the licensee and acts as a surrounding boundary to the facility.

Chelating Agent means certain organic compounds capable of forming (multiple) coordinate bonds with metals through two or more atoms of the organic compound, typically resulting in enhanced thermodynamic stability in solution and greatly altered behavior of the metal ions. Examples include amine polycarboxylic acids (*e.g.*, EDTA, DTPA), and polycarboxylic acids (*e.g.*, citric acid, carbolic acid, and gluconic acid).

Chief Executive Officer means the city manager in any city having a city manager, the mayor in any other city, the town manager in any town having a town manager, the chairman of the Board of Selectmen in any other town.

Closure means the permanent termination of low-level radioactive waste acceptance at a facility, including closure prior to the scheduled closing date, and the implementation of a closure plan.

Closure Plan means the plan, required as a condition of a facility license, prepared pursuant to regulations adopted under M.G.L. c. 111H, § 16, to assure safe facility closure after operation.

Commencement of Construction means initiation of site alteration or physical on-site construction activities. 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.

Community means a city or town of the Commonwealth.

Community Supervisory Committee means a committee, established pursuant to M.G.L. c. 111H, § 21, to facilitate the participation of a community, in which a candidate site is located, in the activities established by M.G.L. c. 111H.

Comprehensive Operating Contract means a contract entered into by an Operator and the Board pursuant to M.G.L. c. 111H, § 33.

Container means the primary vessel, exclusive of other reusable shielding or other packaging materials, in which waste is placed and received for treatment, storage or disposal; or the vessel into which waste is repackaged for storage or disposal and potential retrieval.

Days means calendar days; provided that in computing time periods such periods shall exclude the day of the event which starts the period running, and further provided that if the last day of a period falls on a Sunday, legal holiday or declared state of emergency day, such period shall be extended to the close of business on the next business day.

Department means Department of Public Health.

Department Environmental Monitoring Program means a monitoring program established by the Department, after consultation with the department of environmental protection and the board of health of each site community, for the purpose of collecting and analyzing environmental data prior to construction and throughout the construction, operation, closure, post-closure observation and maintenance and institutional control of a facility.

Detailed Site Characterization means the on-site investigatory and analytical step of site selection established in M.G.L. c. 111H, § 23 and conducted prior to the selection of any superior site.

120.803: continued

Development means all activities undertaken with respect to a low-level radioactive waste facility during the period commencing with the selection of any superior site pursuant to M.G.L. c. 111H, § 23 and continuing until the commencement of facility operation pursuant to M.G.L. c. 111H, § 39.

Disposal means the isolation of low-level radioactive waste from the biosphere inhabited by human beings and their food chains.

Disposal Unit means a discrete portion of a facility into which waste is emplaced for disposal.

Dose Modeling Program means a computational program for converting measured or expected radioactivity to dose equivalent for the relevant critical organ(s) which employs a formula selected by the facility operator and approved by the Department.

Emplacement of Waste means the placement of waste into a disposal unit for disposal.

Engineered Barrier means a manmade structure or device that is intended to improve a facility's ability to meet the performance objectives set forth in 105 CMR 120.811 through 120.814.

Facility means a parcel of land, together with the structures, equipment and improvements thereon or appurtenant thereto, which, pursuant to M.G.L. c. 111H, is being developed, is used, or has been used for the treatment, storage or disposal of low-level radioactive waste; but does not include any property used for temporary storage of low-level radioactive waste in sealed containers by a broker.

Facility License means a license to operate a facility issued by the Department pursuant to M.G.L. c. 111H, § 31.

Generator means a person, including a broker, who produces low-level radioactive waste.

Ground Water means water below the land surface in a saturated zone, including perched ground water.

Inadvertent Intruder means a person who, without regulatory authorization, enters upon the site of a facility after closure to engage in normal activities.

Institutional Control means the continued observation, monitoring and care of a facility following transfer of the facility license from the Operator to the Board.

Institutional Control Account means an account within the Low-Level Radioactive Waste Trust Fund established in M.G.L. c. 111H, § 41 for the purpose of paying institutional control costs pursuant to M.G.L. c. 111H, §§ 9 and 47.

Intruder Barrier means a sufficient layer of material surrounding waste that inhibits contact with the waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in 105 CMR 120.800, or engineered structures that provide equivalent protection to the inadvertent intruder.

Low-level Radioactive Waste means radioactive material that:

(1) is neither high-level waste, nor spent nuclear fuel, nor by-product material as defined in Section 11(e)(2) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. §2014(e); and

(2) is classified by the Federal Government as low-level radioactive waste, but not including waste which remains a Federal responsibility, as designated in Section 3(b) of the Low-Level Radioactive Waste Policy Act, as amended, 42 U.S.C. §2021c(b), as in effect as of December 8, 1987.

Low-level Radioactive Waste Trust Fund means a trust fund established pursuant to M.G.L. c. 10, § 35H which shall consist of surcharges collected from users of the low-level radioactive waste facility in an amount determined by the board on an annual basis, which shall be used to meet the obligations set forth in M.G.L. c. 111H, §§ 9 and 47.

120.803: continued

Manifest means a detailed record of the characteristics and quantities of packaged waste as presented for transportation, treatment, storage, or disposal which usually accompanies waste transfers for these purposes.

Mass Wasting means the movement of rock or soil material under the influence of gravity either as the movement of the product of weathering down a slope or as mass movement of rock or soil along joint planes or bedding planes. Mass wasting includes but is not limited to creep, mud flows, earth flow, soil flow, rock avalanche, landslide, landslip and slumping.

Mixed Waste means low-level radioactive waste containing material that either:

(1) is listed in 310 CMR 30.131 through 30.136; or
(2) causes the waste to exhibit any of the characteristics identified in 310 CMR 30.120.

Monitoring means observing and making measurements to provide data on a facility, its site, its surrounding environment, and its health safety and environmental impacts.

NARM means any naturally occurring or accelerator-produced radioactive material as defined in 105 CMR 120.001. It does not include byproduct, source, or special nuclear material.

Neighboring Community means a community, other than a site community, which, according to the most recent federal census, has at least 20% of its population residing within three miles of any superior site.

Operation means the control, supervision or implementation of the actual physical activities involved in the acceptance, storage, treatment, disposal or monitoring of low-level radioactive waste at a facility and the maintenance of the facility and any other responsibilities of the operation pertaining to the facility.

Operator means a person designated in accordance with the procedures established in M.G.L. c. 111H, §§ 22 and 27 to develop and operate a low-level radioactive waste facility.

Operator Environmental Monitoring Program means a monitoring program conducted by the Operator for the purpose of collecting and analyzing environmental data during the preoperational, operational, closure, post-closure observation and maintenance, and institutional control stages of a facility.

Person means any agency or political subdivision of the federal government or the commonwealth or of any state, any public or private corporation or authority, individual, firm, joint stock company, partnership, association, trust, estate, institution or other entity, and any officer, employee or agent of such person, and any group of such persons.

Post-closure Observation and Maintenance means the active monitoring and maintenance of a facility which has been closed in preparation for transfer of the facility's license from the Operator to the Board.

Public Interest means the common welfare, convenience, benefit and necessity of the people of the Commonwealth, including public health, safety and the environment.

Public Meeting means a public hearing, satisfying the requirements of M.G.L. c. 30A, § 2, in which an agency presents information, responds to inquiries and hears testimony of interested persons.

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

Radionuclide means an isotope that eventually undergoes spontaneous disintegration, with the emission of radiation.

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

Retrieval means the recovery of waste in an intact container.

120.803: continued

Retrievability means the ability to recover waste in an intact container without substantial destruction of the engineered barriers surrounding the waste containers.

Shallow Land Burial means a land disposal method that relies on the site's natural characteristics as the primary barrier for isolation of the waste.

Site means a parcel of land which, pursuant to M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P is being considered, developed or used or has been used as a location for a facility.

Site Community means the community in which is located all or any part of any superior site.

Source Minimization means minimizing the volume of radioactivity of low-level radioactive waste prior to its generation by such methods as:

(1) avoiding unnecessary contamination of items during the use of radioactive materials;
(2) carefully segregating radioactive waste from non-radioactive trash; or
(3) substituting non-radioactive isotopes or radioisotopes with shorter half-lives where practicable.

Stability means structural stability.

Storage means the holding of low-level radioactive waste for treatment or disposal.

Subsidence means the process by which the earth's surface sinks, either rapidly or slowly, with little or no horizontal motion.

Superior Site means any site selected by the Board, after detailed site characterization, pursuant to M.G.L. c. 111H, § 23.

Surveillance means observation of a facility for purposes of visual detection of the need for maintenance or custodial care, evidence of intrusion, or compliance with other license or regulatory requirements.

Temporary Closure means the nonpermanent termination of low-level waste acceptance at a facility prior to its scheduled closing date.

Treatment means any method, technique, or process including source minimization, volume minimization, and storage for decay, designed to change the physical, radioactive, chemical, or biological characteristics or composition of low-level radioactive waste in order to render such waste safer for management, amenable for recovery, convertible to another usable material or reduced in volume.

Violation means any act or failure to act which constitutes or results in one or more of the following:

(1) engaging in any business or other activity without a license or approval whenever engaging in such business or activity requires such license or approval.
(2) engaging in any activity prohibited by, or not in compliance with, any statute, by-law, ordinance or regulation.
(3) not fully doing, or not doing in timely fashion, anything required by any statute, by-law, ordinance or regulation.

Volume Minimization means treatment of low-level radioactive waste after its generation in order to minimize the physical dimensions of the waste and the. space required for disposal.

Waste means low-level radioactive waste.

Waste Form means those physical and chemical characteristics of waste of primary importance in influencing its stability in a disposal environment.

Waste Management Area means that portion of a facility where low-level radioactive waste has been, is being or will be treated, stored or disposed of.

120.810: General Requirements

(A) No person may treat, store or dispose of waste received from other persons, unless authorized by a license issued by the Department pursuant to 105 CMR 120.800 and 120.100.

(B) No license shall be issued to operate a disposal facility which does not permit monitoring and retrieval of the waste.

(C) In order to obtain a facility license pursuant to 105 CMR 120.800, an applicant shall provide full documentary evidence of having been designated an Operator, and shall demonstrate that the facility site has been selected and the facility is designed and will be constructed, operated, closed and controlled after closure so that the environmental and human exposure performance objectives set forth in 105 CMR 120.811 through 120.814 are satisfied.

(D) Any facility so licensed shall be constructed, operated, closed and controlled after closure so that environmental and human exposure performance objectives set forth in 105 CMR 120.811 through 120.814 are satisfied.

120.811: Protection of the General Population from Releases of Radioactivity

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants, or animals shall not result in an annual dose exceeding an equivalent of 25 millirems (0.25 mSv) to the whole body, 75 millirems (0.75 mSv) to the thyroid, and 25 millirems (0.25 mSv) to any other organ of any member of the public. The Operator shall assume initiatives which are necessary to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

120.812: Protection of Individuals from Inadvertent Intrusion

Design, operation, and closure of a facility shall ensure protection of any individual inadvertently intruding into the facility and occupying the site or contacting the waste at any time after active institutional controls over the facility are removed.

120.813: Protection of Individuals During Operations

Operations at a facility shall be conducted in compliance with the standards for radiation protection set out in 105 CMR 120.200, except for releases of radioactivity in effluents from the facility, which shall be governed by 105 CMR 120.811. The Operator shall assume initiatives which are necessary to maintain radiation exposures as low as is reasonably achievable.

120.814: Stability of the Facility After Closure

The facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the facility and to eliminate, to the extent practicable, the need for long-term active maintenance of the facility following closure so that only surveillance, monitoring, or minor custodial care are required.

120.815: Facility Design

(A) Any disposal method utilized at a facility shall permit retrieval and monitoring of the waste.

(B) Retrieval of waste from disposal units must be feasible through the institutional control period without adversely affecting the ability of the facility to meet the performance objectives set forth in 105 CMR 120.811 through 120.814.

(C) The Operator shall provide extensive security for the facility during the development, operation, closure, post-closure observation and maintenance, and institutional control of the facility for a period of time that ensures the health and safety of the general public and the environment. The Operator shall allow site community participation in this security planning process.

120.815: continued

(D) Any facility accepting waste for disposal shall, to the extent practicable, be designed, operated, closed and controlled after closure so as to maintain the gross physical properties and identity of such waste and containers for a minimum of 100 years for Class A waste, 300 years for Class B waste, and 500 years for Class C waste.

(E) Any disposal facility shall have its engineered structures designed with the goal to totally hold their waste content for the period of the hazardous life of the radioactive waste (zero release design objective).

120.816: Facility Institutional Control

(A) The design of any facility accepting waste for disposal shall be based on the assumption that the period of active institutional controls shall not exceed 100 years.

(B) The actual institutional control period shall not be less than the minimum time required for any waste present at the site to decay to the maximum concentrations above natural background levels permitted to be released into air or water in unrestricted areas under federal and state law.

120.820: License Required

(A) No person may treat, store or dispose of low-level radioactive waste received from other persons unless authorized by a license issued by the Department pursuant to 105 CMR 120.800 and 120.100.

(B) The Department shall not license any facility pursuant to 105 CMR 120.800 unless the Operator has provided a certification by the Board that the facility is proposed to be sited on a superior site selected pursuant to M.G.L c. 111H, § 23(g). Such certification shall not be made unless the time period set forth in M.G.L. c. 111H, § 24(a) for the filing of a petition for an adjudicatory proceeding has expired without such a petition being filed or, if such petition has been filed, until the Department of Environmental Protection has issued a final decision approving the selection of the superior site pursuant to M.G.L. c. 111H, § 24(c).

(C) Except as provided in M.G.L. c. 111H, § 12(b)(10), the Department shall not issue a facility license unless the person making application for such license has provided full documentation of having been designated an Operator in accordance with the procedures established pursuant to M.G.L. c. 111H, §§ 22 and 27.

(D) The Department shall not issue such a license unless the Operator has obtained all other permits and licenses required by law in order to commence construction of a facility.

120.821: Licensing Process

The procedures for a license application shall include the following:

(A) An Operator shall file an application with the Department pursuant to 105 CMR 120.124 and obtain a license as provided in 105 CMR 120.800 before commencement of construction of the facility. Failure to comply with this requirement may be grounds for denial of a license.

(B) After an Operator files, with the Secretary of the Executive Office of Environmental Affairs (EOEA), its notification of intent to apply for a facility license, it may file a facility license application with the Department.

(C) The license application shall be determined to be complete when the Department finds that all information required by 105 CMR 120.800 has been submitted and any additional requirements of 105 CMR 120.800 have been satisfied.

(D) The Department may deny a facility license if the Operator fails or refuses to correct deficiencies in the application within 30 days after notification of such a deficiency by the Department. Such summary denial shall be accompanied by an explanation of the reasons for the denial.

120.821: continued

(E) The Department shall set a decision schedule, for each complete application, setting forth the date by which it intends to prepare a draft license or draft denial and to issue a final license decision. The Department shall adhere to such decision schedule unless it finds that an extension of the schedule, not to exceed 90 days, is necessary to protect public health or the environment, in which case the Department must adhere to such decision schedule as extended.

(F) The Department shall give notice of the commencement of the public comment period by mail to the Operator, the community supervisory committee of each site community and the Board, and by publication in accordance with regulations adopted pursuant to M.G.L. c. 30, § 62A (MEPA), in a daily or weekly newspaper of general circulation within each site and neighboring community and by broadcasting on radio stations serving each such community.

(G) The public comment period shall continue for 45 days after the issuance of a draft license or draft denial. The Department shall extend the public comment period if it issues a modified draft license until 45 days after the issuance of such a modified draft license.

(H) Anyone may submit comments to the Department during the comment period. The Department shall make copies of all comments received available to persons upon request.

(I) The Department shall conduct at least one public meeting on the license application and the draft license or draft denial within each site community and other public meetings in neighboring communities upon request by the Chief Executive Officer of such community.

(J) The Department shall, after action by the Secretary of the Executive Office of Enviromental Affairs on a draft environmental impact report pursuant to M.G.L. c. 111H, § 30 and M.G.L. c. 30, § 62C, prepare a draft license or draft denial. A draft license shall include facility design and performance specifications and all conditions required to operate the facility.

(K) A copy of the draft license or draft denial shall be sent to the Operator, the community supervisory committee of each site community, the Board and, upon request, to other interested persons, and shall be accompanied by an explanation of the reasons therefor and a description of the procedures to be followed in reaching a final license decision. Such description shall include the date on which the public comment period is to end; the dates and locations of scheduled public meetings on the draft license or draft denial, the procedures to be followed by persons wishing to participate in the process leading to the final license decision, and the name, address and telephone number of the person within the Department to contact for additional information.

(L) The Department shall send a copy of the final facility license decision to the Operator, the community supervisory committee of each site community, the Board, any person who submitted written comments during the public comment period and, upon request, to other interested persons. Such final decision shall be accompanied by a summary response to comments received during the public comment period and an explanation of the reasons for any difference between the draft license or denial and the final license decision.

120.822: Content of Application

(A) In addition to the requirements set forth in 105 CMR 120.100, an application for a facility license shall include the general information, specific technical information, institutional information, financial information, and the results of preoperational environmental monitoring set forth in 105 CMR 120.823 through 120.828.

(B) The applicant shall prepare, and submit as part of the application, a Safety Analysis Report (SAR). The Safety Analysis Report must follow the format described in the most current revision of United States Nuclear Regulatory Commission's publication, *Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility*, (NUREG-1199). The SAR must include all of the applicable information required in NUREG-1199, in addition to the information required in 105 CMR 120.823 through 120.828, and will be reviewed by the Department following the guidance contained in the most current revisions of NUREG-1200 and NUREG-1300.

120.822: continued

Only certain general sections of NUREG-1199, which do not specifically address disposal facilities, are of direct relevance to treatment and storage facilities.

120.823: General Information

The general information shall include each of the following:

(A) Identity of the Operator including:
(1) The full name address, telephone numbers and description of the business or occupation of the Operator; and
(2) If the Operator is a partnership, the name and address of each partner and the principal location where the partnership does business.
(3) If the Operator is a corporation or an unincorporated association:
(a) The state where it is incorporated or organized and the principal location where it does business; and
(b) The names and addresses of its directors and principal officers.
(4) If the Operator is acting as an agent or representative of another person in filing the application, all information required under 105 CMR 120.823(A) must be supplied with respect to the other person.

(B) Qualifications of the Operator:
(1) The organizational structure of the Operator, both offsite and onsite, including a description of lines of authority, key positions and assignments or responsibilities, whether in the form of administrative directives, contract provisions, or otherwise. The Operator shall, at any time during licensing, development, operation, closure, post-closure observation and maintenance or institutional control of the facility, immediately notify the Department of any significant change in its organizational structure information;
(2) The technical qualifications, including training and experience, of the Operator and members of the Operator's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in 105 CMR 120.823(B)(1) must be provided. The Operator shall, at any time during licensing, development, operation, closure, post-closure observation and maintenance or institutional control of the facility, immediately notify the Department of any significant change in its technical qualifications information;
(3) A description of the Operator's personnel training program; and,
(4) A plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, treatment, storage, and disposal operations in a safe manner.

(C) A description of:
(1) The location of the proposed facility;
(2) The general character of the proposed activities;
(3) The types and quantities of waste to be treated, stored, and/or disposed of; and
(4) The proposed facility and equipment.

(D) Proposed schedules for construction, receipt of waste, treatment and storage of waste, and first emplacement of waste at the proposed facility.

120.824: Specific Technical Information

The specific technical information shall include the following information needed for demonstration that the performance objectives and applicable technical requirements of 105 CMR 120.800 will be met:

(A) A description of the natural characteristics of the site and demographic characteristics of the surrounding areas and populations as determined by site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, cultural, scenic, historical, ecologic, archaeologic, meteorologic, climatologic, and biotic features of the facility and vicinity.

120.824: continued

(B) An identification of any known natural resources, the exploitation of which could result in inadvertent intrusion upon the site.

(C) A description of the design features of the facility, its waste management areas and any disposal units including, in particular, design features or other provisions for normal and abnormal or accident conditions. The description shall include those design features related to the following:

(1) Prevention or minimization of infiltration by water, plants, and animals;
(2) Water management features for water that may enter any disposal units or other waste management areas;
(3) Integrity and stability of engineered barriers;
(4) Stability of intruder barriers surrounding wastes;
(5) Facility drainage;
(6) Adequacy of the size of the buffer zone;
(7) Monitoring;
(8) Retrievability;
(9) Occupational exposures;
(10) Facility closure;
(11) Minimization to the extent practicable of long term active maintenance; and,
(12) Protection from inadvertent intrusion.

(D) A description of the relationship of the principal design features of the facility to the performance objectives set forth in 105 CMR 120.811 through 120.814, and to natural site characteristics and natural events or phenomena associated with the site.

(E) A description of codes and standards which the Operator has applied to the design and which will apply to construction of waste management areas and any disposal units. Such standards shall meet local, state and national building code standards.

(F) A description of the construction and operation of the facility, its waste management areas and any disposal units. The description shall include as a minimum the following:

(1) Methods of constructing any disposal units;
(2) Types of intruder barriers and onsite traffic controls;
(3) Methods and areas of waste treatment and storage;
(4) Drainage systems to control surface water or groundwater access to the wastes;
(5) Operator's environmental monitoring and surveillance;
(6) Receipt and handling of waste and inspection of waste and package integrity;
(7) Procedures for and areas of waste segregation;
(8) Any waste emplacement;
(9) Worker monitoring and surveillance;
(10) Survey control program; and,
(11) Methods to be employed in the handling and any disposal of wastes containing chelating agents or other non-radiological substances that might affect meeting the performance objectives set forth in 105 CMR 120.811 through 120.814.

(G) A description of the kind, amount, classification and specifications of waste proposed to be treated, stored or disposed of at the facility and a description of total facility design capacity and facility expected operating life.

(H) A description of the quality assurance program for the determination of natural site characteristics and for quality assurance during the design, construction, operation, and closure of the facility including, in particular, the receipt, handling, and emplacement of waste. Audits and managerial controls must be included.

(I) A description of the radiation safety program for control of radioactive effluents to ensure compliance with the performance objective set forth in 105 CMR 120.811; for control of occupational radiation exposure to ensure compliance with the requirements of 105 CMR 120.200 and for control of contamination of personnel, vehicles, equipment, buildings, and the facility. Both routine operations and accidents shall be addressed. The program description must include procedures, instrumentation, facilities, and equipment.

120.824: continued

(J) A description of the Operator's environmental monitoring and the Operator's plans for taking remedial measures when necessary.

(K) A description of the administrative procedures that the Operator will apply to control activities at the facility.

(L) A description of the plan for facility closure and post closure observation and maintenance including those design features intended to facilitate facility closure and to minimize the need for long term active maintenance. Such plan shall include:

(1) A description of the relationship between individual waste containers (or disposal units, in the case of a disposal facility) and final closure;

(2) Procedures to be implemented to ensure that any disposal units at a facility will not be adversely affected by closure.

(M) A description of the waste containment within any disposal units as it applies to the design objective to provide total containment of wastes within disposal units for 100 years for Class A waste, 300 years for Class B waste, and 500 years for Class C waste.

(N) A description of the circumstances under which retrieval of waste would be necessary or desirable and the plans and the procedures to be used to effect retrieval. The description shall include an analysis of the impacts of waste retrieval on public and worker health and safety and the environment.

(O) A description of the waste minimization program that would be instituted to reduce the volume and activity of low-level radioactive waste generated at the facility pursuant to 105 CMR 120.890.

120.825: Technical Analyses

(A) The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives set forth in 105 CMR 120.811 through 120.814 will be met:

(1) Pathways analyzed in demonstrating protection of the general population from releases of radioactivity shall include air, soil, groundwater, surface water, plants and animals. The analyses shall clearly identify and differentiate between the roles performed by the natural site characteristics and facility design features in isolating and segregating the wastes. The analyses shall demonstrate that there is assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in 105 CMR 120.811.

(2) Analyses of the protection of individuals from inadvertent intrusion shall demonstrate that waste classification and segregation requirements will be met and that intruder barriers will be provided.

(3) Analyses of the protection of individuals during operations shall include assessments or expected exposures due to routine operations and potential accidents during handling, treatment, storage, and disposal of waste. The analyses shall demonstrate that exposures will be controlled to meet the requirements of 105 CMR 120.200.

(4) Analyses of the long term stability of the facility and the need for active long-term maintenance after closure shall be based upon analyses of active natural processes (such as, in the case of a disposal facility, erosion, mass wasting, slope failure, settlement of wastes, infiltration through adjacent soils, and surface drainage of the facility). The analyses shall demonstrate that there will not be a need for long term active maintenance of the facility following closure.

(B) The Operator shall, at any time during licensing, development, operation, closure, post-closure observation and maintenance or institutional control of the facility, immediately notify the Department of any significant change in its technical analysis required to be submitted pursuant to 105 CMR 120.800. Such notification shall include a substitute technical analysis, satisfying the requirements of the Section and demonstrating that the performance objectives set forth in 105 CMR 120.811 through 120.814 will be met by the facility.

120.826: Institutional Information

The institutional information submitted by the Operator shall include:

(A) Certifications by the Board that the facility is proposed to be sited on land owned by the Commonwealth in fee simple absolute and that the Board is prepared to accept transfer of the license when the provisions of 105 CMR 120.870 are met and to assume responsibility for institutional control of the facility after closure and post-closure observation and maintenance are completed.

(B) All material submitted to, or substantially relied upon by the Board in support of its certification of the operator pursuant to M.G.L. c. 111H, § 22(c).

120.827: Financial Information

(A) The Operator shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of facility development, construction, operation, and closure. The Operator shall demonstrate that it is in compliance with all the financial criteria for operator certification set forth in 345 CMR 3.12: *Financial Criteria for Operator Certification*.

(B) The Operator shall provide the Department with a certification issued by the Board that the amount expected to be contained in the institutional control account of the Low-Level Radioactive Waste Trust Fund will be adequate to pay the costs of institutional control of the facility pursuant to M.G.L. c. 111H, §§ 9 and 47. At any time that the Board determines that changes in inflation, technology of facility operations or other changes have significantly altered the factual basis for the certification issued pursuant to 105 CMR 120.827(B), it shall immediately notify the Department. Such notification shall include any proposal for changes in the schedule of surcharges for the Low-Level Radioactive Waste Trust Fund, adopted pursuant to M.G.L. c. 111H, § 38(c), deemed necessary by the Board.

120.828: Preoperational Environmental Monitoring

(A) At the time a license application is submitted, the Operator shall present the results of preoperational environmental monitoring conducted to provide basic environmental data on the facility and site characteristics. The preoperational environmental monitoring program shall conform with that described in NUREG-1388 to the extent applicable to the type of facility, M.G.L. c. 111H, and the requirements of 105 CMR 120.831. The Operator shall include information about the ecology, meteorology, climate, hydrology, geology including geophysics and geotechnical engineering, geochemistry, seismology, and radiologic characteristics of the site and all other relevant information required in 105 CMR 120.824, 120.825 and 120.831 necessary to demonstrate the suitability of the site for the intended use.

(B) For those characteristics that are subject to seasonal variation, any data collected by the Operator, together with data from the detailed site characterization conducted by the Board, shall cover a period of at least 12 consecutive months.

(C) The Operator shall continue the preoperational environmental monitoring program through the Department's license review period.

120.829: Standards for Issuance of a License

A facility license may be issued by the Department, following action of the Secretary of Environmental Affairs on a final environmental impact report pursuant to M.G.L. c. 111H, § 30 and M.G.L. c. 30, § 62C, if it finds that:

(A) The issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

120.829: continued

(B) The Operator is qualified by reason of training and experience to carry out the proposed treatment, storage, or disposal operations in a manner that protects health and minimizes danger to life or property;

(C) The Operator's proposed facility design, environmental monitoring plan, equipment, operations, procedures, facility closure, post-closure observation and maintenance and institutional control are adequate to protect the public health and safety and demonstrate that the performance objectives set forth in 105 CMR 120.811 through 120.814 will be satisfied;

(D) The Operator has demonstrated that the applicable technical requirements of 105 CMR 120.800 will be met;

(E) The Operator's proposal for institutional control demonstrates that such control will be provided for a length of time not less than the minimum time required for any waste present at the site to decay to the maximum concentrations above natural background levels permitted to be released into air or water in unrestricted areas under federal and state law, and that the institutional control meets the requirements of 105 CMR 120.871;

(F) The financial and surety arrangements comply with all the financial criteria for operator certification set forth in 345 CMR 3.12; and

(G) The Operator has provided a written statement indicating that the Operator's proposed facility design, equipment, operations procedures, closure, post-closure observation and maintenance, and institutional control meet all applicable environmental, public health, labor, occupational health and safety standards and regulations.

120.830: Conditions of Licenses

(A) Each person licensed by the Department pursuant to 105 CMR 120.800 shall confine possession and use of materials to the locations and purposes authorized in the license.

(B) The Operator shall not treat, store or dispose of waste until the Operator has received written notification from the Department that the Department has inspected the facility and has found it to be in conformance with the design and construction described in the application for a license.

(C) The Operator shall be subject to the provisions of M.G.L. c. 111H, and to all rules, regulations, and orders of the Department. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, regulations, and orders issued in accordance with the terms of M.G.L. c. 111H.

(D) The Department may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the Operator's receipt, possession, treatment, storage, or disposal of waste as it deems appropriate or necessary in order to protect public health, safety or environment.

(E) The Department may require tests, reports and the keeping of records, and provide for such inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of M.G.L. c. 111H and 105 CMR 120.800.

(F) The Department may issue orders to assure compliance with 105 CMR 120.800, or to cease activity in violation of 105 CMR 120.800; it may revoke, suspend or modify licenses and impose a civil penalty or have the Attorney General bring an action to restrain, prevent or enjoin any conduct prohibited by 105 CMR 120.800 or compel action ordered by the Department as shall be stated in 105 CMR 120.016: *Enforcement*.

120.830: continued

(G) Each Operator shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The Operator;

(2) An entity (as that term is defined in 11 U.S.C. §101(14)) controlling the Operator or listing the license of Operator as property of the estate; or,

(3) An affiliate (as that term is defined in 11 U.S.C. §101(2)) of the license.

Such notification shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(H) A license issued under 105 CMR 120.800, or any right thereunder, may not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Department finds, after securing full information, that the transfer is in accordance with the provisions of M.G.L. c. 111H and 105 CMR 120.800 and the Department gives its consent in writing in the form of a license amendment.

(I) The Operator shall submit written statements under oath upon request of the Department, at any time before transferring of the license, to enable the Department to determine whether the license should be modified, suspended, or revoked.

(J) The license may be transferred to the Board upon the full implementation of the facility closure plan as approved by the Department, and completion of post-closure observation and maintenance in accordance with 105 CMR 120.800.

(K) The authority to treat, store, and dispose of wastes expires on the date stated in the license. Any expiration date on a license applies only to the site operations activities and to the authority to treat, store, and dispose of waste. Failure to renew the license shall not relieve the Operator of responsibility for implementing site closure, post-closure observation and maintenance, or transfer of the license to the Board.

120.831: Environmental Monitoring

(A) The Operator must submit an environmental monitoring plan, of which the preoperational environmental monitoring required in 105 CMR 120.828 is a component, as part of the complete license application. The extent and duration of the Operator environmental monitoring program shall take into account the nature of the licensed operation. In the case of a low-level radioactive waste disposal facility, the Operator environmental monitoring program shall, at a minimum, conform to the general guidance provided in U.S. Nuclear Regulatory Commission publication, *Environmental Monitoring of Low-Level Radioactive Waste Disposal Facility*, NUREG-1388 (published in 1989).

The Operator shall submit with the license application a baseline health study of the site community and any affected community. The study shall be paid for by the Operator and conducted by the Department's Bureau of Environmental Health Assessment following the design requirements for such a study that are currently being used by the Department. A comparison health study shall be conducted every five years and paid for by the Operator.

The environmental monitoring programs for treatment and storage facilities shall be designed for the specific needs of those facilities.

(B) During facility development, construction, operation, closure, post-closure observation and maintenance, until the facility license is transferred to the Board, the Operator shall establish and conduct the Operator environmental monitoring program as required by 105 CMR 120.831 and in accordance with the environmental monitoring plan approved by the Department as a condition of the final license.

(C) Within 30 days of the issuance of a facility license, the Department shall, after consultation with the Department of Environmental Protection and the Board of Health of each site community, establish and conduct a comprehensive environmental monitoring program at the facility site which will compliment and validate the Operator environmental monitoring program.

120.831: continued

(D) The Department environmental monitoring program and the Operator environmental monitoring program shall each employ the best available monitoring technology to collect and analyze data concerning standing and running surface water and drainage; groundwater samples from offsite, site boundary and waste management area wells; soil and sedimentation samples, air samples, vegetation and wildlife samples, and direct radiation measurements offsite, at the site boundary and in the waste management area.

(E) Both the Department environmental monitoring program and the Operator environmental monitoring program shall be designed to:

(1) Establish baseline environmental data on the site;

(2) Provide data to allow evaluation of facility impacts on public health, safety and the environment, and evaluate the need for mitigative measures at the facility;

(3) Provide early warning of the magnitude and extent of any migration of radionuclides and/or any hazardous chemicals;

(4) Determine compliance with applicable regulations, with conditions of the facility license pursuant to 105 CMR 120.830, and with the terms of the comprehensive operating contract; and

(5) Provide reliable environmental data throughout development, operation, closure, post-closure observation and maintenance and institutional control at the facility.

(F) Both the Department environmental monitoring program and the Operator environmental monitoring program shall be designed to detect:

(1) Any seepage through engineered barriers.

(2) The structural stability of engineered barriers.

(3) External or internal conditions that may cause physical changes leading to enhanced water movement or compromises in stability.

(G) Both the Department environmental monitoring program and the Operator environmental monitoring program shall include:

(1) Facility measurements.

(a) Soil sampling

(b) Pore water sampling

(c) Pore gas sampling

(d) In situ measurements

(e) Geophysical remote sensing

(f) Photogrammetric techniques

(g) Subsurface hydrological monitoring

(h) Subsurface physical monitoring

(i) Subsurface chemical monitoring

(2) Measurements at a representative test area.

(a) Use of a surrogate facility for area testing.

(b) Use of replaceable monitoring and nondestructive test systems.

(c) Undisturbed region not directly impacted by engineered facility or facility activity (representative of natural or background conditions).

(H) Both the Department environmental monitoring program and the Operator environmental monitoring program shall include a quality assurance program utilizing the best available methods of monitoring plan formulation, data acquisition, database creation, data verification, and data validation to minimize instances of false negative measurements. Data shall be processed, synthesized and organized so as to be suitable for use to evaluate the performance of the facility's engineered barriers and to ensure the protection of the public health, safety and the environment.

(I) Both the Department environmental monitoring program and the Operator environmental monitoring program shall be upgraded to provide the maximum protection of public health, safety and the environment based on the results of the quality assurance program.

120.831: continued

(J) A copy of all Department environmental monitoring program and Operator environmental monitoring program records and analyses shall be kept at the Board field office in the site community for public review.

(K) The Department environmental monitoring program shall provide, to the maximum extent feasible, for the participation of officials and citizens of each site community and the training of such persons to facilitate their participation.

(L) The Board of Health of each site community shall be entitled to obtain portions of the samples collected pursuant to the environmental monitoring programs for independent analysis by a laboratory certified to conduct such analysis by the U.S. Environmental Protection Department.

(M) The Operator shall cooperate with the Department environmental monitoring program and shall reimburse the Department and each site community annually for the costs thereof until the facility license is transferred to the Board pursuant to 105 CMR 120.870.

(N) The Department shall:

(1) Issue an annual report describing and evaluating the findings of the environmental monitoring program.

(2) Hold a public meeting within 60 days of the issuance of the report for public review and comment on the report in:

(a) Each site community; and,

(b) Each affected and neighboring community, if the chief executive officer of such a community so requests.

(3) Consider and evaluate all comments made at such public meetings or submitted in writing within 60 days of the issuance of the report.

(O) The Operator shall have plans for taking corrective measures if either the Department environmental monitoring program or the Operator environmental monitoring program detects, or indicates the threat of, migration of radionuclides or hazardous chemicals or increased on-site or off-site radiation levels which would indicate that the performance objectives set forth in 105 CMR 120.811 through 120.814 may not be met including:

(1) A restorative and protection action plan.

(2) A dose modeling program for site workers and the general public.

(3) A dose modeling program in the event of an accidental release to the environment.

(P) The Department, in consultation with the Board, may issue an order to temporarily close the facility if it finds that there is a potential hazard to public health, safety or the environment which justifies such temporary closure. A facility that is temporarily closed shall remain closed as long as necessary for remedial action, and, in any event, through any period of facility clean-up and stabilization. Prior to authorizing the reopening of a temporarily closed facility, the Department shall:

(1) Conduct a minimum of one public meeting relative to the reopening in each site community, and other public meetings in neighboring communities upon the request of the chief executive officer of such community;

(2) Issue a summary response to all comments made at such public meetings or made in writing during the time the facility is temporarily closed, and an explanation of the reasons for authorizing the reopening.

120.832: Facility Design

(A) Facility design features shall be directed toward long-term isolation of waste and avoidance of the need for continuing active maintenance after closure.

(B) The facility design and operation shall be compatible with the facility closure and closure plan and lead to closure that ensures that the performance objectives set forth in 105 CMR 120.811 through 120.814 will be met.

120.832: continued

(C) The facility shall be designed to complement and improve, where appropriate, the ability of the facility's natural characteristics to assure that the performance objectives will be met.

(D) Engineered barriers shall be designed to minimize to the extent practicable, water infiltration, to direct percolating of surface water away from waste, and to resist degradation by surface geologic processes and biotic activity.

(E) Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance.

(F) The facility shall be designed to minimize to the extent practicable the contact of percolating or surface water with waste.

(G) The facility design shall incorporate subsidence monitoring and minimization; long term stability of any disposal units, storage and structural components; and facility safety systems to ensure protection of facility workers, members of the general public, and the environment.

(H) The design of any disposal facility shall incorporate structural monitoring provisions for a program which allows:

(1) Regular visual inspections of the exterior portions of any disposal units;
(2) Remote sensing of inaccessible areas, where applicable; and,
(3) Meters and gauges, as necessary.

(I) The Operator shall ensure that the facility design and operation plans allow for proper inspection and receipt of all incoming waste shipments and packages.

(J) The buffer zone shall not be used for receipt or storage of waste.

NOTE: Short-term and long-term performance of a disposal facility may be achieved by a combination of factors, including disposal method and engineered barriers, waste form and packaging, facility operation, institutional controls, natural site features, and waste classification and inventory limits.

120.833: Facility Construction

(A) The Operator shall present facility construction plans to be approved by the Department prior to commencement of construction.

(B) The Operator may begin construction once the Department has determined that:

(1) The operator environmental monitoring program and Department environmental monitoring program, together with the detailed site characterization of the site, has yielded comprehensive baseline data.
(2) All required financial assurances have been accepted.
(3) All pre-construction conditions of the facility license have been satisfied.

(C) The Operator shall ensure that construction of the facility meets all the requirements of 105 CMR 120.800 and the license.

(D) The Board shall appoint a resident engineer who shall represent the Board daily at the site during construction of the facility and who shall, in cooperation with officials at each site community, check, inspect, and report to the Board as to events at the construction site.

(E) The Department will periodically inspect the construction process to ensure that the requirements of 105 CMR 120.800 and the license are being met.

(F) The Operator shall construct, install, and make additions and improvements to such structures and equipment as are determined by the Department to be necessary.

120.834: Operating Budget Reimbursements

Once a license has been issued, and annually thereafter until the facility license is transferred to the Board pursuant to 105 CMR 120.870, the Department shall establish a payment to be made by the Operator. This payment shall equal the Department's expected annual operating budget for the next fiscal year for its activities with respect to the facility, except that the payment shall be adjusted by the amount of any operating deficit or surplus previously incurred by the Department. The Operator shall make such payment to the Commonwealth prior to the commencement of the fiscal year.

120.840: Facility Opening

(A) Prior to the acceptance of waste at a facility, the Operator shall notify the Department and the Board that the construction of the facility is complete and in compliance with all requirements of 105 CMR 120.800 and all license conditions, and that the facility is ready to accept waste.

(B) Prior to the acceptance of waste at a facility, the Operator shall file with the Department the waste acceptance criteria, approved by the Board, that will be utilized at the facility.

(C) Upon written notification from the Department that the Operator is in compliance with all the regulations and conditions of the facility license, and upon a determination of compliance with the comprehensive operating contract by the Board, commencement of operations may begin. The Operator shall be required to begin accepting waste within 30 days after such notification.

(D) No person may ship or transport any waste to a facility without the written consent of the Operator.

120.841: Facility Operation

(A) Wastes designated as Class A pursuant to 105 CMR 120.247 shall be segregated from other wastes by emplacing them in disposal units that are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of 105 CMR 120.800. This segregation is not necessary for Class A wastes if they meet the stability requirements in 105 CMR 120.247(B).

(B) Wastes designated as Class C pursuant to 105 CMR 120.247 shall be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

(C) Waste arriving at the facility shall comply with all other pertinent Sections of 105 CMR 120.000 with regard to waste classification, waste characteristics, labeling, manifests, the waste acceptance criteria approved by the Board and any applicable provisions of the comprehensive operating contract.

(D) The Operator shall have specific procedures to ensure compliance of waste with all applicable waste acceptance criteria.

(E) The Operator of any disposal facility shall require evidence of a certificate signifying the Department's approval of the waste minimization statement or plan of a generator, pursuant to 105 CMR 120.890 as a condition of access to the facility.

(F) Any facility accepting mixed waste shall provide an equivalent level of environmental protection as that required by M.G.L. c. 21C and 310 CMR 30.000.

(G) The Operator shall provide adequate training for all site workers in the proper handling of radioactive waste to ensure radiological controls. Such training shall include, but not be limited to:

120.841: continued

(1) Basic Radiation Principles
(2) Basic Radiation Protection
(3) Radiation Biology
(4) Decontamination Methods
(5) Personnel Safety Precautions/Work Habits
(6) Accident Response Actions/Notifications

120.842: Receipt, Handling, and Inspection of Waste

(A) The Operator shall submit a plan for the receipt, inspection, and handling of waste entering the facility. The plan shall include, but not be limited to, the waste acceptance criteria approved by the Board.

(B) The Operator shall ensure that special inspection and receiving plans are in place in case of damaged transportation vehicles or packages, incorrect manifests or shipping documents, or non-compliance with any Section of 105 CMR 120.000.

(C) The plans and procedures for moving the waste shall be implemented and equipment shall be utilized so as to minimize contact or the possibility of contact with water.

(D) Upon arrival to the facility, all waste shall enter a waste inspection area and remain there until the Department can inspect the manifests and the integrity of the waste being received.

(E) The Department shall inspect each shipment of waste before the shipment is accepted for storage, treatment or disposal. Any shipment that is not found to be in compliance with applicable regulations, license conditions, and waste acceptance criteria shall be held in a controlled area within the facility until a representative from the generator is contacted, and the generator or its agent remedies the deficiency; the operator shall notify the board of health of each site community of any such failure of compliance.

(F) The generator shall be assessed a daily penalty until the deficiency is remedied and the shipment complies with applicable regulations, license conditions and waste acceptance criteria.

(G) After a transport vehicle is unloaded and leaves the waste management area, it shall not leave the facility until it is again inspected by the Department and decontaminated, if necessary.

(H) Once inspected, wastes accepted for disposal shall be emplaced in a manner to ensure that container integrity is maintained during emplacement, and that the minimization of void spaces between the containers permits the ability to fill the void spaces. Once inspected, wastes accepted for storage shall be placed in storage in a manner to ensure that container integrity is maintained throughout the period of storage.

(I) Void spaces between waste containers in disposal units shall be filled with material appropriate to reducing future subsidence of the disposal units.

(J) Closure measures set forth in the approved facility closure plan shall be carried out as each disposal unit is filled and sealed.

(K) Waste shall be emplaced and sealed in a manner that limits the radiation dose rate at the surface of the engineered barrier to levels that at a minimum will permit the Operator to comply with all provisions of 105 CMR 120.207 at the time of license transferral as provided in 105 CMR 120.800.

(L) Waste shall be handled in a manner to minimize workers exposure to radiation utilizing ALARA (As Low As Reasonably Achievable) techniques.

(M) Waste shall be emplaced to ensure retrievability and the ability to monitor through the end of the institutional control period.

120.842: continued

(N) Following receipt and acceptance of a shipment of waste, the Operator shall record the date of any emplacement of the waste, the waste's location in the facility, the condition of the waste containers as received, any remedial measures taken pursuant to 105 CMR 120.842(E), any discrepancies between materials listed on the manifest and those received, and any evidence of leaking or damaged containers or radiation or contamination levels in excess of limits specified in the regulations of the U.S. Department of Transportation (49 CFR 173.441 and 173.443, revised as of November 1, 1984, as amended) and the Department. The Operator shall briefly describe any repackaging operations of any of the waste containers included in the shipment, plus any other information required by the Department as a license condition.

(O) Facility operations shall not have an adverse effect on the implementation of closure plan measures.

(P) Only wastes containing or contaminated with radioactive material shall be accepted at the facility.

(Q) Waste received at a disposal facility shall not be intentionally diluted by the Operator to alter its classification as identified on the manifest.

120.843: Facility Boundaries and Markers

(A) The boundaries and locations of any disposal unit shall be accurately located, adequately marked, and mapped.

(B) A buffer zone of land shall be maintained between the waste management area and the facility boundary. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in 105 CMR 120.831 and satisfy the requirements of 310 CMR 41.27(b).

120.844: Contingency Plans for Facility Operations

(A) The Operator shall have contingency plans for unplanned occurrences, such as fires, accidents, radiological contaminations or releases of radioactivity into the environment, severe natural events, and any operational repair and waste recovery activities that may adversely affect the health and safety of the facility workers or general public. Any retrieval of waste pursuant to such contingency plans shall conform to the terms approved in the license.

(B) The plans shall identify the necessary minimal training, management, procedures, equipment, communications and notification systems, and human resources needed and required to provide emergency response to unplanned occurrences.

(C) The Operator shall include in the license application:

(1) Signed agreements with necessary emergency units that will respond to the requests from the Operator.

(2) A demonstration of adequate emergency response capability as deemed appropriate by the Department.

120.845: Facility Maintenance

The Operator shall maintain the facility so as to remain in compliance with all the terms and conditions of the license and 105 CMR 120.000.

120.850: Funding for Facility Closure

(A) The Operator shall provide assurances prior to the commencement of operations, that sufficient funds will be available to carry out facility closure. These assurances shall be based on Department-approved cost estimates reflecting the Department-approved facility closure plan. The Operator's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the closure work. The assurances shall establish that there will be sufficient funds for:

120.850: continued

(1) Decontamination, stabilization or dismantlement of facility components.
(2) Closure of the facility so that following transfer of the facility license to the Board, the need for ongoing active maintenance is minimized to the extent practicable and only minor custodial care, surveillance, and monitoring are required.

(B) In order to avoid unnecessary duplication and expense, the Department may accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of Federal or other State agencies or local governmental bodies for such closure. The Department may accept these arrangements only if they are considered adequate to satisfy the requirements of 105 CMR 120.800 and that the portion of the surety which covers the closure of the facility is clearly identified and committed for use in accomplishing these activities.

(C) The Operator's financial or surety arrangement shall be submitted annually for review by the Department to ensure that sufficient funds are available for completion of the closure plan assuming that the work has to be performed by an independent contractor.

(D) The amount of the Operator's financial or surety arrangement shall change in accordance with changes in the predicted costs of implementing the closure plan. Factors affecting closure cost estimates include, but are not limited to inflation, increases in the amount of disturbed land, changes in engineering plans, and closure that has already been accomplished. The financial or surety arrangements shall be sufficient at all times to cover the costs of closure of any disposal units that are expected to be used before the next license renewal.

(E) Financial or surety arrangements shall be written for a specified period of time and provide for automatic renewal unless the person who issues the surety notifies the Department, the Board, and the Operator not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the Operator must submit a replacement surety within 30 days after notification of cancellation. If the Operator fails to provide a replacement surety acceptable to the Department, the Board may collect on the original surety.

(F) Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the Operator cannot provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on any surety instrument which is not open ended, and shall be agreed to by all parties.

(G) Financial or surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the Department. Self-insurance, or any arrangement which essentially constitutes pledging the assets of the Operator, will not satisfy the surety requirement.

(H) The Operator's financial or surety arrangement shall remain in effect until closure has been completed and approved by the Department, and the license has been transferred to the Board.

120.851: Application for Renewal or Closure

An application for renewal or an application for closure must be filed at least one year prior to the date scheduled for facility closure in the facility closure plan. A final closure application shall include a final revision and specific details of the facility closure plan included as part of the license application submitted under 105 CMR 120.824(L) that includes each of the following:

(A) Any additional geologic, hydrologic, or other data pertinent to the long-term containment of any emplaced wastes obtained during the operational period.

120.851: continued

(B) The results of tests, experiments, or any other analyses relating to treatment, storage or disposal of waste, final closure and sealing, migration of radionuclides and interaction with emplacement media, or any other tests, experiments, or analysis pertinent to the long-term containment of any emplaced waste within the facility.

(C) Any proposed revision of plans for:
(1) Decontamination, stabilization and/or dismantlement of facility components; or,
(2) Post-closure observation and maintenance of the facility.

(D) Any significant new information regarding the environmental impact of final closure activities and long-term performance of the facility.

120.852: Procedures for Review of Application for Facility Closure and Closure Plan

(A) The Department shall conduct a public meeting on the final closure plan at times to be determined after consultation with the Board in each site community, and other public meetings in neighboring communities upon request by the chief executive office of such community. The Board shall participate in each such public meeting.

(B) The Department shall accept written comments on the submitted plan from any interested person within 45 days of public notice of the availability of the plan. Prior to its acceptance of the plan, the Department shall consider and evaluate all comments made at a public meeting or submitted in writing.

(C) Upon review and consideration of an application for closure, the Department shall permit closure of the facility if there is assurance that the long-term performance objectives set forth in 105 CMR 120.814 will be met during post closure observation and maintenance and institutional control of the facility.

120.853: Facility Closure

(A) The Operator shall monitor the facility and carry out the closure plan until the facility closure is complete. The Department shall, in cooperation with appropriate officials of each site community, periodically inspect the Operator's implementation of the facility closure plan to ensure that the requirements in 105 CMR 120.800 and the conditions of the facility license are satisfied.

(B) Facility closure shall be conducted so as to ensure the stability of the facility until the facility license is transferred to the Management Board pursuant to 105 CMR 120.870: *Post-closure Observation and Maintenance*.

120.860: Post-closure Observation and Maintenance

The Operator shall observe, monitor, and carry out necessary maintenance and repairs at the facility until a period of five years after the site closure is complete and the license is transferred by the Department in accordance with 105 CMR 120.870. The Operator environmental monitoring program of the facility shall continue as approved by the Department. Responsibility for the facility must be maintained by the Operator for not less than five years. A longer time period for post-closure observation and maintenance may be required as part of the site closure plan, based on facility-specific conditions.

120.870: Transfer of License

Following the period of post-closure observation and maintenance, the Operator may apply to transfer the facility license to the Board. The license shall be transferred under M.G.L. c. 111H, § 46 if the Department finds:

(A) That the closure of the facility has been completed in conformance with the Operator's facility closure plan, as amended and approved as part of the license;

120.870: continued

(B) That the performance objectives set forth in 105 CMR 120.811 through 120.814 are met;

(C) That all records of the Operator's development, operation, closure and post-closure observations and maintenance of the facility have been transferred to the Board in compliance with M.G.L. c. 111H, § 44, and that the Board has certified the adequacy of the amount contained in the institutional control account of the Low-level Radioactive Waste Trust Fund to pay the costs of institutional control of the facility pursuant to M.G.L. c.111H, §§ 9 and 47;

(D) That the Board has adopted a plan for institutional control of the facility and to accept transfer of the license, and is prepared to continue the Operator environmental monitoring program; and

(E) That the Management Board is prepared to assume responsibility for and satisfy the institutional requirements as set forth in 105 CMR 120.800.

120.871: Institutional Control

The Board shall conduct an institutional control program which shall physically control access to the facility following transfer of control of the facility from the facility Operator. The institutional control program shall also include, but not be limited to, continuing the Operator environmental monitoring, periodic surveillance, minor custodial care, and other requirements as determined by the Department; and administration of funds to cover the costs for these activities. The period of institutional controls shall be determined by the Department and shall satisfy the requirements set forth in 105 CMR 120.816.

120.880: Maintenance of Records, Reports, and Transfers

(A) The Operator shall maintain any records and make any reports in connection with the licensed activities as are required by the conditions of the license or by 105 CMR 120.800 or any order of the Department.

(B) Records required by 105 CMR 120.800 or by license conditions shall be maintained for a period specified by 105 CMR 120.800 or by license condition. If a retention period is not otherwise specified, these records shall be maintained and transferred to the Board as a condition of license transfer unless the Department authorizes their disposition because of inaccuracies or obsolescence or that disposing of such records will not adversely affect the public health and safety of the general public and the environment.

(C) Records which are required to be maintained pursuant to 105 CMR 120.800 may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(D) Copies of all records of the location and the quantity of wastes contained in the facility shall be transferred to the Board upon license transfer to the Board.

(E) Following receipt and acceptance of a shipment of radioactive waste, the licensee shall record the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at the disposal site, the containment integrity of the waste disposal containers as received, any discrepancies between materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and any evidence of leaking or damaged disposal containers or radiation or contamination levels in excess of limits specified in Department of Transportation and Agency regulations. The licensee shall briefly describe any repackaging operations of any of the disposal containers included in the shipment, plus any other information required by the Agency as a license condition. The licensee shall retain these records until the Agency transfers or terminates the license that authorizes the activities described in 105 CMR 120.800.

120.880: continued

(F) Annual reports:

(1) The Operator shall submit an annual report to the Department by the end of the first calendar quarter of each year for the preceding year.

(2) The annual reports shall include:

(a) A copy of the Operator's financial report or a certified financial statement,

(b) Specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year,

(c) The data of the Operator environmental monitoring program,

(d) A summary of any disposal unit surveys and maintenance activities,

(e) A summary, by waste class, of activities and quantities of any radionuclides disposed of,

(f) Any instances in which observed site characteristics were significantly different from those described in the application for a license; and,

(g) Any other information the Department may require.

(3) The report shall identify and discuss any instance, during the reporting period, in which monitoring results, maintenance performed or the quantities of waste released are significantly different from those expected.

(G) The Operator shall comply with the recordkeeping requirements of 105 CMR 120.001.

(H) Any transfer of byproduct, source, and special nuclear materials by the Operator is subject to the requirements in 105 CMR 120.140.

(I) In addition to the other requirements of 105 CMR 120.880, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

(1) The manifest information that must be electronically stored is:

(a) That required in 10 CFR part 20, Appendix G, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and,

(b) That information required 105 CMR 120.880(E).

(2) As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium.

120.881: Tests on Facilities

Each Operator shall perform, or permit the Department to perform, any tests the Department deems appropriate or necessary for the administration of 105 CMR 120.800, including, but not limited to, tests of:

(A) Wastes and facility components used for the receipt, storage, treatment, handling or disposal of wastes;

(B) Radiation detection and monitoring instruments; or,

(C) Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste.

120.882: Department Inspection of Facilities

(A) Each Operator shall annually, and at such other times as requested by the Department, provide detailed and accurate information, in a report, for the purpose of determining compliance with 105 CMR 120.800, including, but not limited to:

(1) The type, volume, radioactivity, source and characteristics of the waste treated, stored, or disposed of at the facility;

(2) The Operator's current and projected waste management activities, including source minimization, volume minimization, on-site storage, treatment, packaging and transportation practices.

120.882: continued

(B) The Operator shall allow the duly authorized representatives of the Department, at all reasonable times, without advance notice to enter and examine any property, facility, or activity involving treatment, storage, and disposal of the waste. The Operator shall afford such inspectors unfettered access, equivalent to access provided to persons regularly employed at the facility, following proper identification and compliance with applicable access control measures for security, radiological protection and personal safety. Such inspectors are authorized to make such inspections, conduct such test, reviews, studies, monitoring, or sampling or examine books, paper and records as the Department deems necessary for administration or enforcement of M.G.L. c. 111H or 105 CMR 120.800. Such inspectors may copy and take away copies of, for the Agency's use, any record required to be kept pursuant to 105 CMR 120.800.

(C) An annual summary of the Department's inspection and enforcement activities with respect to the facility shall be transmitted to the Board and to the board of health of each site community.

120.885: Waivers

The Department may waive the application of any provision of 105 CMR 120.800 if it finds that:

(A) The performance objectives set forth in 105 CMR 120.811 through 120.814 will be met; and,

(B) Public health, safety and the environment will be protected; and,

(C) Strict application of the section to be waived would undermine the public interest; and,

(D) Specific substitute requirements can be adopted which will result in the substantial protection of the process established in M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P and the rights of persons affected by the action and the Operator; and,

(E) The action made possible by the waiver will not violate the provisions of M.G.L. c. 111H or any other state or federal law.

120.890: LOW-LEVEL RADIOACTIVE WASTE MINIMIZATION REGULATIONS GENERAL PROVISIONS

120.891: Purpose and Scope

(A) The purpose of 105 CMR 120.890 is to ensure that source and volume minimization and storage for decay are integral parts of every radioactive material user's, as well as generator's, waste management program. 105 CMR 120.890 has been made, after consultation with the Board, as required in M.G.L. c. 111H, § 13.

(B) 105 CMR 120.890 apply to all radioactive material users, licensees and generators as defined in 105 CMR 120.893.

(C) 105 CMR 120.890 do not apply to radioactive materials that are exempt from licensing as specified in 105 CMR 120.100.

(D) The requirements of 105 CMR 120.890 are in addition to, and not in substitution for, 105 CMR 120.001, 120.100, 120.200 and 120.800.

120.892: Regulatory Authority

The authority for the Department of Public Health to promulgate 105 CMR 120.890 is found in: M.G.L. c. 111, §§ 3, 5M, 5N, 5O, 5P; M.G.L. c. 111H, §§ 1, 7, 8, 11, 13, 16, 31.

120.893: Definitions

As used in 105 CMR 120.890, the following definitions apply:

120.893: continued

Board means the Low-level Radioactive Waste Management Board established in M.G.L. c. 111H, § 2.

Days means calendar days; provided that in computing time periods such periods shall exclude the day of the, event which starts the period running, and further provided that if the last day of a period falls on a Sunday, legal holiday or declared state of emergency day, such period shall be extended to the close of business on the next business day.

Department means the Department of Public Health.

Development means all activities undertaken with respect to a low-level radioactive waste facility during the period commencing with the selection of any superior site pursuant to M.G.L. c. 111H, § 23 and continuing until the commencement of facility operation pursuant to M.G.L. c. 111H, § 39.

Disposal means the isolation of low-level radioactive waste from the biosphere inhabited by human beings and their food chains.

Generator means a person, including a broker, who produces low-level radioactive waste.

Generator Guidance means the document titled *Low-level Radioactive Waste Minimization Guidance* compiled by the Department for the guidance of waste generators.

Half-life means the time in which half the atoms of a particular radioactive substance disintegrate to another nuclear form.

Licensee means a person holding a license issued pursuant to 105 CMR 120.100 by the Department of Public Health to transfer, acquire, own, possess or use quantities of, or devices or equipment utilizing, radioactive material.

Low-level Radioactive Waste means radioactive material that"

(1) is neither high-level waste, nor spent nuclear fuel, nor by-product material as defined in section 11(e)(2) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. §2014(e); and
(2) is classified by the Federal Government as low-level radioactive waste, but not including waste which remains a Federal responsibility, as designated in section 3(b) of the Low-Level Radioactive Waste Policy Act, as amended, 42 U.S.C. §2021c(b), as in effect as of December 8, 1987.

Management means the storage, packaging, treatment, transportation, or disposal, where applicable, of low-level radioactive waste.

Management Plan means the low-level radioactive waste management plan adopted by the board pursuant to M.G.L. c. 111H, § 12 to provide for the safe and efficient management of low-level radioactive waste.

Manifest means a detailed record of the characteristics and quantities of packaged waste as presented for transportation, treatment, storage, or disposal which usually accompanies waste transfers for these purposes.

Minimization Plan means the plan required by each generator which identifies actions to allow for "storage for decay" of short-lived radioisotopes, and actions to achieve source and volume minimization.

Mixed Waste means low-level radioactive waste containing material that either:

(1) is listed in 310 CMR 30.131 through 30.136; or
(2) causes the waste to exhibit any of the characteristics identified in 310 CMR 30.120.

120.893: continued

Person means any agency or political subdivision of the federal government or the commonwealth, or of any state, any public or private corporation or authority, individual, firm, joint stock company, partnership, association, trust, estate, institution or other entity, and any officer, employee or agent of such person, and any group of such persons.

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

Radioactive Material User means any person who requires a license or registration with the Department of Public Health pursuant to 105 CMR 120.000 to use radioactive materials for any purpose.

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

Source Minimization means minimizing the volume of radioactivity of low-level radioactive waste prior to its generation by such methods as:

(1) avoiding unnecessary contamination of items during the use of radioactive materials;
(2) carefully segregating radioactive waste from non-radioactive trash; or
(3) substituting non-radioactive isotopes or radioisotopes with shorter half-lives where practicable.

Storage means the holding of low-level radioactive waste for treatment or disposal.

Storage for Decay means a procedure in which low-level radioactive waste with a relatively short half-life is held for natural radioactive decay in compliance with applicable federal and state regulations.

Treatment means any method, technique, or process including source minimization, volume minimization, and storage for decay, designed to change the physical, radioactive, chemical, or biological characteristics or composition of low-level radioactive waste in order to render such waste safer for management, amenable for recovery, convertible to another usable material or reduced in volume.

Volume Minimization means treatment of low-level radioactive waste after its generation in order to minimize the physical dimensions of the waste and the space required for disposal.

Waste means low-level radioactive waste.

Waste Facility means a facility that is licensed in Massachusetts for the purposes of treating, storing or disposing of low level radioactive waste.

120.895: Objectives

The following are the objectives of 105 CMR 120.890:

(A) To protect public health and safety and the environment by ensuring that radioactive material users avail themselves of all the opportunities to produce less waste.

(B) To minimize the use of radioactive sources (this is a major objective of the Department's minimization program).

(C) To reduce the amount of waste requiring treatment, storage and disposal. To this end all radioactive materials users should strive to achieve "zero production" of low-level radioactive waste and frivolous or unnecessary uses of radioactive materials should be avoided, especially if non-radioactive alternatives are available.

(D) To ensure waste material is well characterized so as to reduce disposal liabilities and conserve disposal capacity.

120.895: continued

(E) To permit evaluation of the waste generation activity, allowing for optimal minimization controls that are consistent with waste management policies and procedures authorized by federal and state law and regulation as of December 8, 1987.

(F) To identify opportunities to achieve source minimization, volume minimization and storage for decay. These opportunities shall include activities required in M.G.L. c. 111H, § 13, including avoiding unnecessarily contaminating items while using radioactive materials; segregating radioactive waste from non-radioactive trash; and identifying the objective of substituting short-lived radionuclides or non-radioactive materials for long-lived radionuclides, where possible.

(G) To be consistent with the promotion of responsible research and innovation.

120.896: Statement and Plan Requirements

All radioactive material users and generators of low-level radioactive waste are required to examine their operations and institute waste minimization/reduction/elimination programs as follows:

(A) All radioactive material users, as well as all generators, of low-level radioactive waste must prepare a statement indicating the measures they have taken to minimize/ reduce/eliminate any waste that may result from their operations. The statement should contain the rationale for the use of a radioactive material, the quantities proposed, and the choice of radionuclide. The statement should contain a consideration of the fate of any anticipated radioactive waste that would be generated.

(B) Those persons whose operations result in 100 cubic feet or more of waste per annum, and such waste requires disposal, must develop and institute waste minimization programs predicated on detailed plans. The required elements of such a waste minimization program are described in 105 CMR 120.897.

(C) A minimization statement or plan, as applicable, shall be submitted with each new application for a license to manufacture, produce, transfer, receive, acquire, own, possess, or use radioactive materials. Current licensees shall submit a minimization statement or plan within 90 days of the promulgation of 105 CMR 120.890. The minimization statement or plan shall be updated yearly as part of the annual survey required by M.G.L. c. 111H, § 7.

(D) Persons who do not require a license from the Department for their operations but require access to a waste facility licensed by the Department shall submit, pursuant to 105 CMR 120.890, a statement or plan regarding their waste which shall be updated yearly as part of the annual survey required by M.G.L. c. 111H, § 7.

(E) The Department shall evaluate each minimization statement or plan submitted pursuant to 105 CMR 120.896(D) in accordance with 105 CMR 120.895, 120.896, 120.897, and upon approval, shall issue a certificate.

(F) The approved minimization statement or plan shall be written into the license as a condition of the license as required in 105 CMR 120.100.

120.897: Waste Minimization Plan Content

A waste minimization plan shall include:

(A) A waste minimization policy statement that presents the generator's goals for achieving waste minimization/reduction/elimination, and assigns responsibility to an individual or group to accomplish the objectives. The plan shall be approved by the highest official of the company or institution or his/her designee, and include a statement committing to a defined implementation schedule.

120.897: continued

(B) A summary report which characterizes the generator's waste streams and assesses the opportunities for waste minimization. The report shall include a systematic review of processes, current applicable technologies, procedures and cost requirements. An operational assessment of the generator's activities will be required in order to collect the necessary data and compile the summary report. Sample assessment forms and a flow chart illustrating the assessment overview can be found in the Department's *Low-Level Radioactive Waste Minimization Guidance*. The following assessment activities are expected to be included in the waste minimization plan and will be used to evaluate the plan:

(1) A description of the facility and the process or service that generates the waste. This may be accomplished by reviewing design, operating and maintenance documentation.

(2) Identification and characterization of the waste streams which result from the process or service. Potential sources of information include process flow diagrams, analytical test data, waste shipment manifests, radioactive material purchase and inventory records.

(3) Prioritization of the radioactive sources and waste streams to select one or more for minimization. Concerns which should be addressed when making this selection will include:

- minimization potential
- reclassification potential
- compliance with current and future regulations
- potential liability
- volume and activity of the waste
- cost/benefit relationship

(4) Analysis and selection of a technically-feasible minimization technique or technology. The process or service that generates the waste will be analyzed relative to the candidate techniques or technologies. If techniques or technologies have been developed, and minimization is believed to have reached optimum levels, the summary report will indicate what activities will allow minimization to continue.

(5) Analysis of the direct and indirect capital costs and operating costs associated with the minimization activity as compared to on-site storage and increasing disposal costs.

(6) Evaluation of both tangible and intangible benefits and detriments of minimization.

(7) Evaluation of the progress or success of the minimization effort. This action should be undertaken periodically after minimization plans are instituted.

(8) An operational assessment whenever a new product or substantial change in service is being considered.

(9) Procedures which rely on reduction of the radioactivity of the waste through decay in storage. These should include the following:

(a) Identification of the radioisotopes and waste which can be considered for decay in storage, and development of a written set of procedures outlining handling and processing steps necessary to isolate those wastes.

(b) Identification of an area where the storage for decay can occur, and evaluation of the size of the area to ensure it is spacious enough to accommodate all wastes to be accumulated through the entire decay cycle.

(c) Identification of adjacent unrestricted areas to ensure adequate shielding is available to maintain radiation levels below specified limits.

(d) Establishment of adequate security measures for the storage for decay area.

(e) Establishment of a radiation survey procedure to measure radiation levels in adjacent unrestricted areas at least weekly.

(f) Development of written procedures to monitor the waste in the storage for decay area to ensure it has decayed to background levels prior to disposal.

(g) Maintenance of all records for all storage for decay and disposal activities, especially radiation surveys.

(C) Specification of the considerations necessary to achieve the required goals. These considerations shall include:

(1) The scope of work necessary to develop and implement the program;

(2) A best estimate of the schedule for implementing each identified task;

(3) Requirements for anticipated personnel, materials and equipment;

(4) A range of cost estimates of all program elements; and

(5) If a minimization program is already in place, the measures necessary to allow minimization to continue at an optimum level should be indicated.

120.897: continued

(D) A statement describing how future business plans will evaluate source and volume minimization for the expected waste streams.

(E) A description of the strategies to be used to measure the success of the minimization program.

(F) A summary of employee training activities which ensure that:
(1) All employees who work with radioactive materials have basic knowledge of common waste problems;
(2) All workers involved directly with the minimization program have the necessary technological skills.

[Note: Guidance for the preparation of a minimization plan may be found in the Generator Guidance which is available from the Department.]

120.900: RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

120.901: Purpose and Scope

(A) 105 CMR 120.900 prescribes requirements for the issuance of a license or certificate of registration authorizing the use of sources of radiation for well logging in a single well. 105 CMR 120.900 also establishes radiation safety requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers, and subsurface tracer studies. The requirements of 105 CMR 120.900 are in addition to, and not in substitution for, the requirements of 105 CMR 120.001, 120.020, 120.750, 120.100 and 120.200.

(B) 105 CMR 120.900 applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral logging, radioactive markers, uranium sinker bars, or subsurface tracer studies. 105 CMR 120.900 does not apply to the use of radioactive material in tracer studies involving multiple wells, such as field flood studies, or to the use of sealed sources auxiliary to well-logging but not lowered into wells.

120.902: Definitions

As used in 105 CMR 120.900, the following definitions apply:

Energy Compensated Source (ECS) means a small sealed source with an activity not exceeding 3.7 megabecquerel (100 μCi), used within a logging tool or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

Field Station means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

Fresh Water Aquifer for the purpose of this part, means a geologic formation that is capable of yielding fresh water to a well or spring.

Injection Tool means a device used for controlled subsurface injection of radioactive tracer material.

Irretrievable Well-logging Source means any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

Logging Assistant means the 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 105 CMR 120.951.

120.902: continued

Logging Supervisor means the individual who uses licensed material or provides personal supervision of the utilization of sources of radiation at a temporary jobsite and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Agency's regulations and the conditions of the license or registration.

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 logging supervisor who is physically present at a temporary jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

Personnel Monitoring Badge means an individual personnel dosimeter that is processed and evaluated by accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.

Radioactive Marker means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

Safety Review means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the result of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

Source Holder means a housing or assembly into which a 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 unsealed radioactive material or a substance tagged with radioactive material for the purpose of tracing the movement or position of the radioactive material or tagged substance in the well-bore or adjacent formation.

Surface Casing for Protecting Fresh Water Aquifers means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

Temporary Jobsite means a location to which radioactive materials have been dispatched to perform wireline service operations or subsurface tracer studies.

Tritium Neutron Generator Target Source means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

Uranium Sinker Bar means a weight containing depleted uranium used to pull a logging tool toward the bottom of well.

Well-bore means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

Well-logging means 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 and/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.

120.903: Licensing and Registration Requirements for Wireline Service Operations

The Agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

(A) The applicant satisfies the general requirements specified in 105 CMR 120.020 for radiation machine facilities or 105 CMR 120.100 for radioactive material, as applicable, and any special requirements contained in 105 CMR 120.900;

(B) The applicant submits an adequate program for training logging supervisors and logging assistants that includes:

(1) Initial training;
(2) On-the-job training;
(3) Annual safety revies provided by the licensee;
(4) Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with 105 CMR 120.900 and licensing requirements and the applicant's operating and emergency procedures; and
(5) 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.

(C) The applicant shall submit to the Agency written operating and emergency procedures as described in 105 CMR 120.932 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(D) 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 105 CMR 120.000, license or registration requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three years after each annual internal inspection.

(E) 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;

(F) If an applicant intends to perform leak testing of sealed sources, the applicant shall identify the manufacturers and 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 to the Agency. The description must include the:

(1) Instruments to be used;
(2) Methods of analyzing the samples; and
(3) Pertinent experience of the person who will analyze the wipe samples.

120.904: Agreement with Well Owner or Operator

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. The licensee shall retain a copy of the written agreement for three years after the well logging operation has been completed. The written agreement shall identify who will meet the following requirements:

(A) (1) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made.
(2) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.
(3) The licensee shall conduct radiation monitoring to detect any contamination.
(a) If the licensee detects evidence of that a sealed source has ruptured or licensed materials have caused contamination, the licensee shall initiate immediately the emergency procedures required in 105 CMR 120.932.
(b) If contamination results from the use of licensed material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.

120.904: continued

(c) During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluid from the well, if any, to check for contamination resulting from damage to the sealed source.

(4) 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.

(5) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

(a) Each irretrievable well logging source must be immobilized and sealed in place with a cement plug.

(b) A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and,

(c) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm (seven inches) square and three mm (c ”) thick. The plaque must contain:

1. The word "CAUTION";
2. The radiation symbol (the conventional color requirement need not be met);
3. The date of abandonment;
4. The name of the well operator or well owner;
5. The well name and well identification number(s) or other designation;
6. The sealed source(s) by radionuclide and quantity of activity;
7. The source depth and the depth to the top of the plug; and,
8. An appropriate warning, depending on the specific circumstances of each abandonment. (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 Massachusetts Radiation Control Program".)

(B) In the event a decision is made to abandon the sealed source downhole, the requirements of 105 CMR 120.904(A) and any other Commonwealth Agency having applicable regulations shall be met.

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

(D) A licensee may apply, pursuant to 105 CMR 120.904, for Agency approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a nanner not otherwise authorized in 105 CMR 120.904(A)(5).

EQUIPMENT CONTROL

120.911: Labels, Security, and Transport Requirements

(A) Labels.

(1) The licensee may not use a source, source holder, or logging tool that contains licensed material unless the smallest component that is transported as a separate piece of equipment with the licensed material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in 105 CMR 120.237(A) without the conventional color requirements, and the wording "DANGER (or CAUTION) RADIOACTIVE MATERIAL."

(2) The licensee may not use a container to store licensed material unless the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in 105 CMR 120.237(A) and the wording "CAUTION (or DANGER), RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

(3) The licensee may not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with 105 CMR 120.775.

120.911: continued

(B) Security Precautions during Storage and Transportation.

(1) The licensee shall store each source containing licensed material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of licensed or registered material from storage by unauthorized personnel. The licensee shall store licensed or registered material in a manner which will minimize danger from explosion or fire.

(2) The licensee shall lock and physically secure the transport package containing licensed or registered material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed or registered material from the vehicle.

120.914: Radiation Survey Instruments

(A) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments capable of detecting beta and gamma radiation at each field station and temporary jobsite to make physical radiation surveys as required by 105 CMR 120.900 and 120.221. Instrumentation shall be capable of measuring 0.1 milliroentgen (2.58×10^{-8} C/kg) per hour through at least 50 milliroentgens (1.29×10^{-5} C/kg) per hour.

(B) Each radiation survey instrument shall be calibrated:

(1) At intervals not to exceed six months and after each instrument servicing;

(2) For linear scale instruments, at two points located approximately a and b 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 appropriate points; and,

(3) So that accuracy within plus or minus 20% of the true radiation level can be demonstrated on each scale.

(C) Calibration records shall be maintained for a period of three years for inspection by the Agency.

(D) The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them in a timely manner from a second party.

120.915: Leak Testing of Sealed Sources

(A) Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of becquerel (mμCi)and maintained for inspection by the Agency for three years after the leak test is performed.

(B) Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The wipe sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of (185 becquerel) (0.005 μCi) of radioactive material on the wipe sample.

(C) Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. Each ECS that is not exempt from testing in accordance with 105 CMR 120.915(A) shall be tested at intervals not to exceed three years. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

120.915: continued

(D) Leaking or Contaminated Sources. If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with 105 CMR 120.200. The licensee shall check the equipment associated with the leaking or contaminated source for radiation contamination and, if contaminated, have it decontaminated or disposed of by an NRC or Agreement State licensee. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the Agency within five working days.

(E) Exemptions. The following sources are exempted from the periodic leak test requirements of 105 CMR 120.915(A) through (D):

(1) Hydrogen-3 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- and/or gamma-emitting radioactive material with an activity of 3.7 megabecquerel) (100 μCi)) or less; and
(5) Sources of alpha-emitting radioactive material with an activity of 0.370 MB (10 μCi) or less.

120.916: Physical Inventory

Each licensee or registrant shall conduct a semi-annual physical inventory to account for all sources of radiation. Records of inventories shall be maintained for three 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. Physical inventory records may be combined with leak test records.

120.917: Utilization Records

Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the Agency for three 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 and the identity of the logging assistants present;

(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 and the disposition of any unused tracer materials.

120.918: Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations

(A) A licensee may use a sealed source for well logging applications if:

(1) The sealed source is doubly encapsulated;
(2) The sealed source contains licensed radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and
(3) Meets the requirement of 105 CMR 120.918(B), (C),or (D).

(B) For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source for well logging applications, if it meets the requirements of USAI N5.10-1968, “Classification of Sealed Radioactive Sources,” or the requirements of 105 CMR 120.918(C) or (D).

120.918: continued

(C) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for well logging applications; if it meets the oil-well logging requirements of ANSI/HPS N.43.6-1997, "Sealed Radioactive Sources-Classifications."

(D) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for well logging applications, if:

(1) The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(a) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for one hour and then be subject to a thermal shock test with a temperature drop from 600°C to 20 C within 15 seconds.

(b) Impact Test. A five kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.

(c) Vibration Test. The test source must be subjected to a vibration from 25 Hz to 500 Hz at five g amplitude for 30 minutes.

(d) Puncture Test. A one gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

(e) Pressure Test. The test source must be subject to an external pressure of 1.695×10^7 pascals (24,600 pounds per square inch absolute).

(E) The requirements of 105 CMR 120.918(A), (B), (C), and (D) do not apply to sealed sources that contain radioactive material in gaseous form.

(F) The requirements in 105 CMR 120.918(A) through 105 CMR 120.918(D) do not apply to energy compensated sources (ECS). ECSs must be registered with the Agency under 105 CMR 120.128(N) or with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

120.920: Inspection, Maintenance and Opening of a Source or Source Holder

(A) Each licensee shall visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the equipment involved, defects found, and retained for three years after the defect is found.

(B) Each licensee or registrant shall have a program for semi-annual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uraniun sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations performed, any defects found, and any actions taken to correct the defects. Records of inspection and maintenance shall be maintained for a period of three years for inspection by the Agency.

(C) Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to 105 CMR 120.932 has been approved either by the Agency pursuant to 105 CMR 120.903(C), the NRC, an Agreement State or a Licensing State.

(D) If a sealed source is struck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiselling, on the source holder unless the licensee is specifically approved by the Agency to perform such operation.

(E) 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.

120.922: 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.

120.923: Subsurface Tracer Studies

(A) The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other appropriate protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of the field stations and temporary jobsites.

(B) A licensee may not knowingly inject radioactive material into fresh water aquifers without prior written authorization from the Agency.

120.924: Radioactive Markers

The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in 105 CMR 120.196: *Appendix B Table I*. The use of radioactive markers is subject to the requirements of 105 CMR 120.916.

120.925: Uranium Sinker Bars

The licensee may use a uranium sinker bar in well logging after the effective date of 105 CMR 120.000 only if it is legibly impressed with the words "CAUTION -- RADIOACTIVE -- DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

120.926: Use of a Sealed Source in a Well Without a Surface Casing

The license may use a sealed source in a well without casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Agency pursuant to 105 CMR 120.903(C).

120.927: Energy Compensated Sources

The licensee may use an energy compensated source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of radioactive material not exceeding 3.7 megabecquerel. (100 μCi).

(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 105 CMR 120.915, 120.916 and 120.917.

(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 105 CMR 120.904, 120.915, 120.916, 120.917, 120.926 and 120.954.

120.928: Tritium Neutron Generator Target Source

Use of a tritium neutron generator target source, containing quantities not exceeding 1.110 terabecquerels (30 Ci) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of 105 CMR 120.900 except 105 CMR 120.904, 120.918 and 120.954.

(B) Use of a tritium neutron generator target source containing quantities exceeding 1.110 terabecquerels (30 Ci) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of 105 CMR 120.900 except 120.918.

120.929: 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 controlled or shielded so that the requirements of 105 CMR 120.200, as applicable, are met.

RADIATION SAFETY REQUIREMENTS

120.931: Training Requirements

(A) The licensee or registrant may not permit any individual to act as a logging supervisor as defined in 105 CMR 120.900 until such individual has:

(1) Successfully completed a course recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, at least 24 hours of formal training in the subjects outlined in 105 CMR 20.960: *Appendix A*;

(2) Received copies of and instruction in the regulations contained in 105 CMR 120.900 and the applicable sections of 105 CMR 120.001, 120.200 and 120.750 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures;

(3) Demonstrated understanding of the requirements of 105 CMR 120.931(A)(1) and 120.931(A)(2) by successfully completing a written examination administered by the licensee or registrant;

(4) Completed 320 hours of on-the-job training under the supervision of a logging supervisor; and

(5) Demonstrated through a field evaluation, competence to use sources of radiation, related handling tools, and survey instruments which will be used on the job.

(B) The licensee or registrant may not permit any individual to act as a logging assistant until such individual has:

(1) Received copies of and instruction in the regulations contained in 105 CMR 120.900 and in the applicable sections of 105 CMR 120.001, 120.200 and 120.750 and the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof;

(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 provide safety review for logging supervisors and logging assistants at least once during each calendar year.

(D) The licensee or registrant shall maintain records documenting the training and reviews required by 105 CMR 120.931(A), (B) and (C) for inspection by the Agency for three years following termination of employment.

120.932: 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, including the use of sealed sources in wells without surface casing for protecting fresh water aquifers if appropriate;

(B) Methods and occasions for conducting radiation surveys, including surveys for detecting contamination;

(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 to prevent accidental loss, tampering or unauthorized removal;

120.932: continued

(F) Minimizing exposure of individuals in the event of an accident;

(G) Procedure for notifying proper personnel in the event of an accident;

(H) Maintenance of records, including records generated by logging personnel at temporary jobsites;

(I) Inspection and maintenance of sealed sources, source holders, logging tools, source handling tools, storage containers, transport containers, injection tools and uranium sinker bars;

(J) Procedure to be followed in the event a sealed source is lodged downhole;

(K) Procedures to be used for picking up, receiving, and opening packages containing radioactive material;

(L) For the use of tracers, decontamination of the environment, equipment, and personnel;

(M) 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 105 CMR 120.914(B);

(O) The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources; and

(P) Identifying and reporting to the Agency defects and noncompliance as required by 10 CFR Part 21 of the NRC regulations

120.933: Personnel Monitoring

(A) The licensee or registrant may not permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears, at all times during the handling of licensed radioactive material and sources of radiation, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Each personnel monitoring badge shall be assigned to and worn by only one individual. Film badges shall be replaced at least monthly and other personnel monitoring badges replaced at least quarterly. After replacement, each personnel dosimeter must be promptly processed. If a personnel monitoring badge is lost or damaged, the worker shall cease work immediately until a replacement badge is provided and the exposure is calculated by the RSO or the RSO's designee for the time period from issuance to loss or damage of the badge. The results of the calculated exposure and the time period for which the personnel monitoring badge was lost or damaged shall be provided to the processor to adjust the individual's occupational exposure record.

(B) The licensee shall provide bioassay services to individuals using radioactive materials in tracer studies if required by the license.

(C) Personnel monitoring records shall be maintained for inspection until the Agency authorizes disposition.

120.941: Radiation Surveys

(A) Radiation surveys shall be made and recorded for each area where radioactive materials are stored.

(B) Before transporting licensed material, radiation surveys and/or calculations shall be made and recorded for the radiation levels in positions occupied by each individual in the vehicle and on the exterior of each vehicle used to transport the licensed radioactive material. Such surveys and/or calculations shall include each source of radiation or combination of sources to be transported in the vehicle.

120.941: continued

(C) If the sealed source is removed from the logging tool before the departure from the temporary jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(D) If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

(F) Records required pursuant to 105 CMR 120.951(A) through (E) 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 three years after completion of the survey.

120.951: Security

(A) A logging supervisor must be physically present at a temporary jobsite whenever licensed material are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in the well.

(B) During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized and/or unnecessary entry into a restricted area, as defined in 105 CMR 120.005.

120.952: 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;

(B) Operating and emergency procedures;

(C) Applicable regulations;

(D) Records of the latest survey instrument calibrations pursuant to 105 CMR 120.914;

(E) Records of the latest leak test results pursuant to 105 CMR 120.915;

(F) Quarterly inventories required pursuant to 105 CMR 120.916;

(G) Utilization records required pursuant to 105 CMR 120.917;

(H) Records of inspection and maintenance required pursuant to 105 CMR 120.920;

(I) Survey records required pursuant to 105 CMR 120.951; and,

(J) Training records required pursuant to 105 CMR 120.931.

120.953: 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 105 CMR 120.951 for the period of operation at the site;

120.953: continued

(C) Evidence of current calibration for the radiation survey instruments in use at the site;

(D) When operating in the Commonwealth under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and,

(E) Shipping papers for transportation of radioactive material.

120.954: 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 provisions of 105 CMR 120.281 and 120.282 and 120.142.

(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; and,

(2) Notify the Agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter 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 an appropriate method of abandonment, which shall include:

(a) The immobilization and sealing in place of the radioactive source with a cement plug;

(b) The setting of a whipstock or other deflection device; and,

(c) The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by 105 CMR 120.954(D);

(2) Notify the Agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and

(3) File a written report with the Agency within 30 days of the abandonment, setting forth the following information:

(a) Date of occurrence and a brief description of attempts to recover the source;

(b) A description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form;

(c) Surface location and identification of well;

(d) Results of efforts to immobilize and set the source in place;

(e) Depth of the radioactive source;

(f) Depth of the top of the cement plug;

(g) Depth of the well; and,

(h) Information contained on the permanent identification plaque.

(D) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore (an example of a suggested plaque is shown in 105 CMR 120.900: *Appendix* 120.770(B). 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:

(a) The word "CAUTION";

(b) The radiation symbol without the conventional color requirement;

(c) The date of abandonment;

(d) The name of the well operator or well owner;

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

(f) The sealed source(s) by radionuclide and quantity of activity;

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

(h) An appropriate warning, depending on the specific circumstances of each abandonment. (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 Massachusetts Radiation Control Program".)

120.954: continued

(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, describe the magnitude and extent of loss of radioactive material, the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

120.960: 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

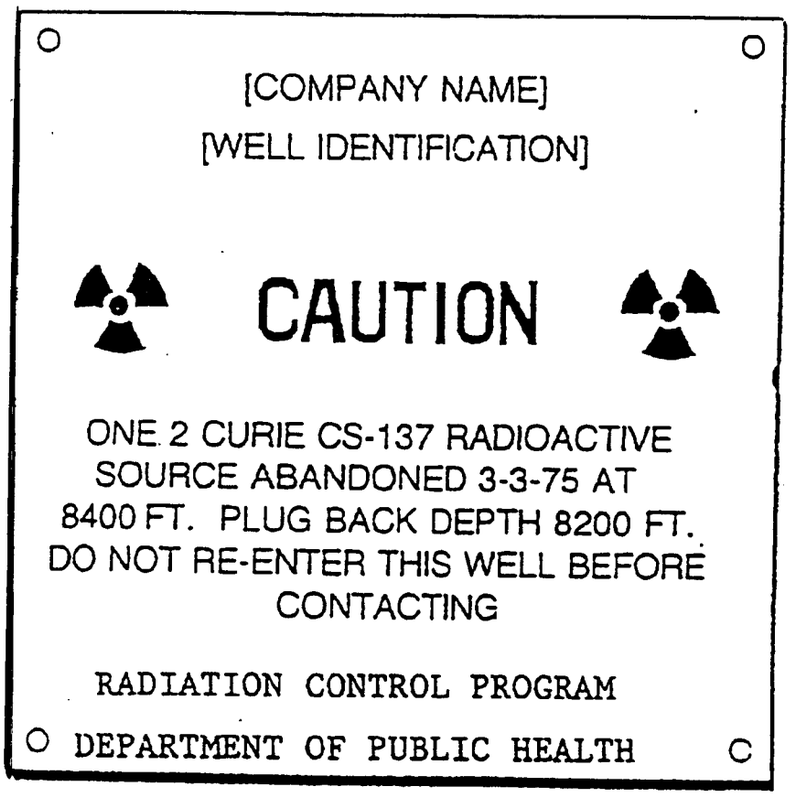
III. Equipment to be Used.
- A. Handling equipment
- B. Sources of radiation
- C. Storage and control of equipment
- D. Operation and control of equipment

IV. The Requirements of Pertinent Federal and Commonwealth Regulations

V. The Licensee's or Registrant's Written Operating and Emergency Procedures

VI. The Licensee's or Registrant's Record Keeping Procedures

120.961: Appendix B -- Example of Plaque for Identifying Wells Containing Sealed Sources Containing Radioactive Material Abandoned Downhole



The size of the plaque should be convenient for use on active or inactive wells, *e.g.*, a seven-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, *e.g.*, ½-inch and ¼-inch letter size, respectively.

REGULATORY AUTHORITY

105 CMR 120.000: M.G.L. c. 111, §§ 3, 5, 5M, 5N, 5O and 5P.