STATE OF MAINE
RADIATION PROTECTION RULE

10-144 CODE OF MAINE RULES
Chapter 220

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PART A.

GENERAL PROVISIONS

1. **Scope.** Except as otherwise specifically provided, this rule applies to all persons who receive, possess, use, transfer, own or acquire any source of radiation; provided, however that nothing in this rule shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.[1]

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

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.

Accelerator-produced material means any material made radioactive by a particle accelerator. (See Appendix B of Part C.)

Act means 22 MRS Ch.160.

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).

Added filtration means any filtration which is in addition to the inherent filtration.

Additional authorized use/storage site (See Field Station.)

Address of use means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

Adult means an individual 18 or more years of age.

Agency means the Maine Department of Health and Human Services.

Agreement state means any state with which the U.S. Nuclear Regulatory Commission (NRC) or the U.S. Atomic Energy Commission has entered into effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended.

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

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

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

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

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

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.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

ANSI means American National Standards Institute.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

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

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 (SARs) and self-contained breathing apparatus (SCBA) units.

Atomic energy means all forms of energy released in the course of nuclear fission or nuclear transformation.

Background radiation means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and

including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under control of the licensee. Background radiation does not include sources of radiation from radioactive materials regulated by the Agency.

Barrier (See Protective barrier.)

Beam axis means the axis of rotation of the beam-limiting device.

Beam limiting device means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the 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.

Becquerel (See Units of radioactivity.)

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 this rule, radio-bioassay is an equivalent term.

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

Byproduct Material means:

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

(2). The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

Calendar quarter means not less than 12 consecutive weeks or more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of this rule except at the beginning of a year.

Calibration means the determination of:

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

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

CFR means Code of Federal Regulations.

Changeable filters, means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

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

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 fewer than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of this rule, lung class and inhalation class are equivalent terms.

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.

Commencement of construction means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other pre-construction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

Committed dose equivalent (H_{T50}) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent (CEDE)($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma_{WT} H_{T50}$).

Consortium means an association of medical use licensees and a positron emission tomography (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 federal facility or a medical facility.

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

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason

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

Curie (See Units of radioactivity.)

Cyclotron means a type of particle accelerator that is used for the production of radioactive material.

Cyclotron/PET Facility means a facility comprised of a cyclotron and a nuclear pharmacy that specializes in the preparation of PET radiopharmaceuticals.

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

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

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.

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

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

Dentist means an individual duly registered and licensed to practice dentistry or dental surgery or any branch thereof under 32 MRSA §1084.

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.

Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of this rule, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

Derived air concentration-hour (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

Detector (See Radiation detector.)

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

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.

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, or total effective dose equivalent as defined in other definitions in this part. For purposes of this rule , radiation dose is an equivalent term.

Dose commitment means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For the purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

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 the rem.

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

Dosimetry processor means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

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

Effective kilogram means:

(1) For the source material uranium in which the uranium isotope uranium-235 is greater than 0.005 (0.5 weight percent) of the total uranium present: 10,000 kilograms, and

(2) For any other source material: 20,000 kilograms.

Effective kilograms of special nuclear material means:

(1) For plutonium and uranium-233 their weight in kilograms;

(2) For uranium with an enrichment in the isotope U-235 of 0.01 (1%) and above, its element weight in kilograms multiplied by the square of its enrichment expressed as a decimal weight fraction; and

(3) For uranium with an enrichment in the isotope U-235 below 0.01 (1%), by its element weight in kilograms multiplied by 0.0001.

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

Entrance or access point means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

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

Exposure means being exposed to ionizing radiation or to radioactive material, or
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 units of exposure are the coulomb per kilogram (C/kg) and the roentgen (R).

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, and arm below the elbow; or foot, knee, and leg below the knee.

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

Field station or site means a facility where licensed or registered material may be stored or used and from which equipment is dispatched. This includes an additional authorized use/storage site. The term authorized use/storage site refers to those authorized use/storage locations specifically named on a license or certificate of registration other than:

(1) The main site specified on a license or certificate of registration, or

(2) Other temporary job sites.

Filtering face piece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the face piece or with the entire face piece composed of the filtering medium.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit Test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

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.

Formula quantity means strategic special nuclear material in any combination in a quantity of 5000 grams or more computed by the formula: grams = (grams contained U-235) + 2.5 (grams U-233 + grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

GED means general educational development.

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 (See Units of dose.)

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

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

Healing arts means any discipline which involves the diagnosis or treatment of individuals by a practitioner who is licensed for that purpose by the State of Maine, and which discipline, prior to the original effective date of this rule, included the intentional exposure of individuals to sources of radiation for diagnosis or treatment

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 from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or 30 centimeters 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.

HVL (See Half-value layer.)

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 (1) by bioassay or (2) 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 Part D].

Individual monitoring devices means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this rule, personnel dosimeter and dosimeter are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, personal air sampling devices, and optically stimulated luminescence (OSL) devices.

Inhalation class (see Class.)

Inspection means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, orders, requirements and conditions of the Agency.

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

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

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 one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

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

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

License means a license issued by the Agency in accordance with this rule 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 this rule.

Limits (See Dose limits.)

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

Lost or missing licensed [or registered] source of radiation means licensed [or registered] source of radiation whose location is unknown. This definition includes 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.

Lung class (See Class.)

mA means milliampere.

Major processor means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers or small industrial programs. Type A and B quantities are defined in Section 71.4 of 10 CFR Part 71.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or that person's delegate or delegates.

Member of the public means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

Microcurie (µCi) means that amount of radioactive material which disintegrates at the rate of 37 thousand atoms per second.

Millicurie (mCi) means that amount of radioactive material which disintegrates at the rate of 37 million atoms per second.

Minor means an individual less than 18 years of age.

Monitoring means the measurement of radiation levels, radioactive material concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this rule, 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. See Appendix B of Part C.

Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in Appendix E of Part 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 face piece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Nonstochastic effect means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this rule, deterministic effect is an equivalent term.

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 duties involve exposure to radiation or to radioactive material from licensed, or registered, and unlicensed, or unregistered, sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Part G, from voluntary participation in medical research programs, or as a member of the public.

Offshore waters means that land and water, within the Agreement States' Submerged Lands Act jurisdiction, on or above the U.S. Outer Continental Shelf. The territorial waters of Maine extend to a line three geographical miles distant from the coastline.

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

Particle accelerator (See Accelerator.)

Patient means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

Permanent storage site means any location that is specifically named on a license or certificate of registration and that is used only for storage of sources of radiation.

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing but not including Federal Government agencies.

Personnel monitoring equipment (See Individual monitoring devices.)

Phantom means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

Pharmacist means an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.

Physician means a medical doctor or doctor of osteopathy duly registered and licensed to practice medicine or surgery or any branch thereof under 32 MRSA §3270.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

Podiatrist means an individual duly registered and licensed to practice podiatry or any branch thereof under 32 MRS §3552.

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 as 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 face piece when the positive pressure is reduced inside the face piece by inhalation.

Primary protective barrier: (See Protective barrier.)

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(1) Primary protective barrier means the material, excluding filters, placed in the useful beam.

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

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

Production facility means production facility as defined in the rule contained in Part C of this rule.

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background

radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under Part G, from voluntary participation in medical research programs.

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

Qualified expert means an individual who is either a radiological physicist, or an x-ray survey technician (see Part F.4.) and has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and advise regarding radiation protection needs. 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.

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 Tables I and II of A.13 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.

Quarter means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Rad (See Units of dose.)

Radiation means ionizing radiation and nonionizing radiation.

(1) Ionizing radiation means gamma rays and x rays, alpha and beta particles, high-speed electrons, neutrons, protons and other nuclear particles; but not sound or radio waves, or visible, infrared or ultraviolet light.

(2) Nonionizing radiation means any electromagnetic radiation, other than ionizing electromagnetic radiation, and any sonic, ultrasonic or infrasonic wave.

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

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 dose (See Dose.)

Radiation machine means any device capable of producing radiation except those, which produce radiation only from radioactive material.

Radiation safety officer is 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 or registrant.

Radiation therapy physicist means an individual qualified in accordance with Part G §961 of this rule.

Radioactive material means any material which emits ionizing radiation spontaneously. It includes accelerator-produced, by-product, naturally occurring, source and special nuclear materials.

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

Radio-bioassay (See Bioassay.)

Radiological physicist means an individual who:

(1) Is certified by the American Board of Radiology in therapeutic radiological physics, diagnostic radiological physics, or medical nuclear physics; or

(2) Has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or sealed source teletherapy unit; or

(3) Has a master's degree or doctorate in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

Reference man means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to this rule.

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

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

REM (See Units of dose.)

Research and development means (a) theoretical analysis, exploration, or experimentation; or (b) 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.

Residential location means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

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 all radioactivity from all licensed, or registered, 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 Part D.

Respiratory protection device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

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 radiation and radioactive material. 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 (See Units of dose.)

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.

Scattered radiation means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.

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

Secondary dose monitoring system means a system that will terminate irradiation in the event of failure of the primary dose monitoring system.

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 of the whole body or the skin of 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 (See Units of dose.)

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.

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

Source material means:

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

(2) Ores which contain by weight one-twentieth of one percent (0.05 percent) 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 definition of byproduct material.

Sources of radiation means, collectively, radioactive material and radiation generating equipment.

Special form 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 5 millimeters (0.2 inch); and

(3) It satisfies the test requirements specified by the U.S. NRC. A special form encapsulation designed in accordance with the NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985 may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985 must meet requirements of this definition applicable at the time of its design or construction.

Special nuclear material means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Agency declares by order to be special nuclear material after [2] the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

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

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

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 this rule, probabilistic effect is an equivalent term.

Storage area means any location, facility, or vehicle which is used to store and secure a radiation machine, 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 machine, device, container, or source.

Storage container is a device in which a sealed source is secured and stored

Storage facility is a structure designed to house one or more sources of radiation to provide security and shielding at a permanent storage site. A storage facility is also known as a vault.

Stray radiation means the sum of leakage and scattered radiation.

[2] This wording is provided for states that cannot automatically adopt changes made by the Nuclear Regulatory Commission.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

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 radiological material or other sources of radiation. When appropriate, such an evaluation includes, but is not limited to, a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentration or quantities of radioactive material present.

Temporary job site means a location where radiographic operations are conducted and where sources of radiation may be stored other than those location(s) of use authorized on the license or a certificate of registration.

Termination of irradiation means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Test means the process of verifying compliance with applicable regulation.

This rule means all parts of the Maine Radiation Protection Rule 10-144 CMR 220.

Tight-fitting face piece 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 effective dose equivalent and the committed effective dose equivalent to the organ receiving the highest dose as described in D.2106.A(6) of this rule.

Transport container means a package that is designed to provide radiation safety and security when sealed sources are transported and that meets all applicable requirements of the U.S. Department of Transportation.

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.

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 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, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

Units of Dose: The units of radiation dose are:

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

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

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

(4) **REM** (rem) is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

(5) **Sievert** (Sv) is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

Units of radioactivity: The units of activity are:

(1) **Becquerel** (Bq) is the SI unit for the expression of activity. One becquerel is equal to 1 disintegration per second (dps). One bequerel = 2.7×10^{-11} curie.

(2) **Curie** (Ci) is a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegration per second (dps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.0001 curie = 3.7×10^{7} tps. One microcurie (μCi) = 0.000001 curie = 3.7×10^{4} dps.

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

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

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rads) in one hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.[2]

Virtual source means a point from which radiation appears to originate.

Waste means those low-level radioactive wastes containing source, special nuclear, or radioactive material, that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste cannot also be classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or radioactive material as defined in the definition of radioactive material set forth in this section.

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

Wedge filter means a filter which causes continuous change in transmission over all or a part of the useful beam.

Week means seven consecutive days starting on Sunday.

Weighting factor w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ/Tissue	**w_T**
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	**1.00[b]**

a. 0.30 results from 0.06 for each of 5 remainder organs, excluding the skin and the lens of the eye, that receive the highest doses.

b. For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors

[2] 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.

for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

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

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

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

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

X-Ray Survey Technician means a person with a high school diploma and who has:

(1) A BS/BA degree in health physics or radiological health and one years' experience in the field of diagnostic x-ray as outlined in Appendix E of Part F; or

(2) A BS/BA degree in a natural science and two year's experience in the field of diagnostic x-ray as outlined in Appendix E of Part F; or

(3) A license in the State of Maine as a radiologic technologist with three year's experience in the field of diagnostic x-ray as outlined in Appendix E of Part F; or

(4) Educational training equivalent to one of the above criteria; as determined by the Agency; and five year's experience in the field of diagnostic x-ray as outlined in Appendix E of Part F.

X-ray tube means any electron tube that is designed to be used primarily for the production of x-rays.

Year means the period of time beginning in January used to determine compliance with the provisions of this rule. 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.

3. Exemptions.

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

B. U.S Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories

operating within this State is exempt from this rule to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

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

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

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

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

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

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

C. Common and contract carriers, freight forwarders, and warehousemen are exempt from the requirements for a license to the extent that they transport or store radioactive material in the regular course of carriage for another.

4. **Records**. 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 this rule.

5. **Inspections.**

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

B. Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to this rule.

C. Inspection frequencies are indicated in Appendix A to Part C, and Part F.3.C for radiation material and x-ray machines respectively.

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

A. Source of radiation;

B. Facilities wherein sources of radiation are used or stored;

C. Radiation detection and monitoring instruments; and

D. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

7. **Additional requirements**. The Agency may, by rule, or order, impose upon any licensee or registrant such requirements in addition to those established in this as it deems appropriate or necessary to minimize danger to public health and safety or property.

8. **Violations.** An injunction or other court order may be obtained prohibiting any violation of any rule or order issued thereunder. Any person who willfully violates any rule or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

9. **Impounding**. Sources of radiation shall be subject to impounding pursuant to Section 688 (2) of the Act.

10. **Prohibited uses.**

A. Hand-held fluoroscopic screens shall not be used.

B. Shoe-fitting fluoroscopic devices shall not be used.

11. **Interpretations.** Except as specifically authorized by the Agency in writing, no interpretation of this rule by an officer or employee of the Agency other than a written interpretation by the legal counsel will be recognized to be binding upon the Agency.

12. **Communications.** All communications and reports concerning this rule, and applications filed thereunder, should be addressed to the Radiation Control Program, Maine Center for Disease Control and Prevention, Department of Health and Human Services, 11 State House Station, Augusta, Maine 04333-0011.

13. **The International system of units (SI).** The Metric Conversion Act of 1975 (PL 94-168) urged the increasing awareness and use of the International System of Units (SI). The generally accepted regulatory values in the narrative portions of this document are followed by the SI equivalents in parentheses. Where appropriate, schedules and appendices are provided, with notes concerning conversion factors. The inclusion of the SI equivalent is for informational purposes only unless otherwise specified.

A. Units of Exposure and Dose

(1) Absorbed dose. The unit of absorbed dose is the gray (Gy) which is equal to 1 joule per kilogram. One rad is equal to 1×10^{-2} gray. Sub-multiples included in this document are the milligray (mGy) and the microgray (□Gy).

(2) Dose equivalent. The unit of dose equivalent is the sievert (Sv) which is equal to 1 joule per kilogram. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor. One REM is equal to 1×10^{-2} sievert. Submultiples included in this document are the millisievert (mSv) and the microsievert (□Sv).

(3) Exposure. The unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air. Submultiples of this unit are the millicoulomb per kilogram (mC/kg) and the microcoulomb per kilogram (□C/kg).

(4) Quality factors. As used in this rule, the quality factors for converting absorbed dose to dose equivalent are shown in Table I. (next page)

TABLE I

Quality Factors and Absorbed Does Equivalencies

Absorbed Dose Type of Radiation	Quality Factor (Q)	Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

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

(5) If it is more convenient to measure the neutron influence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in A.13.A(4), 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of this rule, be assumed to result from a total influence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

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

Mean Quality Factors Q, and Fluence Per Unit Dose Equivalent for Monoenergetic Neutrons

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

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

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

B. Units of Activity. For purposes of this rule, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(1) The unit of measurement of radioactivity is the becquerel (Bq) and it is equal to one transformation per second.

(2) One curie is equal to 3.7 x 10^{10} disintegrations or transformations per second (dps or tps) = 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm). Multiples included in this document are kilobecquerel (kBq), megabecquerel (MBq), gigabecqueral (GBq), and petabecquerel (PBq).

PART B.

ENFORCEMENT ACTIONS, PROCEDURES, AND CIVIL PENALTIES

1. Purpose and scope

A. The following statement of general policy and procedure explains the enforcement policy and procedures of the Maine Center for Disease Control and Prevention, Radiation Control Program in initiating enforcement actions. This statement is applicable to enforcement in matters involving the public health and safety, and the environment.

B. The purpose of the enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

(1) Ensuring compliance with regulations and license conditions;

(2) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;

(3) Deterring future violations and occurrences of conditions adverse to quality; and

(4) Encouraging improvement of licensee and vendor[1]/performance, and by example, and that of industry, including the prompt identification and reporting of potential safety problems.

C. Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees or vendors who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the Agency expects. It is the State's intent that sanctions should be designed to ensure that a licensee or vendor does not deliberately profit from violations of these requirements. Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

2. Severity of violations

A. Regulatory requirements have varying degrees of safety or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

B. Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

I. Health physics;
II. Transportation;
III. Materials operations;
IV. Miscellaneous matters; and
V. Emergency preparedness.

[1] The term "vendor" means a supplier of products or services to be used by a licensee or registrant in a licensed or registered facility or activity.

C. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations 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.

D. 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

E. While examples are provided in Appendix 1 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 is designed to illustrate the significance which the Radiation Control Program places on a particular type of violation of State requirements. Each of the examples is predicated on a violation of regulatory requirement.

F. 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.

G. 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" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. 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 Radiation Control Program. 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.

H. The Radiation Control Program expects licensees to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in Appendix 1, 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. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

3. Enforcement conferences

A. 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 will normally hold 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

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

(2) Determine whether there are any aggravating or mitigating circumstances, and

(3) Obtain other information which will help determine the appropriate enforcement action.

B. In addition, during the enforcement conference, the licensee or vendor will be given an opportunity to explain to the Agency what corrective actions (if any) were taken or will be taken following discovery of the potential violation or nonconformance. Licensees or vendors will be told when a meeting is an enforcement conference.

C. When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, or revoking a license, will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken.

4. Enforcement actions

A. This Part describes the enforcement sanctions available to the Agency and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters, notices of nonconformance and notices of deviation are used to supplement the enforcement program.

B. In selecting the enforcement sanctions to be applied, the Agency will consider enforcement actions taken by other State regulatory bodies having concurrent jurisdiction, such as in environmental or transportation matters. With very limited exceptions, whenever a violation of Agency requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved.

C. For the vast majority of violations, action by the Agency is appropriate in the form of a notice of violation requiring a formal response from the recipients describing its corrective actions.

D. In situations involving nonconformance on the part of a vendor, a Notice of Nonconformance will be issued.

E. Elevated enforcement actions include civil penalties orders modifying, suspending or revoking licenses; or orders to cease and desist from designated activities.

5. Notice of violation

A. Before instituting any proceeding to modify, suspend, or revoke a license or to take other action for alleged violation of any provision of the Radiation Protection Act or this rule or the conditions of the license, the Agency will serve on the licensee or other person subject to the jurisdiction of the Agency a written notice of violation, except as provided in paragraph (3) of this section. The notice of violation will concisely state the alleged violation and will require that the licensee or any other person submit, within 20 working days of the date of the notice or other specified time, a written explanation or statement in reply including:

(1) Corrective steps which have been taken by the licensee or other person and the results achieved;

(2) Corrective steps which will be taken; and

(3) The date when full compliance will be achieved.

B. Because the Agency wants to encourage and support licensee initiative for self-identification and correction of problems, the Radiation Control Program will not generally issue a notice of violation for a violation that meets all of the following tests:

(1) It was identified by the licensee;

(2) It fits in Severity Level IV or V;

(3) It was reported; if required;

(4) It was or will be corrected, including measures to prevent recurrence, within a reasonable time; and

(5) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

C. Licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors. Enforcement actions involving individuals, including licensed operators, will be determined on a case-by-case basis, and must be approved by the Director of the Division of Environmental and Community Health, Maine Center for Disease Control and Prevention, Department of Health and Human Services.

D. The notice may require the licensee or other person subject to the jurisdiction of the Agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if any adequate reply is not received within the time specified in the notice, the Agency may issue an order to show cause why the license should not be modified, suspended or revoked or why such other action as may be proper should not be taken.

E. When the Agency finds that the public health, safety, or interest so requires, or that the violation is willful, the notice of violation may be omitted and an order to show cause issued.

6. Civil penalties

A. A civil penalty is a monetary penalty that may be imposed for violation of:

(1) Certain specified licensing provisions of the Radiation Protection Act or these rules, or orders, or

(2) Any requirement for which a license may be revoked. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

B. Before instituting any proceeding to impose a civil penalty authorized under 22 MRSA Section 690 of the Radiation Protection Act, the Agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to Part B.5. The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged, and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and shall state the amount of each penalty which the Agency proposes to impose. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation, or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the Agency, if any, the penalty may, unless compromised, remitted or mitigated, be collected by civil action pursuant to the Act.

C. Generally, civil penalties are 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 for which the licensee did not take effective corrective action.

D. In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

E. Civil penalties will normally be assessed for known and conscious violations of the reporting requirements of these rules and for any willful violation of any Agency requirement including those at any severity level.

F. Within 20 working days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments, denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

G. If the person charged with the violation fails to answer within the time specified in paragraph (F) of this Part, the Agency will issue an order imposing the civil penalty in the amount set forth in the notice of violation described in paragraph (B) of this Part

H. If the person charged with violation files an answer to the notice of violations, the Agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 working days of the date of the order or other time specified in the order, request a hearing.

I. If the person charged with violation requests a hearing, the Agency will issue an order designating the time and place of hearing.

J. If a hearing is held, an order will be issued after the hearing by the Agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

K. If the civil penalty is not compromised, or is not remitted and if payment is not made within ten 10 working days following either the service of the order described in paragraph (G) or (J) of this section, or the expiration of the time for requesting a hearing described in paragraph (H) of this

section, no such request having been made, the Agency may refer the matter to the Office of the Maine Attorney General for collection.

L. The Agency may impose different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the base civil penalties for various areas. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater potential consequences to the public and licensee employees will receive higher civil penalties.

M. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the agency's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's ability to pay. In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, the Agency will consider as necessary an increase or decrease on a case-by-case basis.

N. The Agency attaches great importance to the comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

O. Ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Agency intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to statutory limit. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.

P. Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

Q. The Agency reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees.

R. Payment of civil penalties imposed under 22 MRSA Section 690 of the Act shall be made by check, draft, or money order payable to the Treasurer of State of Maine, and mailed to: Radiation Control Program, Maine Center for Disease Control and Prevention, Department of Health and Human Services, 11 State House Station, Augusta, Maine 04333-0011.

7. Adjustment factors

A. After considering all relevant circumstances, adjustments to the civil penalty values may be made for the factors described below:

(1) Prompt identification and reporting. Reduction of up to 50 percent of the base civil penalty may be given when a licensee identifies the violation and promptly reports the violation to the Agency. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.

(2) Corrective action to prevent recurrence. Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive correction action may result in reducing the proposed civil penalty as much as 50 percent of the base value shown in Table 1A. The civil penalty may be increased as much as 50 percent of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action - such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

(3) Past Performance. Reduction by as much as 100 percent of the base civil penalty shown in Table 1 may be given for prior good performance in the general area of concern. On the other hand, the base civil penalty may be increased as much as 100 percent for prior poor performance in the general area of concern. In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as prior enforcement history including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.

(4) Prior notice of similar events. The base civil penalty may be increased as much as 50 percent for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific NRC or industry notification, and had failed to take effective preventive steps.

(5) Multiple occurrences. The base civil penalty may be increased as much as 50 percent where multiple examples of a particular violation are identified during the inspection period.

B. The above factors are additive. However, in no instance will a civil penalty for any one violation exceed $10,000 per day.

C. The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

(1) If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and, as such, subject to a separate additional civil penalty.

(2) If a licensee is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.

(3) Alternatively, whether a licensee is aware or should have been aware of a violation that continues for more than one day, the civil penalty imposed for one violation may be increased to reflect the added significance resulting from the duration of the violation.

D. The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, to focus on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem may be based on the amount shown in the table for a problem of that Severity Level, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

8. Orders

A. An order is a written Agency directive to modify, suspend, or revoke a license to cease and desist from a given practice or activity or to take such other action as may be proper. Orders may be issued as set forth below. Orders may also be issued in lieu of, or in addition to, civil penalties as appropriate.

(1) License Modification Orders are issued when some change in licensee equipment, procedures, or management controls is necessary.

(a) The Agency may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within 20 working days from the date of the notice or such longer period as the notice may provide.

(b) The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. If the licensee requests a hearing during this 20-day period, the amendment will become effective on the date specified in an order made following the hearing.

(2) Suspension Orders may be used:

(a) To remove a threat to the public health and safety or the environment;

(b) To stop facility construction when: (a) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, to include shielding, or (b) the licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

(c) When the licensee has not responded adequately to other enforcement action;

(d) When the licensee interferes with the conduct of an inspection or investigation; or

(e) For any reason not mentioned above for which license revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

(3) Revocation Orders may be used:

(a) When a licensee is unable or unwilling to comply with this rule;

(b) When a licensee refuses to correct a violation;

(c) When a licensee does not respond to a notice of violation where a response was required;

(d) When a licensee refuses to pay as stated in Appendix 1 to Part C.

(e) For any other reason for which revocation is authorized under Section 677 of the Radiation Protection Act (e.g., any condition which would warrant refusal of a license on an original application).

(4) Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by the Agency that such Activity is unauthorized.

(5) Show Cause Orders.

(a) The Agency may institute a proceeding to modify, suspend, or revoke a license or for such other action as may be proper by serving on the licensee an order to show cause which will:

(i) Allege the violations with which the licensee is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the proposed action;

(ii) Provide that the licensee may file a written answer to the order under oath or affirmation within 20 working days of its date, or such other time as may be specified in the order;

(iii) Inform the licensee of his right, within 20 working days of that date of the order, or such other time as may be specified in the order, to demand a hearing;

(iv) Specify the issues; and

(v) State the effective date of the order.

(b) A licensee may respond to an order to show cause; by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order to show cause, and may set forth the matters of fact and law on which the licensee relies. The answer may demand a hearing.

(c) If the answer demands a hearing, the Agency will issue an order designating the time and place of hearing.

(d) An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order to show cause.

(e) The consent of the licensee to the entry of an order shall constitute a waiver by the licensee of a hearing, findings of fact and conclusions of law, and of all right to seek Agency and judicial review or to contest the validity of the order in any forum. The order shall have the same force and effect as an order made after hearing by the Agency.

B. Orders are made effective immediately, without prior opportunity for hearing whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the Agency believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

9. Escalation of enforcement sanctions

A. The Agency considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, the Agency will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Agency 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 sections 5, 6, 7, and 8 of this Part.

B. Examples of enforcement actions that could be taken for similar Severity Level I, II or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

C. Normally, the progression of enforcement actions for similar violations will be based on violations under a single license. When more than one facility is covered by a single license, the normal progression will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that 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 division 1 of a dual unit hospital that repeats an earlier violation of division 2 might be considered similar.

TABLE 1A - Base Civil Penalties

	Health Physics, Operations, EP, and Miscellaneous	Transportation	
		Greater Than Type A Quantity[1]	Type A Quantity or less[2]
a. Industrial users of material[3]	$10,000	$5,000	$2,000
b. Waste disposal licensees	$10,000	$5,000	$2,000
c. Academic or medical institutions[4]	$5,000	$2,500	$1,000
d. Other material licenses	$2,000	$2,500	$1,000
e. X-ray facilities	$1,000		

[1] Includes quantities requiring Type B packaging.
[2] Includes low specific activity waste, low level waste, Type A packages and excepted quantities and articles.
[3] Includes industrial radiographers, nuclear pharmacies, and other industrial users.
[4] This applies to nonprofit institutions not otherwise categorized under section a through e in this table.

TABLE 1B - Base Civil Penalties

Severity Level	Base Civil Penalty[1]
I	100%
II	80%
III	50%
IV	15%
V	5%

[1] Percent of amount listed in able 1A.

TABLE 2 - Examples Of Progressions Of Escalated Enforcement Actions For Similar Violations In The Same Activity Area Under The Same License

Severity of Violation	Number of similar violations from the date of the last inspection or within the previous two years (whichever period is greater)		
	1ST	2ND	3RD
I	a+b	a+b+c	d
II	a	a+b	a+b+c
III	----	a	a+b

a. Civil penalty.
b. Suspension of affected operations until the Radiation Control Program Manager is satisfied that there is reasonable assurance that the licensee can operate in compliance with the applicable requirements or modification of the license, as appropriate.
c. Show cause for modification or revocation of the license, as appropriate.
d. Further action, as appropriate.

10. **Related administrative actions** In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, the Agency also uses administrative mechanisms, such as bulletins, circulars, information notices, generic letters, notices of deviation, notices of nonconformance and confirmatory action letters to supplement its enforcement program. The Agency expects licensees and vendors to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to licensees to make sure that such commitments are met.

A. Bulletins, circulars, information notices and generic letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.

B. Notices of deviation are written notices describing a licensee's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee to provide a written explanation or statement describing corrective steps taken (or planned), the result achieved, and the date when corrective action will be completed.

C. Confirmatory action letters are letters confirming a licensee's or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

D. Notices of nonconformance are written notices describing non-licensees' failure to meet commitments which have not been made legally binding requirements by the Agency. Notices of nonconformances request non-licensees to provide written explanation or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.

11. **Referrals to department of the attorney general** Alleged or suspected criminal violations of the Radiation Protection Act (and of other relevant state laws) are referred to the Department of the Attorney General for investigation. Referral to the Attorney General does not preclude the Agency from taking other enforcement action. However, such actions will be coordinated with the Department of the Attorney General to the extent practicable.

12. **Public disclosure of enforcement actions** In accordance with the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases are generally issued for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Level I, II, or III, press releases are issued at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally issued for Notices of Violation.

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.

1. Severity Level I - Most significant violations

A. Health Physics

1. Single exposure of a worker in excess of 25 rems (0.25 Sv) of radiation to the whole body, 150 rems (1.5 Sv) to the skin of the whole body, or 375 rems (3.75 Sv) to the feet, ankles, hands, or forearms;

2. Annual whole body exposure of a member of the public in excess of 2.5 rems (0.025 Sv) of radiation;

3. Release of radioactive material to an unrestricted area in excess of ten times the limits of section D.1302;

4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of section D.2001;

5. Exposure of a worker in restricted areas of ten times the limits of section D.1201.;

B. Transportation

1. Annual whole body radiation exposure of a member of the public in excess of 0.5 rems (0.005 Sv) of radiation; or

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

C. Materials Operations

1. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

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

D. Miscellaneous Matters

1. A Material false statement[2] (MFS) in which the statement made was deliberately false;

2. 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

3. A knowing and intentional failure to provide the notice required by this rule.[2]

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

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

E. Emergency Preparedness. In an emergency, licensee failure to promptly:

1. Correctly identify the event;

2. Make required notifications to responsible federal, State, and local agencies; or

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

2. Severity Level II - Very significant violations

A. Health Physics

1. Single exposure of a worker in excess of 5 rems (0.05 Sv) of radiation to the whole body, 30 rems (0.3 Sv) to the skin of the whole body or 75 rems (0.75 Sv) to the feet, ankles, hands or forearms;

2. Annual whole body exposure of a member of the public in excess of 0.5 rems (0.005 Sv) of radiation;

3. Release of radioactive material to an unrestricted area in excess of five times the limits of Part D.1302.;

4. Failure to make an immediate notification as required by Parts D.2201 and D.2202;

5. Disposal of license material in quantities or concentrations in excess of five times the limits of Part D.2001;

6. Exposure of a worker in restricted areas in excess of five times the limits of Part D.1201;

7. 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.

8. A fluoroscopic x-ray system with a tabletop entrance exposure rate of greater than or equal to 25 R/min (0.25 Gy/min) at the point where the center of the useful beam enters the patient, except:

[2] 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 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, careless disregard, or deliberateness. 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.

(a) During recording of fluoroscopic images, or

(b) When an optional high level control is activated.

9. A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier, or

10. Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, etc.

11. Therapy system, with improper operator/patient communication/observation.

B. Transportation

1. Breach of package integrity resulting in surface contamination or external radiation levels in excess of Agency requirements;

2. Surface contamination or external radiation levels in excess of five times Agency limits that did not result from a breach of package integrity; or

3. Failure to make required initial notifications associated with Severity Level I or II violations.

C. Material Operations

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or

2. A system designed to prevent or mitigate a serious safety event being inoperable.

D. Miscellaneous Matters

1. 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;

2. A MFS made with careless disregard;

3. Deliberate falsification of records which the Agency requires be kept involving significant information; or

4. A failure to provide the notice required.

5. Failure to register sources of radiation or services as required by these rules.

6. Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency.

E. Emergency Preparedness

1. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

3. Severity Level III - Significant violations

A. Health Physics

1. Single exposure of a worker in excess of 3 rems (0.3 Sv) of radiation to the whole body, 7.5 rems (0.075 Sv) to the skin of the whole body, or 18.75 rems (0.1875 Sv) to the feet, ankles, hands or forearms;

2. A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem (1 mSv) in a one hour period or 500 millirem (5 mSv) in any seven consecutive days;

3. Failure to make a 24-hour notification or an immediate notification as required by Part D.2202;

4. Substantial potential for an exposure or release in excess of Part D of these rules, 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);

5. Release of radioactive material to an unrestricted area in excess of the limits of Part D.1302;

6. Improper disposal of licensed material not covered in Severity Level I or II;

7. Exposure of worker in restricted areas in excess of the limits of Part D.1201.;

8. 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;

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

10. Conduct of licensee activities by a technically unqualified person;

11. Significant failure to control licensed material;

12. Failure to use exposure reduction devices properly (e.g., collimators, filtration);

13. For a fluoroscopic system where the maximum allowable tabletop exposure rate is 5 R/min (0.05 Gy/min), test values of greater than or equal to 7 R/min. (0.07 Gy/min) (uncorrected), but less than 25 R/min (0.25 Gy/min). Correspondingly, for a maximum allowable rate of 10 R/min (0.10 Gy/min), test values of greater than or equal to 14 R/min (0.14 Gy/min) (uncorrected) but less than 25 R/min (0.25 Gy/min) are included;

14. 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 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

15. 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 9 centimeters or which exhibit a minimum SSD less than 16 centimeters.

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

17. Mammographic x-ray systems in which the edge of the x-ray field at the chestwall extends beyond the edges of the image receptor by more than 5 percent of the source to image receptor distance.

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

B. Transportation

1. Breach of package integrity

2. 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;

3. 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

4. Failure to make required initial notification associated with Severity Level III violations.

C. Materials Operations

1. Failure to control access to licensed materials for radiation purposes as specified by Agency requirements;

2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

3. Use of radioactive material on humans where such use is not authorized;

4. Conduct of licensed activities by a technically unqualified person;

5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or

6. Therapeutic medical event.

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

D. Miscellaneous Matters

1. An MFS not amounting to a Severity Level I or II violation; or

2. 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.

E. Emergency Preparedness.

1. Violations of lesser severity than Severity Level II violations.

4. Severity Level IV - Violations

A. Health Physics

1. Exposures in excess of the limits of Part D. not constituting Severity Level I, II, or III violations;

2. A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem (20 µSv) in a one-hour period or 100 millirem (1 mSv) in any seven consecutive days;

3. Failure to make a 30-day notification required by Part D.2202;

4. Failure to make a follow-up written report as required by Parts D.2201, D.2203, and J.4; or

5. Any other matter that has more than minor safety or environmental significance.

6. A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr (30 µGy/hr), but less than 25 mR/hr (250 µGy/hr).

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

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

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

10. 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 percent of the SID.

B. Transportation

1. Package selection or 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

2. Other violations that have more than minor safety or environmental significance.

C. Material Operations

1. 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;

2. Other violations that have more than minor safety or environmental significance; or

3. Failure to report diagnostic medical event.

D. Miscellaneous Matters

1. 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.

2. 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

E. Emergency Preparedness

1. Violations of lesser severity than Severity Level III violations.

5. Severity Level V - Minor violations

A. Health Physics

1. For a fluoroscopic x-ray system where the maximum allowable tabletop exposure rate is 5 R/min (0.05 Gy/min), test values of greater than 5.0 R/min (0.05 Gy/min) (uncorrected), but less than 7.0 R/min (0.07 Gy/min). Correspondingly, if the maximum allowable tabletop exposure rate is 10 R/min (0.10 Gy/min), test values of greater than 10.0 R/min (0.10 Gy/min) (uncorrected) but less than 14.0 R/min (0.14 Gy/min) are included.

2. Other violations that have minor safety or environmental significance.

B. Transportation

1. Other violations that have minor safety or environmental significance.

C. Materials Operations

1. Other violations that have minor safety or environmental significance.

D. Miscellaneous Matters

1. Other violations that have minor safety or environmental significance.

G. Emergency Preparedness

1. Other violations that have minor safety or environmental significance.

PART C.

LICENSING OF RADIOACTIVE MATERIAL

1. Purpose and scope

A. Parts C, E, G, I, L, N, and Q of this rule, provide for the licensing of radioactive material and the assignment of fees for such licenses.[1] No person shall manufacture, produce, receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this Part or as otherwise provided in Parts E, G, I, N or Q of this rule or in a specific or general license issued pursuant to Parts C, G or L, or as otherwise provided in these Parts. Fees are specifically addressed in Appendix A to Part C.

B. This Part and Part B also give notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor or sub-contractor, any components, equipment, materials, or other goods or services that relate to a licensee's, applicant's or certificate of registration holder's activities subject to these rules, that those persons may be individually subject to Agency enforcement action for violation as prescribed in Part B.

C. In addition to the requirements of this Part, all licensees are subject to the requirements of Parts A, D, J and L of this rule. Licensees engaged in industrial radiographic operations are subject to the requirements of Part E, licensees involved in the medical use of radioactive material are subject to the requirements of Part G, licensees using particle accelerators, excluding medical therapy accelerators, are subject to the licensing requirements of Part I of this rule, licensees using irradiators are subject to the requirements of Part Q of this rule, licensees engaged in the use of technically enhanced naturally occurring radioactive material (TENORM) are subject to the requirements of Part N of this rule, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part K of this rule.

EXEMPTIONS FROM THE REGULATORY REQUIREMENTS

2. Source material

A. Any person is exempt from this Part to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

B. Any person is exempt from this Part to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

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

C. Any person is exempt from this Part 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 2 grams of thorium,

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

(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, provided that the glaze contains not more than 20 percent by weight source material,

(b) Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, or ceramic used in construction, or

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

(d) Piezoelectric ceramic containing not more than 2 percent by weight source material;

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

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

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

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

(b) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "**DEPLETED URANIUM**,"

(c) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "**UNAUTHORIZED ALTERATIONS PROHIBITED**," and

(d) 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 one-eighth inch (3.2 mm);

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent 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 manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

(b) The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

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

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

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

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

D. The exemptions in C.2.C do not authorize the manufacture of any of the products described.

3. Radioactive material other than source material

A. Exempt Concentrations

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

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.3.A(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State except in accordance with a specific license issued pursuant to C.11.A. or as provided in 10 CFR 32.11.

(3) This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(4) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in the Act and from this rule to the extent that he or she transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Schedule A of Part C and introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

B. Exempt Quantities

(1) Except as provided in C.3.B.3 and 4, any person is exempt from the Act and this rule to the extent that such person receives possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B of this Part.

(2) Any person who possesses radioactive material received or acquired before September 25, 1971 under the general license then provided under 10 CFR 31.4 or similar general license of an Agreement State is exempt from the requirements for a license set forth in this Part to the extent that such person possesses, uses, transfers or owns such radioactive material.

(3) This paragraph (C.3.B) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.3.B or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State except in accordance with a

specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32.18 which license states that the radioactive material may be transferred by the licensee to persons exempt under C.3.B or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State

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

C. Exempt Items

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who desire to initially transfer for sale or distribute the following products containing radioactive material, any person is exempt from this rule to the extent that he or she receives, possesses, uses, transfers, owns, or acquires the following products:[2]

(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:

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

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

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

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

(v) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.

(vi) 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).

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

(vii) The levels of radiation 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 10 centimeters from any surface.
(b) For pocket watches, 0.1 millirad (1 µGy) per hour at 1 centimeter from any surface.
(c) For any other timepiece, 0.2 millirad (2 µGy) per hour at 10 centimeters from any surface.

(viii) One microcurie (37 kBq) of radium-226 per timepiece in timepieces manufactured prior to the November 30, 2007.

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

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

(i) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube.
(ii) 1 microcurie (37 kBq) of cobalt-60.

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

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

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

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

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

(e) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material, provided that:

[3] For purposes of C.3.C.1.(g), 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.

(i) Each source contains no more than one exempt quantity set forth in Schedule B of this Part, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this Part, provided that the sum of such fractions shall not exceed unity.

(iii) For purposes of this paragraph, 0.05 microcurie (1.85 kBq) of americium-241 is considered an exempt quantity under Schedule B of this Part.

(f) Ionization chamber smoke detectors containing not more than 1 microcurie (37 kBq) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(2) Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in C.3.C.(1) (a), or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from C.3.C.(1) (a)

(3) Self-Luminous products containing radioactive material

(a) Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from this rule to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in C.3.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 this rule 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 or manufactured prior to July 1, 1999.

(c) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to C.3.C.(3) (a), should apply for a license pursuant to10 CFR 32.22, which license states that the

product may be transferred by the licensee to persons exempt from C.3.C.(3)(a).or equivalent regulations of an Agreement State.

(4) Gas and aerosol detectors containing radioactive material

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution, gas and aerosol detectors containing radioactive material, any person is exempt from the requirements set forth in this rule to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission[4] pursuant to Section 32.26 of 10 CFR Part 32; This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by the Agency, the NRC, or an Agreement State authorizing distribution to persons exempt from regulatory requirements.

(b) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under C.3.C(3)a, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of C.11.C.

(c) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to C.3.C.(4)(a) should apply for a license pursuant to 10 CFR 32.26, which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to C.3.C(4)(a) or equivalent regulations of the NRC or an Agreement State.

(5) Exemptions for capsules containing carbon-14 urea for in-vivo diagnostic use for humans

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in the regulations in this Part and Part G of 10-144A CMR 220, provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for in-vivo diagnostic use for humans.

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

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part G of 10-144A CMR 220.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsule shall apply for and receive a specific license pursuant to C.7 of this Part.

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

(6) Additional exemptions are available in Parts A, D, E, G, N, L and W of this rule, as applicable.

LICENSES

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

A. General licenses provided in this Part are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular person, although the filing of a certificate with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of this rule and any limitations of the general license.

B. Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of this rule as well as any limitations specified in the licensing document.

C. The general licenses provided in Part C are subject to the general provisions of Parts A, D and J of this rule unless indicated otherwise in the specific provision of the general license.

D. Each general licensee or registrant that is required to register by this Part shall make all necessary reports as required by C.15.D of this Part.

E. Each general licensee or registrant that is required to file an application to the Agency by this Part shall file the applicable form with the Agency annually and include all addresses for locations of use by the registrant. This includes, but is not limited to the verification, correction, and in addition to the information provided in a request for information from the Agency.

GENERAL LICENSES

5. 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 use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license may not

receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

B. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in C.5.A. are exempt from the provisions of Parts D and J of this rule to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

C. Persons who receive, posses, use, or transfer source material pursuant to the general license in C.5.A. are prohibited from administering source material, or the radiation there from, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

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.

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 C.5.E(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in C.5.E(1) applies only to industrial products or devices which have been manufactured or initially transferred either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to C.11.L. 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 C.5.E(1) shall file Agency Form HHE 860, Registration Certificate - Use of Depleted Uranium Under General License, with the Agency and pay the registration fee referenced in Appendix A of this Part. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium or 30 days after the effective date of this rule for depleted uranium acquired prior to the effective date. The registrant shall furnish on Agency Form HHE 860 the following information and such other information as may be required by that form:

(i) Name and address of the registrant;

(ii) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in C.5.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

(iii) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in C.5.ED(3)a(ii).

(b) The registrant possessing or using depleted uranium under the general license established by C.5.E(1) shall report in writing to the Agency any changes in information furnished by him in Agency Form HHE 860 Registration 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 C.5.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 C.21. In the case where the transferee receives the depleted uranium pursuant to the general license established by C.5.E(1), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form HHE 860. 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 regulations equivalent to C.5.E(1)., the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form HHE 860 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation.

(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.

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

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

6. General licenses - radioactive material other than source material

A. Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of A.4 through A.9, C.3.A(2), C.14, C.21, C.22, and Parts D, J and L of this rule.

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

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

B. A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of this Part, a general licensee under C.6 is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

C. Certain measuring, gauging or controlling devices

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provision of C.6.C(2), (3), (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in C.6.C(1) applies only to radioactive material contained in devices, which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.11.D or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of the Code of Federal Regulations, Title 21. The devices must have been received from one of the specific licensees described in C.6.C(2) or through a transfer under C.6.C(3)(i)

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.6.C(1) shall

file Agency Form HHE 861, Registration Certificate - Use of Fixed Measuring, Gauging or Controlling Devices, Agency Form HHE 862, Registration Certificate - Use of Portable Measuring, Gauging or Controlling Devices or Agency Form HHE 864, Registration Certificate for use of Static Eliminators, Electron Capture Devices, Gas Chromatographs, or Other Devices which Contain Radioactive Material Under a General License with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such device or 30 days after the effective date of this rule for devices acquired prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part and:

(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,

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

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

(c) Shall assure that the tests required by C.6.C(3)(b) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

(ii) 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 C.6.C(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. Records of tests for leakage of radioactive material required by C.6.C(3)(b) shall be maintained for three years after the next required leak test is performed or until the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by C.6.C(3)(b) shall be maintained 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. Records which are required by C.6.C(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;

(e) Upon the occurrence of 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 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device 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, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to 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;

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

(g) Shall not export the device containing radioactive material except in accordance with 10 CFR Part 110;

(h) (i) Shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph (g) of this section, by transfer to another general licensee as authorized in paragraph (i) of this section, or to a person authorized to receive the device by a specific license issued under Part C, that authorizes possession, use, waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (h)(iii) of this section.

(ii) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Manager, Radiation Control Program. The report must contain:

(a) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(b) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(c) The date of the transfer.

(iii) Shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; 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 paragraph (a) of this section) so that the device is labeled in compliance with Part D.1904; however the manufacturer, model number, and serial number must be retained;

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

(d) Reports the transfer under paragraph (h)(ii) of this section.

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

(i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this Section, a copy of Sections 10 CFR 31.2, C.25, D.2201, D.2202, and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency: the manufacturer's (or initial transferor's) name and model and serial number of device transferred, the name , address for the location of use of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or

(ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;

(j) Shall comply with the provisions of D.2201. and D.2202. of this rule for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts D and J of this rule;

(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 Radiation Control Program 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) (i) Shall register, in accordance with C.6.C.(3)(m)(ii) and (iii), 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 megabecquerels (0.1 millicurie) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic ((i)e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph C.6.C.(3)(m)(iii)(d), represents a separate general licensee and requires a separate registration and fee.

(ii) If in possession of a device meeting the criteria of C.6.C(3)(m)(i), shall register these devices annually with the Agency and shall pay the required 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 license holding devices meeting the criteria of C.6.C.(3)(m)(i) is subject to bankruptcy notification requirement in Part C.

(iii) In registering devices, 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 paragraph C.6.C(3)(l). of this section.

(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.

(iv) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph C.6.C.(3)(m)(i) this section are not subject to registration requirements if the devices are used in areas subject to Agency jurisdiction for a period fewer 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 Radiation Control Program Manager within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

o. Shall 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 C.6.C(3)(c) 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 C.6.C(1) does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in C.6.C(1) is subject to the provisions of A.4 through A.9., C.14., C.21., C.22. and Part L of this rule.

D. 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 Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in C.6.C.1. are exempt from the requirements of Part D and Part J of this rule except that they shall comply with the provisions of D.2201 and D.2202.

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

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

(5) This general license is subject to the provisions of A.4. through A.9., C.14., C.21., C.22. and Part L of this rule.

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

D. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Part, this general license does not authorize the manufacture, production, transfer, receipt, possession, use, or import or export of radioactive material, except as authorized in a specific license.

E. Calibration and reference sources

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of C.6.E. (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 C.6.E. (4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of C.6.E. (4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(4) The general licenses in C.6.E.(1),(2) and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

(5) The general licenses provided in C.6.E(1), (2) and (3) are subject to the provisions of A.4 through A.9, C.14, C.21, C.22, and Parts D, J and L of this rule. 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 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 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 the following statement, as appropriate, or a substantially similar statement which contains the information called for in the following statement, as appropriate:

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

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)[5]
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;

[5] Showing only the name of the appropriate material

(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.

F. General license for use of radioactive material for certain in vitro clinical or laboratory testing

(1) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of C.6.F. (2), (3), (4), (5), and (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 there from, to human beings or animals:

(a) Iodine-125, in units not exceeding 370 kBq (10 µCi) each;

(b) Iodine-131, in units not exceeding 370 kBq (10 µCi) each;

(c) Carbon-14, in units not exceeding 370 kBq (10 µCi) each;

(d) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 µCi) each;

(e) Iron-59, in units not exceeding 740 kBq (20 µCi) each;

(f) Cobalt-57, in units not exceeding 370 kBq (10 µCi) each;

(g) Selenium-75, in units not exceeding 370 kBq (10 µCi) each; or

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

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.6.F.(1) until he or she has filed Agency Form HHE 863, Certificate- In Vitro Testing with Radioactive Material Under General License, with the Agency as well as the registration fee referenced in Appendix A to this Part and received from the Agency a validated copy of Agency Form HHE 863 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form HHE 863 the following information and such other information as may be required by that form:

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

(b) The location of use; and

(c) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in-vitro clinical or laboratory tests with radioactive material as authorized under the general license in C.6.F.(1). and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by C.6.F.(1) shall comply with the following:

(a) The general licensee shall not possess at any one time, pursuant to the general license in C.6.F.(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 C.6.F.(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 or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(e) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in C.6.F.(1). as required by D.1310. of this rule.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.6.F(1):

(a) Except as prepackaged units, which are labeled in accordance with the provisions of an applicable specific license, issued pursuant to C.11.G. or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under C.6.F 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 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 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 there from, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
(Name of manufacturer)

(5) The registrant possessing or using radioactive material under the general license of C.6.F.1. shall report in writing to the Agency, any changes in the information furnished by him in the Certificate - In-Vitro Testing with Radioactive Material Under General License, Agency Form HHE 880. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of C.6.F.(1). is exempt from the requirements of Part D and Part J of this rule with respect to radioactive material covered by that general license, except that such persons using the mock iodine-125 described in C.6.F.(1). shall comply with the provisions of D.1310, D.1902, and D.1903 of this rule.

G. 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 any Agreement State to the manufacturer of such device pursuant to the licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in C.6.G.(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 D.1310 of this rule;

(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 Part D and Part J of this rule except that such person shall comply with the provisions of D.2001, D.2201, and D.2202.

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

(4) This general license is subject to the provisions of A.4., through A.9., C.14., C.21., C.22., and Part L of this rule.

H. 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 C.6.H.(2) through (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 this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(b) Intact timepieces containing greater than 1 microcurie (0.037 MBq), non-intact 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 1 microcurie (0.037 MBq) of radium-226. For the purposes of this paragraph, ‘‘small radium sources’’ means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in C.6.H.(1) are exempt from the provisions of Parts D and J, and C.25 of this rule, to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this Part.

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

(a) 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 Agency within 30 days.

(b) Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to D.2008 of this rule 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) Not export products containing radium-226 except in accordance with 10 CFR Part 110.

(d) Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under this Part, or equivalent regulations of the NRC or an Agreement State, or as otherwise approved by the Agency.

(e) Respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Agency, by an appropriate method listed in 10 CFR 30.6(a), a written justification for the request.

(4) The general license in C.6.H(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

I. General license to install devices generally licensed in C.6.C.

(1) Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in C.6.C(1) within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in Part A of this rule; provided that:

(a) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.

(b) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

SPECIFIC LICENSES

7. Filing application for specific licenses

A. Applications for specific license shall be filed on a form prescribed by the Agency.

B. The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the 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 their behalf.

D. An application for a license filed pursuant to this rule will be considered also as an application for a license authorizing other activities for which licenses are required, provided that the application specifies the additional activities for which the license is requested and complies with the appropriate regulations.

E. All sections of the application must be completed, clearly and concisely, with the applicable required information and submitted with the applicable fee, if required.

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. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

(1) Identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210, or with an Agreement State or for a source or a device containing radium-226 or accelerator-produced radioactive material with an Agreement State under provisions comparable to 10 CFR 32.210; or

(2) Contain the information identified in 10 CFR 32.210(c).

(3) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the NRC under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:

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

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are

adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

H. 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 Part G or equivalent Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this Part, NRC requirements, 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 C.11.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 C.11.J(2)(b).

(4) Information identified in C.11.J(1)(c) on the PET drugs to be noncommercially transferred to members of its consortium.

I. Emergency Planning

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Schedule D -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release, must contain either:

(a) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rem (50 mSv) to the thyroid or an intake of 2 milligrams of soluble uranium; or

(b) An emergency plan for responding to a release of any radioactive material and to any associated chemical hazards directly incident thereto.

(2) One or more of the following factors may be used to support an evaluation submitted under paragraph I.(1)(a) of this section:

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

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

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

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

(e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule D;

(f) Operating restrictions or procedures would prevent a release fraction as large as that shown in Schedule D; or

(g) Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph I.(1)(a) of this section must include the following information:

(a) Facility description. A brief description of the licensee's facility and area near the site.

(b) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(c) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(d) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(e) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(f) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(g) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Agency; also responsibilities for developing, maintaining, and updating the plan.

(h) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must 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 this Agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

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

(j) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training 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.

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

(l) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee 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.

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

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it the Agency. The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

8. **General requirements for the issuance of specific licenses**. A license application will be approved if the Agency determines that:

A. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this rule in such a manner as to minimize danger to public health and safety or property;

B. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

C. The issuance of the license will not be inimical to the health and safety of the public; and

D. The applicant satisfies any applicable special requirements in C.9, C.10. or C.11. and Part E, Part G, and Part K of this rule.

E. Environmental report, commencement of construction. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, the Agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other pre-construction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

F. Financial surety for decommissioning, recovery or site reclamation.

(1) Each applicant for a specific license authorizing the possession and use of special nuclear material, source material, or unsealed radioactive material in quantities and amounts in excess of those indicated in Table F.1 shall submit a decommissioning funding plan, as described in paragraph (4) of this section, in the event of planned or unplanned decommissioning, recovery, or site reclamation. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 105 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of quantity of each isotope to the applicable value in Part C, Appendix E.

Table F.1

Type	**Exceeding**
Special Nuclear Material	10^5 times Part C, App. E
Source Material	100 μCi in readily dispersible form
Radioactive Material	Half-life greater than 120 days and 10^5 times Part C, App. E

(2) Each applicant for or holder of a specific license authorizing possession and use of special nuclear material, source material, or radioactive material (for sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix E of Part C, or when a combination of isotopes is involved if R, as defined in C.8.F(1), divided by 10^{12} is greater than 1) in excess of those indicated in Table F. 2) shall either:

(a) Submit a decommissioning funding plan as described in paragraph (4) of this section; or

(b) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Table F.2 of this section using one of the methods described in paragraph (4) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material.

Table F.2

Type of Radioactive Material	**Exceeding**	**Assurance Amount**
Special Nuclear	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities*	$1,125,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities*	$225,000
Source Material	Greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form	$225,000
Radioactive Material	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in unsealed form*	$1,125,000

	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in unsealed form*	$225,000
	Greater than 10^{10} times the applicable quantities in sealed sources	$113,000

*****As indicated in Part C, App. E

(3) Each applicant for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in C.8.F(5).

(4) Each applicant for a specific license authorizing possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either—

(a) Submit a decommissioning funding plan as described in paragraph C.8.F(5) of this section; or

(b) Submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 by June 2, 2005 using one of the methods described in C.8.F(6). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC prior to receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of C.8.F(5).

(5) Each funding plan must contain a cost estimate for decommissioning, recovery or reclamation, and a description of the method of assuring funds for such including means of adjusting cost estimates and associated funding levels over the life of the facility. Cost estimates must be adjusted at intervals not to exceed three years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of C.8.F(4).

(6) Financial assurance 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 that will retain their value over the projected operating life of the facility and that are in an amount such that the principal plus accumulated earnings would be sufficient to

pay the necessary costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(b) A surety method insurance or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are contained in Appendix C of this Part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test are as contained in Appendix D of this Part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any other situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance must contain the following conditions:

(i) The surety 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 or insurance must also provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

(ii) The beneficiary of the surety or insurance must be a trustee acceptable to the Agency such as an appropriate State or federal government agency or a major financial organization.

(iii) The surety or insurance must remain in effect until the Agency has terminated the license.

(c) 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 the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficient to pay the necessary costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(d) In the case of State, or local government licensees, a certification that the appropriate government entity will be guarantor of funds.

(e) Other funding methods, which are demonstrated by the applicant or licensee to provide comparable assurance to methods, listed in paragraphs (4)(a) through (c) of this section.

(f) Each person licensed under this Part 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. Before licensed activities are transferred or assigned in accordance with this Part, licensees shall transfer all records described in this paragraph to the new licensee. 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:

(i) 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.

(ii) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes, which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(iii) 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:

(a) All areas designated and formerly designated restricted areas as defined in A.2;

(b) All areas outside of restricted areas that require documentation under C.8.F(4)(f)(i);

(c) All areas outside of restricted areas where current and previous wastes have been buried as documented under D.2108; and

(d) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Part D or apply for approval for disposal under D.2002.

(iv) 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. Special requirements for the use of sealed sources in industrial radiography. In addition to the requirements set forth in C.8, a specific license for use of sealed sources in industrial radiography will be issued if the applicant meets the requirements set forth in Part E of this rule.

10. Special requirements for specific licenses of broad scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.[6]

A. The different types of broad licenses are set forth below:

(1) A Type A specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multi-curie (multi-Becquerel) 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 Schedule C, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed there under, is the quantity specified for the radionuclide in Schedule C, Column (I) If two or more radionuclides are possessed there under, 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 Schedule 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 Schedule C, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed there under, is the quantity specified for that radionuclide in Schedule C, Column I(I). If two or more radionuclides are possessed there under, the possession limit is determined for each as follows: For each radionuclide

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

determine the ratio of the quantity possessed to the applicable quantity specified in Schedule 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 C.8.;

(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:

(i) Control of procurement and use of radioactive material;

(ii) 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

(iii) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with C.10.B.(3). prior to use of the radioactive material.

C. An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in C.8.; 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:

(i) Control of procurement and use of radioactive material,

(ii) 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

(iii) Review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with C.10.C.(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 C.8;

(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 C.10 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 (3,700 TBq) 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 C.9., or, C.11. or Part G is required; or

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

(2) Each Type A specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of C.10.D.

11. Special requirements for a specific license to manufacture, assemble, repair or distribute commodities, products or devices which contain radioactive material.

A. Licensing the introduction of radioactive material into products in exempt concentrations.

No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.3.A. or equivalent regulations of the NRC, or an Agreement State, except in accordance with a license issued under 10 CFR 32.11

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

C. Licensing the incorporation of radioactive material into gas and aerosol detectors. An application for a specific license authorizing the incorporation of radioactive material into gas and aerosol detectors to be distributed to persons exempt under C.3.will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of Radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq). NARM radionuclides are found in Appendix B to Part C.

D. Licensing the manufacture and distribution of devices to persons generally licensed under C.6.D.

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.6.D or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(a) The applicant satisfies the general requirements of C.8.;

(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:

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

(ii) 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 percent of the limits specified in D.6., and

(iii) 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:

Table D.1

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

(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:

(i) 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),

(ii) 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

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

The receipt, possession, use, and transfer of this device, Model_____, Serial No._____[7] are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL
(Name of manufacturer or distributor)

(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 Part D.1901 of this rule, and the name of the manufacturer or initial distributor.

(e) Each device meeting the criteria of Part C bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "**Caution-Radioactive Material**," and, if practicable, the radiation symbol described in Part D.1901 of this rule.

(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, he or she shall include in his/her 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:

(a) Primary containment (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;

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

(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 C.6.D, or under equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he or she shall include in his/her application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information 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 in one year a dose in excess of 10 percent of the limits specified in D.1201.A.

(4) Conditions of transferring a device for use under a general license in C.11.D. Each person licensed under C.11.D. to initially transfer devices to generally licensed persons shall:

(a) If a device containing radioactive material is to be transferred for use under a general license in C.11.D., each person that is licensed under C. , shall provide the information specified in this paragraph to each person to whom a device may be transferred. The information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the general license contained in C.6.C; if paragraphs C.6.C(3)(b) through (d) or (m) do not apply to the particular device, these paragraphs may be omitted to each person to whom the owner directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in C.6.C.

(ii) A copy of C.25, 2201 and D.2202 of this rule;

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

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

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

(b) If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an Agreement State, each person that is licensed under C.11.D. shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the C.6.A., C.6.D., D.2201, and D.2202 of this rule, or a copy of equivalent NRC or Agreement State's regulations. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agency's or Agreement State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the NRC or an Agreement State;

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

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

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

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

(d) Each device that is transferred after the effective date of this rule shall meet the labeling requirements in C.11.D.(1)(c) through C.11.D.(1)(e)

(e) If a notification of bankruptcy has been made under C.14.E. or the license is to be terminated, each person licensed under C.11.D. shall provide, upon request, to the Agency, the NRC, and to any appropriate Agreement State, records of final disposition required under C.11.D.(5)(c).

(5) Material transfer reports and records. Each person licensed under C.11.D. to initially transfer devices to generally licensed persons shall comply with the requirements of C.11.D.

(a) The person shall report all transfers of devices to persons for use under the general license in C.11.D. and all receipts of devices from persons licensed under C.11.D. in a clear and legible report containing all of the data required.

(b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, or Agreement State's regulation equivalent to C.6.D, or alternatively, furnish a copy of the general license contained in C.6.D to each person to whom he or she directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State. If a copy of the general license in C.6.D is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State or under requirements substantially the same as those in C.6.D.

(c) Report to the Agency all transfers of such devices to persons for use under the general license in C.6.D.

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

(a) The identity of each general licensee by name and 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 radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(iii) For devices received from a C.11.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.

(iv) If the licensee makes changes to a device possessed by a C.11.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.

(v) 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.

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

(vii) If no transfers have been made to persons generally licensed under C.6.D. during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.

(d) Reports to Other Agencies.

(i) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR Part 32.52.

(ii) Report to the responsible State Agency all transfers of devices manufactured and distributed pursuant to C.11.D for use under general license in that State's regulations equivalent to C.6.D.

(iii) Such reports 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 of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(iv) If no transfers have been made to Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the Nuclear Regulatory Commission.

(v) 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 the Agency.

(e) Keep records showing the name, address, and the point of contact for each general licensee to whom he or she directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in C.6.D., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of C.11.D.(4).

(f) If radioactive material is to be transferred in a device for use under an equivalent general license of an Agreement State, or the NRC, each person that is licensed under this Part shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the Agreement State's, or NRC's, regulations equivalent to Parts C and D or a copy of Parts C and D. If a copy of the Agency regulations is provided to a prospective general licensee in lieu of the appropriate regulations, it shall be accompanied by a note explaining that use of the device is regulated by another Agreement State, or the NRC; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

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

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

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

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

(h) Each device that is transferred after February 19, 2002 must meet the labeling requirements in this Part.

(i) If a notification of bankruptcy has been made this Part or the license is to be terminated, each person licensed under Part C shall provide, upon request, to the Agency and to any appropriate Agreement State, or NRC records of final disposition required under this Part.

E. Special Requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft.

(1) An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under C.6.C will be approved if:

(a) The applicant satisfies the general requirements specified in C.8;

(b) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(i) Chemical and physical form and maximum quantity of tritium or promethium -147 in each device;

(ii) Details of construction and design;

(iii) Details of the method of binding or containing the tritium or promethium -147;

(iv) Procedures for and results of prototype testing to demonstrate that the tritium or promethium -147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(v) Any quality control procedures proposed as alternatives to those prescribed by C.11.E.(3).

(vi) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device;

(c) Each device will contain no more than 370 GBq (10 Ci) of tritium or 11.1 GBq (300 mCi) of promethium -147. The levels of radiation from each device containing promethium -147 will not exceed 5 μSv (0.5 mrad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber; and

(d) The Agency determines that:

(i) The method of incorporation and binding of the tritium or promethium -147 in the device is such that the tritium or promethium -147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(ii) The tritium or promethium -147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(iii) The device is so designed that it cannot easily be disassembled; and

(iv) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by C.11.E(4).

(2) Labeling of devices.

(a) A person licensed under C.11.E. to manufacture, assemble, or initially transfer devices containing tritium or promethium -147 for distribution to persons generally licensed under C.6.C of this rule shall, except as provided in C.11.E(2)(b) affix to each device a label containing the radiation symbol prescribed by D.1901 of this rule, such other information as may be required by the Agency including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement[8]:

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[9], containing (identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL
(Name of manufacturer, assembler, or initial transferor).

(b) If the Agency determines that it is not feasible to affix a label to the device containing all the information called for in C.11.E(2)(a) it may waive the requirements of that paragraph and require in lieu thereof that:

(i) A label be affixed to the device identifying:

(a) The manufacturer, assembler, or initial transferor; and

(b) The type of radioactive material; and

(ii) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(a) The name of the manufacturer, assembler, or initial transferor,

(b) The type and quantity of radioactive material,

(c) The model number,

[8] Devices licensed under C.28.E prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.
[9] The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(d) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the NRC or of an Agreement State, and

(e) Such other information as may be required by the Agency, including disposal instructions when appropriate.

(3) Quality assurance; prohibition of transfer.

(a) Each person licensed under C.11.E. shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium -147.

(b) Each person licensed under C.11.E. shall take a random sample of the size required by the table in C.11.E.(14) for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(i) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to one inch of mercury. Lowered pressure shall be maintained for one minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit.

(ii) The immersion test water from the preceding test in C.11.E(3)(a) shall be measured for tritium or promethium -147 content by an apparatus that has been calibrated to measure tritium or promethium -147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium -147 in any device is found to have leaked into the immersion test water, the leaking device shall be considered as a defective unit.

(iii) The levels of radiation from each device containing promethium 147 shall be measured. Any device which has a radiation level in excess of 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, shall be considered as a defective unit.

(c) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by C.11.E.(3)(b), and proposed criteria for acceptance under those procedures. The Agency will approve the proposed alternative procedures if the applicant demonstrates that:

(i) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium-147 in any 24 hour period; and

(ii) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(d) No person licensed under C.11.E. shall transfer to persons generally licensed under C.6. of this rule:

(i) Any luminous safety device which has been tested and found defective under the criteria and procedures specified in this section, unless the defective units have been repaired or reworked and have then met the tests set out in C.11.E.(3)(b); or

(ii) Any inspection lot which has been rejected as a result of the procedures in C.28m or alternative procedures in C.11.E.(3)(c), unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in C.11.E.(3)(b).

(4) Schedule B prototype tests for luminous safety devices for use in aircraft. An applicant for a license pursuant to C.11.E. shall conduct prototype tests on each of five prototype luminous safety devices for use in aircraft as follows:

(a) Temperature altitude test. The device shall be placed in a test chamber as it would be used in service. A temperature altitude condition schedule shall be followed as outlined in the following steps:

Step 1. The internal temperature of the test chamber shall be reduced to 62º C (80º F) and the device shall be maintained for at least one hour at this temperature at atmospheric pressure.

Step 2. The internal temperature of the test chamber shall be raised to 54º C (65º F) and maintained until the temperature of the device has stabilized at 54º C at atmospheric pressure.

Step 3. The atmospheric pressure of the chamber shall be reduced to 83 millimeters of mercury absolute pressure while the chamber temperature is maintained at 54º C.

Step 4. The internal temperature of the chamber shall be raised to 10º C (+14º F) and maintained until the temperature of the device has stabilized at 10º C, and the internal pressure of the chamber shall then be adjusted to atmospheric pressure. The test chamber door shall then be opened in order that frost will form on the device, and shall remain open until the frost has melted but not long enough to allow the moisture to evaporate. The door shall then be closed.

Step 5. The internal temperature of the chamber shall be raised to +85º C (185º F) at atmospheric pressure. The temperature of the device shall be stabilized at +85º C and maintained for two hours. The device shall then be visually inspected to determine the extent of any deterioration.

Step 6. The chamber temperature shall be reduced to +71º C (160º F) at atmospheric pressure. The temperature of the device shall be stabilized at +71º C for a period of 30 minutes.

Step 7. The chamber temperature shall be reduced to +55º C (130º F) at atmospheric pressure. The temperature of the device shall be stabilized at this temperature for a period of four hours.

Step 8. The internal temperature of the chamber shall be reduced to +30º C (86º F) and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of four hours.

Step 9. The temperature of the test chamber shall be raised to +35º C (95º F) and the pressure reduced to 83 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 30 minutes.

Step 10. The internal pressure of the chamber shall be maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to +20º C (68º F) and stabilized. The device shall be maintained under these conditions for a period of four hours.

(b) Vibration tests. This procedure applies to items of equipment (including vibration isolating assemblies) intended to be mounted directly on the structure of aircraft powered by reciprocating, turbojet, or turbo propeller engines or to be mounted directly on gas turbine engines. The device shall be mounted on an apparatus dynamically similar to the most severe conditions likely to be encountered in normal use. At the end of the test period, the device shall be inspected thoroughly for possible damage. Vibration tests shall be conducted under both resonant and cycling conditions.

Vibration Test Schedule Table I
[Times shown refer to one axis of vibration]

Type	Vibration at room temperature (Min.)	Vibration at 160º F. (71º C) (minutes)	Vibration at -65º F. (-54º C) (minutes)
Resonance	60	15	15
Cycling	60	15	15

(i) Determination of resonance frequency. Individual resonance frequency surveys shall be conducted by applying vibration to

each device along each of any set of three mutually perpendicular axes and varying the frequency of applied vibration slowly through a range of frequencies from 5 Hz (5 cycles per second) to 500 Hz (500 cycles per second) with the double amplitude of the vibration not exceeding that shown in Figure 1 for the related frequency.

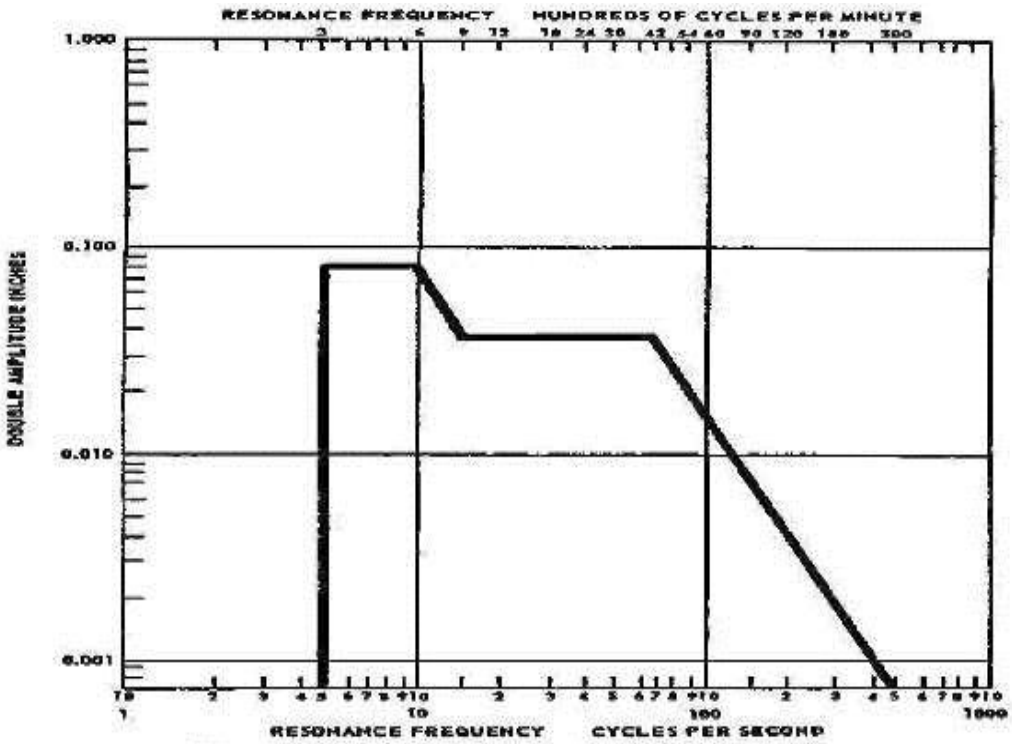


FIGURE 1—Amplitude of vibration at resonance frequency.

(ii) Resonance tests. The device shall be vibrated at the determined resonance frequency for each axis of vibration for the periods and temperature conditions shown in Table I and with the applied double amplitude specified in Figure 1 for that resonance frequency. When more than one resonant frequency is encountered with vibration applied along any one axis, the test period may be accomplished at the most severe resonance or the period may be divided among the resonant frequencies, whichever is considered most likely to produce failure. When resonant frequencies are not apparent within the specified frequency range, the specimen shall be vibrated for periods twice as long as those shown for resonance in Table I at a frequency of 55 cycles per second and an applied double amplitude of 0.060 inch.

(iii) Cycling. Devices to be mounted only on vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10

and 55 cycles per second in one minute cycles for the periods and temperature conditions shown in Table I. Devices to be installed in aircraft without vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.036 inch or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15 minute cycles for the periods and temperature conditions shown in Table (I).

(c) Accelerated weathering tests. The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine. Panels of Corex D glass shall surround the arc to cut off the ultraviolet radiation below a wavelength of 2,700 angstroms. The light of the carbon arcs shall fall directly on the face of the device. The temperature at the sample shall be maintained at 50º C. plus or minus 3º C. Temperature measurements shall be made with a black panel thermometer.

(d) Shock test. The device shall be dropped upon a concrete or iron surface in a three foot free gravitational fall, or shall be subjected to equivalent treatment in a test device simulating such a free fall. The drop test shall be repeated 100 times from random orientations.

(e) Hermetic seal and waterproof test. On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to one inch of mercury. Lowered pressure shall be maintained for one minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the device, or water entering the device, shall be considered leakage.

(f) Observations. After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium -147. Any evidence of damage to or failure of any device which could affect containment of the tritium or promethium -147 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of tritium or promethium -147 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of tritium or promethium-147 in the water used in the hermetic seal and waterproof test prescribed by C.11.E.(4)(e) shall also be measured. Measurements shall be made in an apparatus calibrated to measure tritium or promethium -147, as appropriate. The detection on the filter paper of more than 37 Bq (2,200 disintegrations per minute) of tritium or promethium -147 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of tritium or promethium -147 in any device shall be cause for rejection of the tested device.

(5) Material transfer reports. Each person licensed under C.11.E shall file an annual report with the Agency, which report must state the total quantity of tritium or promethium -147 transferred to persons generally licensed under C.6.C. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium -147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter.

F. Special Requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons Generally licensed under C.6.E.

(1) An application for a specific license to manufacture or initially transfer, calibration or reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under C.6.E will be approved if:

(a) The applicant satisfies the general requirement of C.8;

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

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

(ii) Details of construction and design;

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

(iv) Procedures for and results of prototype testing of sources, which are designed to contain more than 185 Bq (0.005 μCi) of americium -241, radium-226 to demonstrate that the americium -241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

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

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

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

(c) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent;

(d) Each source will contain no more than 185 kBq (5 μCi) of americium -241 or radium-226; and

(e) The Agency determines, with respect to any type of source containing more than 185 Bq (0.005 μCi) of americium -241 or radium-226, that:

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

(ii) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by C.11.F(2), Schedule C, of this Part.

(2) Schedule C prototype tests for calibration or reference sources containing americium -241, plutonium or radium-226. An applicant for a license pursuant to C.11.F shall, for any type of source which is designed to contain more than 185 Bq (0.005 μCi) of americium -241, plutonium or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 185 Bq (0.005 μCi) of americium -241, plutonium or radium-226, as follows:

(a) Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(b) Dry wipe test. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(c) Wet wipe test. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(d) Water soak test. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(e) Dry wipe test. On completion of the preceding test in this section, the dry wipe test described in C.11.F.(2)(b) shall be repeated.

(f) Observations. Removal of more than 185 Bq (0.005 μCi) of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Agency shall be given in terms of radioactivity in microcuries (Bq) and percent of removal from the total amount of radioactive material deposited on the source.

(3) Labeling of devices. Each person licensed under C.11.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[10]:

The receipt, possession, use and transfer of this source, Model No.__, Serial No. __, are subject to a general license and the regulations of the NRC or an Agreement State. 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

(4) Leak testing of each source. Each person licensed under C.11.F shall perform a dry wipe test upon each source containing more than 3.7 kBq (0.1 μCi) of americium -241 or radium-226 prior to transferring the source to a general licensee under C.6. 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 paper shall be measured by using radiation detection instrumentation capable of detecting 185 Bq (0.005 μCi) of americium -241or radium-226. If any such test discloses more than 185 Bq (0.005 μCi) of radioactive material, the source shall be deemed to be leaking or losing americium -241, or radium-226 and shall not be transferred to a general licensee under C.6 or equivalent regulations of an Agreement State.

G. Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

H. Manufacture and distribution of radioactive material for certain in-vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.6.F will be approved if:

(1) The applicant satisfies the general requirements specified in C.8.

[10] Sources licensed under C.28f prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

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

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

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

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

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

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

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

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

(h) 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.

(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 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 (185 Bq) microcurie of americium-241 each; and

(b) Displaying the radiation caution symbol described in D.2001 and the words, "**CAUTION, RADIOACTIVE MATERIAL**," and "**NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS**."

(4) The following statement, as appropriate, 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 there from, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
(Name of manufacturer)

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in

handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in D.2001 of this rule.

(I) Licensing the manufacture and distribution of ice detection devices containing strontium-90.

(1) An application for a specific license to manufacture or initially transfer ice detection devices to persons generally licensed under C.6.G. will be approved if:

(a) The applicant satisfies the general requirements of C.8; and

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(i) Chemical and physical form and maximum quantity of strontium -90 in the device;

(ii) Details of construction and design of the source of radiation and its shielding;

(iii) Radiation profile of a prototype device;

(iv) Procedures for and results of prototype testing of devices to demonstrate that the strontium -90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

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

(vi) Description of labeling to be affixed to the device;

(vii) Instructions for handling and installation of the device;

(viii) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device;

(c) Each device will contain no more than 1.85 MBq (50 μCi) of strontium -90 in an insoluble form;

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by D.1901(a) of this rule, a statement that the device contains strontium 90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is

prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices; and

(e) The Agency determines that:

(i) The method of incorporation and binding of the strontium 90 in the device is such that the strontium -90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(ii) The strontium -90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his/her body in excess of 5 mSv (0.5 rem) in a year under ordinary circumstances of use;

(iii) The device is so designed that it cannot be easily disassembled;

(iv) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by C.11.(I)(1)(c); and

(v) Quality control procedures have been established to satisfy the requirements of C.11.(I)(2).

(2) Quality assurance; prohibition of transfer.

(a) Each person licensed under C.11.I shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium 90.

(b) Each person licensed under C.11.I shall test each device for possible loss of strontium -90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 37 Bq (2,200 disintegrations per minute) of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under C.11.(I) shall take a random sample of the size required by the table in C.11.M. for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(i) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium -90. Absolute pressure of the air above the water shall then be reduced to one inch of mercury. Lowered pressure shall be maintained for one minute or until air

bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium -90, shall be considered as a defective unit.

(ii) The immersion test water from the preceding test in C.11.(I)(2)(c)(i) of this section shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium -90 in any device, the device shall be considered as a defective unit.

(d) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by C.11.I(2)(c). and proposed criteria for acceptance under those procedures. The Agency will approve the proposed alternative procedures if the applicant demonstrates that:

(i) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium -90 in any 24 hour period; and

(ii) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(e) No person licensed under C11.I (2) shall transfer to persons generally licensed under C.6.G. of this rule:

(i) Any device which has been tested and found defective under the criteria and procedures specified in this C.11.I unless the defective units have been repaired or reworked and then met the tests set out in C.11.I(2)(c); or

(ii) Any inspection lot which has been rejected as a result of the procedures in C.11.I(2) or alternative procedures in C.11.(I)(2)(d) unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in C.11.(I)(2)(c)

(3) Schedule D prototype tests for ice detection devices containing strontium 90. An applicant for a license pursuant to C.11.I shall conduct prototype tests on each of five prototype ice detection devices as follows:

(a) Temperature altitude test. The device shall be placed in a test chamber as it would be used in service. A temperature altitude condition schedule shall be followed as outlined in Step 1 through Step 10 of C.11.E.(4) (a)

(b) Vibration tests. The device shall be subjected to vibration tests as set forth in C.11.E.(4)(b).

(c) Shock test. The device shall be subjected to shock test as set forth in C.11.E.(4)(d).

(d) Hermetic seal and waterproof test. On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium -90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for one minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium -90 shall be considered leakage.

(e) Observations. After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of strontium -90. Any evidence of leakage or damage to or failure of any device which could affect containment of the strontium -90 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of strontium -90 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of strontium -90 in the water used in the hermetic seal and waterproof test prescribed in C.11.I(2)(d) shall also be measured. The detection on the filter paper of more than 37 Bq (2,200 disintegrations per minute) of strontium -90 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of strontium -90 in any device, shall be cause for rejection of the tested device.

J. Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under Part G licenses.

(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 Part G will be approved if:

(a) The applicant satisfies the general requirements specified in C.8. of this Part;

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

(i) 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); or

(ii) Registered or licensed with a State Agency as a drug manufacturer; or

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

(iv) Operating as a nuclear pharmacy within a federal medical institution.

(v) A positron emission tomography (PET) drug production facility registered with a State Agency.

(c) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and The applicant satisfies the following labeling requirements:

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

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

(2) A licensee described by paragraph (1)(b)(iii) or (iv) of this section:

(a) May prepare radioactive drugs for medical use, as defined in Part G.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (2)(b) and (2)(c) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in Part G.

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

(i) This individual qualifies as an authorized nuclear pharmacist as defined in Part G.2,

(ii) This individual meets the requirements specified in Part G and the licensee has received an approved license amendment

identifying this individual as an authorized nuclear pharmacist, or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (2)(c) of this section.

(c) The actions authorized in paragraphs (2)(a) and (2)(b) of this section are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in Part A(2)as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an authorized user on a nuclear pharmacy license issued by the Agency under this Part.

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

(ii) The individual practiced 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 dater as noticed by the NRC.

(e) Shall provide to the Agency a copy of each individual's:

(i) Certification by a specialty board whose certification process has been recognized by the Agency, the NRC or an Agreement State as specified in G.55.A with the written attestation signed by a preceptor as required by G.55B(2); or

(ii) The Agency, the NRC the Board of Pharmaceutical Specialties, the Commission or an Agreement State license, or

(iii) NRC master materials license permit, or

(iv) The permit issued by a licensee or NRC masters materials permittee of broad scope, or the authorization form from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, and

(v) Copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, the individual to work as an authorized nuclear pharmacist under paragraphs C.11.J.(2)(b)(i) and C.11.J.(2)(b)(iii).

(vi) 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

(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:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

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

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

K. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. 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 Part G.200 will be approved if:

(1) The applicant satisfies the general requirements specified in C.8.;

(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 Part G.200 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State. The labels, leaflets or brochures required by C.11.J are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his/her reagent kits approved by the Agency for use by persons licensed pursuant to Part G.200 may submit the pertinent information specified in C.11.J.

L. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part G for use as a calibration, transmission, or reference source or for the uses listed in Part G.400, G.500, G.600 and G.1000 will be approved if:

(1) The applicant satisfies the general requirements in C.8 of this Part.

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(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, the 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 name of source or device is licensed by the Agency for distribution to persons licensed pursuant to Part G.65, G.400, G.500 and G.600 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State.

(4) 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/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.

(5) 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 (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 specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.5.D 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 C.8;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in one year a radiation dose in excess of 10 percent of the limits specified in D.1201.; and

(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under C.11.L only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under C.11.L if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.11.L a 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:

(i) 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

(ii) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;

(c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "**DEPLETED URANIUM**";

(d) (i) Furnish a copy of the general license contained in C.5.D and a copy of HHE Form 860 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 C.5.D, or

(ii) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.5.D and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.5.D and a copy of HHE Form 860 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 C.5.D;

(e) Report to the Agency all transfers of industrial products or devices to persons for use under general license in C.5.D. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under C.5.D during the reporting period, the report shall so indicate;

(f) (i) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,

(ii) Report to the responsible State Agency all transfers of devices manufactured and distributed pursuant to C.11.L for use under a general license in that State's regulations equivalent to C.5.D,

(iii) 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,

(iv) 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,

(v) 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; and

(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 C.5.D 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 this section.

12. Special requirements for issuance of specific licenses for source material milling Reserved

13. Issuance of specific licenses

A. Each license issued pursuant to this rule in this Part shall be subject to all provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Agency.

B. No license issued or granted under this Part and no right to possess or utilize radioactive material granted by any license issued pursuant to this Part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect and to all valid rules, regulations and orders of the Agency and shall give its consent in writing.

C. Each person licensed by the Agency pursuant to the regulations in this Part shall confine his/her possession and use of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this Part shall carry with it the right to receive, possess, and use radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with Part L of this rule.

D. The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Part as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property;

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary;

(3) Prevent loss or theft of material subject to this Part; and

(4) Protect restricted data.

14. Specific terms and conditions of license

A. Each license issued pursuant to this Part shall be subject to all provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

B. No license issued or granted pursuant to this rule nor any right to possess or utilize radioactive material granted by any license issued pursuant to this rule shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect and to all valid rules, regulations and orders of the Agency and shall give its consent in writing.

C. Each person licensed by the Agency pursuant to this rule shall confine his/her use and possession of the radioactive material licensed to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to this rule shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport shall be in accordance with Part L.

D. 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 Part G. The licensee shall record the results of each test and retain each record for three years after the record is made.

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(14)) 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.

(4) This notification must indicate:

(a) The bankruptcy court in which the petition for bankruptcy was filed; and

(b) The date of the filing of the petition.

F. Security requirements for portable gauges. Each portable gauge licensee or registrant shall use a minimum of two independent physical controls that for tangible barriers to

secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

G. Positron emission tomography (PET) production

(1) Authorization under C.7.H. 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 C.7.H. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in C.7.H. for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in C.7.H of this rule.

(3) A licensee that is a pharmacy authorized under C.7.H 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:

(a) Authorized nuclear pharmacist that meets the requirements in C.11.J., or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in Part G.

(4) A pharmacy, authorized under C.7.H. 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 C.11.J.

15. Expiration and termination of licenses

A. Except as provided in C.16.B and paragraph D of this section, each specific license expires at the end of the day, in the month and year stated in the license.

B. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. The notification and request for termination of the license must include the reports and information specified in paragraphs .E.(1) d and e of this section. The licensee is subject to the provisions of paragraphs E and F of this section, as applicable.

C. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when no principal activities under the license have been conducted for a period of 24 months, or 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.

D. No fewer than 30 days before the expiration date specified in a specific license the licensee shall either:

(1) Submit an application for license renewal under C.16; or

(2) Notify the Agency in writing if the licensee decides not to renew the license.

E. (1) If a licensee does not submit an application for license renewal under C.16, the licensee shall, on or before the expiration date specified in the license:

(a) Terminate use of radioactive, source, or special nuclear material, as appropriate;

(b) Remove radioactive contamination to the extent practicable except for those procedures covered by paragraph C.15.E.(3) of this section;

(c) Properly dispose of source material;

(d) Submit a completed form, Certificate of Disposition of Material; and

(e) Submit a radiation survey report of the premises to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:

(i) Report levels of radiation in units of microrads (mGy) per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries/Bq) per 100 square centimeters for removable and fixed surfaces, microcuries (or Bq) per milliliter for water, and picocuries per gram for contaminated solids such as soils, or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(2) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the information submitted under this paragraph and paragraphs E(1) d and e of this section is adequate, the Agency will notify the licensee in writing that the license is terminated.

(3) (a) If detectable levels of residual radioactive contamination attributable to activities conducted under a license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Agency notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of paragraph E of this section.

(b) In addition to the information submitted under paragraphs E(1) d and e of this section the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

(c) The licensee shall also submit a plan for completion of decommissioning, recovery, or site reclamation if the procedures necessary to carry these out have not been previously approved by the Agency.

F. The proposed decommissioning, recovery, or site reclamation plan, if required by paragraph C.15.E(3) or by license condition, must include:

(1) Discussion of these planned activities;

(2) Description of methods used to assure protection of workers and the environment against radiation hazards during such activities;

(3) A description of the planned final radiation survey; and

(4) An updated detailed cost estimate, comparison of that estimate with present funds set aside, and plans for assuring the availability of adequate funds for completion of decommissioning, recovery or site reclamation.

(5) The proposed plan will be approved by the Agency if the information therein demonstrates that the objectives of the plan will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

G. Each licensee who possesses residual radioactive material, source material, or special nuclear material under paragraph C.15.E(3), following the expiration date specified in the license, shall:

(1) Limit actions involving source radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

H. As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting Maine Form HHE-892 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 in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in D.60 through D.65. The licensee shall, as appropriate-

(a) Report levels of gamma radiation in units if millirem (or mSv) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of microcuries (or Bq) per 100 square centimeters -- removable or fixed -- for surfaces, microcuries per milliliter for water, and 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.

(I) 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 the criteria for decommissioning in D.1401 through D.1406; or

(b) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in D.1401 through D.1406.

(4) Records required by Part D have been received.

16. Renewal of licenses

A. Applications for renewal of specific licenses shall be filed in accordance with C.7.

B. In any case in which a licensee, not fewer than 30 days prior to expiration of his/her 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 the application has been finally determined by the Agency.

17. Amendment of licenses at request of licensee. Applications for amendment of a license shall be filed in accordance with C.7. and shall specify the respects in which the licensee desires his/her license to be amended and the grounds for such amendment.

18. **Agency action on application to renew and amend**. In considering an application by a licensee to renew or amend his/her license, the Agency will apply the criteria set forth in C.8, and C.9., C.10 or C.11 and Part E, Part G, Part K, and Part N of this rule as applicable.

19. **Persons possessing a license for source, radioactive or special nuclear material in quantities not sufficient to form a critical mass on effective date of this rule.** Any person who, on the effective date of this rule, possesses a general or specific license for source, radioactive, 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 this Part and the Act, such license to expire either 90 days after receipt from the Agency of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

20. **Persons possessing naturally occurring and accelerator-produced radioactive material on effective date of this rule.** Any person who, on the effective date of this rule, possesses NARM for which a specific license is required by the Act or this Part shall be deemed to possess such a license issued under the Act and this Part. Such license shall expire 90 days after the effective date of this rule; 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. NARM radionuclides are shown in Appendix B to Part C.

21. **Transfer of material**

A. No licensee shall transfer radioactive material except as authorized pursuant to this section.

B. Except as otherwise provided in the license and subject to the provisions of C.21.C and D, any licensee may transfer radioactive material:

(1) To the Agency with prior approval of the Agency;

(2) To the U.S. Department of Energy;

(3) To any person exempt from this rule 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 Nuclear Regulatory Commission or any Agreement State, or to any person otherwise authorized to receive such material by the federal government or any Agency thereof, the Agency or any Agreement State; or

(5) As otherwise authorized by the Agency in writing.

C. Before transferring radioactive material to a specific licensee of the Agency, the Nuclear Regulatory Commission or an Agreement State, or to a general licensee who is required to register with the Agency, the Nuclear Regulatory Commission or an Agreement 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. The following methods for the verification required by C.21.C are acceptable:

(1) The transferor may have in his/her possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may possess a written certification by the transferee that he authorizes 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 he or she is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing Agency, and expiration date provided, that the oral certification is confirmed in writing within 10 days;

(4) he transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the Nuclear Regulatory Commission, the licensing Agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in C.21.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 a record confirmation from the Agency, the Nuclear Regulatory Commission or the licensing Agency of an Agreement that the transferee is licensed to receive the radioactive material.

(6) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Part L.

22. Modification, revocation and termination of licenses

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations and orders issued by the Agency.

B. Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to

the institution of proceedings therefore, facts of conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

D. The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

23. Deliberate misconduct

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

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

(2) Deliberately submit to the Agency, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

B. A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures Part B.

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

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

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

RECIPROCITY

24. Reciprocal recognition of licenses

A. Licenses of Radioactive, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to this rule, any person who holds a specific license from the Nuclear Regulatory Commission or any 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 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 working days prior to engaging in such activity and receive Agency approval. 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 and HHE form 865. If, for a specific case, the three working day period would impose an undue hardship on the out-of-state licensee, he or she may, upon application to the Agency, obtain permission to proceed sooner. The Agency requires that the applicable Maine annual license fee accompany the initial request for reciprocity (see Table 1 to Appendix A of this Part). This reciprocity fee will cover a period of one year from the time of application, at which time a new fee submittal will be required. This requirement does not waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.24.A(1).

(c) The out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his/her 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;

(e) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.24.A(1) except by transfer to a person:

(i) Specifically licensed by the Agency or by the Nuclear Regulatory Commission to receive such material, or

(ii) Exempt from the requirements for a license for such material under C.3; and

(f) he out-of-state licensee shall not, under the general license concerning activities within this State, possess or use radioactive materials, or engage in the activities authorized in paragraph A of this section, for more than 180 days accumulative in any calendar year.

(2) Notwithstanding the provisions of C.24.A(1), any person who holds a specific license issued by the Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in C.6.B(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) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Nuclear Regulatory Commission or an Agreement State;

(b) 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**";

(c) Such person shall file Agency Form HHE 867 Registration Certificate – Service of Generally Licensed devices. The form shall be submitted within 30 days after the first entry or 30 days after the effective date of this rule for persons in state prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part. This registration fee will cover a period of one year from the time of application, at which time a new fee submittal will be required.

B. The Agency may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by another Agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

25. Records

A. Each person who receives radioactive material pursuant to a license issued pursuant to this Part and Parts E, G, I, M, N and Q of this rule shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

(1) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another Part of this rule dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Agency terminates each license that authorizes disposal of the material.

B. The licensee shall retain each record that is required by the regulations in this Part and Parts E, G, and N of this rule or by license condition for the period specified by the

appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

C. (1) Records which must be maintained pursuant to this Part and Parts E, G, and N of this rule may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Agency's regulations in this Part and Parts E, G, and N of this rule, license condition, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Part and Parts E, G, and N of this rule for such records shall apply unless the Agency, pursuant to A..3.A. or C.4, has granted a specific exemption from the record retention requirements specified in the regulations in this Part or Parts E, G, and , N of this rule

D. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

(1) Records of disposal of licensed material made under Part D.2001 (including burials authorized before January 28, 1981), Part D.2003, Part D.2004, and Part D; and

(2) Records required by Part D.2103(b)iv. of this rule.

E. If licensed activities are transferred or assigned in accordance with C.3.A(2), 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 Part D.2001 (including burials authorized before January 28, 1981), Part D.2003, Part D.2004, Part D.2005; and

(2) Records required by D.2103(b)iv. of this rule.

F. Prior to license termination, each licensee shall forward the records required by this rule, to the Agency.

SCHEDULE A. EXEMPT CONCENTRATIONS OF RADIOACTIVE MATERIALS WHICH ARE INTRODUCED INTO PRODUCTS *(PART C.3.A)*

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml[11]	Column I Liquid and Solid Concentration µCi/ml[12]
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1X10^{-3}$
Argon (18)	Ar-37	$1X10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1X10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1X10^{-3}$
	Co-60		$5X10^{-4}$
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165		$4X10^{-3}$
	Dy-166		$4X10^{-4}$
Erbium (68)	Er-169		$9X10^{-4}$
	Er-171		$1X10^{-3}$

[11] Values are given in Column I only for those materials normally used as gases.
[12] µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml[13]	Column I Liquid and Solid Concentration µCi/ml[14]
Europium (63)	Eu-152		$6X10^{-4}$
	(Tr=9.2 hr)		
	Eu-155		$2X10^{-3}$
Fluorine (9)	F-18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd-153		$2X10^{-3}$
	Gd-159		$8X10^{-4}$
Gallium (31)	Ga-72		$4X10^{-4}$
Germanium (32)	Ge-71		$2X10^{-2}$
Gold (79)	Au-196		$2X10^{-3}$
	Au-198		$5X10^{-4}$
	Au-199		$2X10^{-3}$
Hafnium (72)	Hf-181		$7X10^{-4}$
Hydrogen (1)	H-3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In-113m		$1X10^{-2}$
	In-114m		$2X10^{-4}$
Iodine (53)	I-126	$3X10^{-9}$	$2X10^{-5}$
	I-131	$3X10^{-9}$	$2X10^{-5}$
	I-132	$8X10^{-8}$	$6X10^{-4}$
	I-133	$1X10^{-8}$	$7X10^{-5}$
	I-134	$2X10^{-7}$	$1X10^{-3}$
Iridium (77)	Ir-190		$2X10^{-3}$
	Ir-192		$4X10^{-4}$
	Ir-194		$3X10^{-4}$
Iron (26)	Fe-55		$8X10^{-3}$
	Fe-59		$6X10^{-4}$
Krypton (36)	Kr-85m	$1X10^{-6}$	
	Kr-85	$3X10^{-6}$	
Lanthanum (57)	La-140		$2X10^{-4}$
Lead (82)	Pb-203		$4X10^{-3}$
Lutetium (71)	Lu-177		$1X10^{-3}$
Manganese (25)	Mn-52		$3X10^{-4}$
	Mn-54		$1X10^{-3}$
	Mn-56		$1X10^{-3}$
Mercury (80)	Hg-197m		$2X10^{-3}$
	Hg-197		$3X10^{-3}$
	Hg-203		$2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147		$6X10^{-4}$
	Nd-149		$3X10^{-3}$
Nickel (28)	Ni-65		$1X10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1X10^{-3}$
	Nb-97		$9X10^{-3}$

[13] Values are given in Column I only for those materials normally used as gases.
[14] µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml[15]	Column I Liquid and Solid Concentration µCi/ml[16]
Osmium (76)	Os-185		$7X10^{-4}$
	Os-191m		$3X10^{-2}$
	Os-191		$2X10^{-3}$
	Os-193		$6X10^{-4}$
Palladium (46)	Pd-103		$3X10^{-3}$
	Pd-109		$9X10^{-4}$
Phosphorus (15)	P-32		$2X10^{-4}$
Platinum (78)	Pt-191		$1X10^{-3}$
	Pt-193m		$1X10^{-2}$
	Pt-197m		$1X10^{-2}$
	Pt-197		$1X10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142		$3X10^{-4}$
	Pr-143		$5X10^{-4}$
Promethium (61)	Pm-147		$2X10^{-3}$
	Pm-149		$4X10^{-4}$
Rhenium (75)	Re-183		$6X10^{-3}$
	Re-186		$9X10^{-4}$
	Re-188		$6X10^{-4}$
Rhodium (45)	Rh-103m		$1X10^{-1}$
	Rh-105		$1X10^{-3}$
Rubidium (37)	Rb-86		$7X10^{-4}$
Ruthenium (44)	Ru-97		$4X10^{-3}$
	Ru-103		$8X10^{-4}$
	Ru-105		$1X10^{-3}$
	Ru-106		$1X10^{-4}$
Samarium (62)	Sm-153		$8X10^{-4}$
Scandium (21)	Sc-46		$4X10^{-4}$
	Sc-47		$9X10^{-4}$
	Sc-48		$3X10^{-4}$
Selenium (34)	Se-75		$3X10^{-3}$
Silicon (14)	Si-31		$9X10^{-3}$
Silver (47)	Ag-105		$1X10^{-3}$
	Ag-110m		$3X10^{-4}$
	Ag-111		$4X10^{-4}$
Sodium (11)	Na-24		$2X10^{-3}$
Strontium (38)	Sr-85		$1X10^{-3}$
	Sr-91		$7X10^{-4}$
	Sr-92		$7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$

[15] Values are given in Column I only for those materials normally used as gases.
[16] µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml[17]	Column I Liquid and Solid Concentration µCi/ml[18]
Technetium (43)	Tc-96m		$1X10^{-1}$
	Sr-89		$1X10^{-4}$
	Tc-96		$1X10^{-3}$
Tellurium (52)	Te-125m		$2X10^{-3}$
	Te-127m		$6X10^{-4}$
	Te-127		$3X10^{-3}$
	Te-129m		$3X10^{-4}$
	Te-131m		$6X10^{-4}$
	Te-132		$3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$
Thallium (81)	Tl-200		$4X10-^{3}$
	Tl-201		$3X10-^{3}$
	Tl-202		$1X10-^{3}$
	Tl-204		$1X10-^{3}$
Thulium (69)	Tm-170		$5X10-^{4}$
	Tm-171		$5X10-^{3}$
Tin (50)	Sn-113		$9X10-^{4}$
	Sn-125		$2X10-^{4}$
Tungsten (Wolfram) (74)	W-181		$4X10-^{3}$
	W-187		$7X10-^{4}$
Vanadium (23)	V-48		$3X10-^{4}$
Xenon (54)	Xe-131m	$4X10^{-6}$	
	Xe-133	$3X10^{-6}$	
	Xe-135	$1X10^{-6}$	
Ytterbium (70)	Yb-175		$1X10^{-3}$
Yttrium (39)	Y-90		$2X10^{-4}$
	Y-91m		$3X10^{-2}$
	Y-91		$3X10^{-4}$
	Y-92		$6X10^{-4}$
	Y-93		$3X10^{-4}$
Zinc (30)	Zn-65		$1X10^{-3}$
	Zn-69m		$7X10^{-4}$
	Zn-69		$2X10^{-2}$
Zirconium (40)	Zr-95		$6X10^{-4}$
	Zr-97		$2X10-^{4}$
Beta and/or gamma emitting radioactive material not listed above with half-life fewer than three years		$1X10^{-10}$	$1X10^{-6}$

[17] Values are given in Column I only for those materials normally used as gases.
[18] µCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes, which are also radioactive. In expressing the concentrations in Schedule A the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of Part C 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 Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" ((i)e., unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = 1$$

NOTE 3: To convert µCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

SCHEDULE B. EXEMPT QUANTITIES OF INDIVIDUAL RADIOACTIVE MATERIALS *(C.3.B)*

Radioactive Material	MicroCuries	Radioactive Material	MicroCuries
Antimony-122 (Sb 122)	100	Gallium-67 (Ga 67)	100
Antimony-124 (Sb 124)	10	Gallium-72 (Ga 72)	10
Antimony-125 (Sb 125)	10	Germanium-68 (Ge 68)	10
Arsenic-73 (As 73)	100	Germanium-71 (Ge 71)	100
Arsenic-74 (As 74)	10	Gold-195 (Au 195)	10
Arsenic-76 (As 76)	10	Gold-198 (Au 198)	100
Arsenic-77 (As 77)	100	Gold-199 (Au 199)	100
Barium-131(Ba 131)	10	Hafnium-181 (Hf 181)	10
Barium-133 (Ba 133)	10	Holmium-166 (Ho 166)	100
Barium-140 (Ba 140)	10	Hydrogen-3 (H 3)	1,000
Bismuth-210 (Bi 210)	1	Indium-111 (In 111)	100
Bromine-82 (Br 82)	10	Indium-113m (In 113m)	100
Cadmium-109 (Cd 109)	10	Indium-114m (In 114m)	10
Cadmium-115m Cd 115m)	10	Indium-115m (In 115m)	100
Cadmium-115 (Cd 115)	100	Indium-115 (In 115)	10
Calcium-45 (Ca 45)	10	Iodine-123 (I 123)	100
Calcium-47 (Ca 47)	10	Iodine-125 (I 125)	1
Carbon-14 (C 14)	100	Iodine-126 (I 126)	1
Cerium-141 (Ce 141)	100	Iodine-129 (I 129)	0.1
Cerium-143 (Ce 143)	100	Iodine-131 (I 131)	1
Cerium-144 (Ce 144)	1	Iodine-132 (I 132)	10
Cesium-129 (Cs 129)	100	Iodine-133 (I 133)	1
Cesium-131 (Cs 131)	1,000	Iodine-134 (I 134)	10
Cesium-134m (Cs 134m)	100	Iodine-135 (I 135)	10
Cesium-134 (Cs 134)	1	Iridium-192 (Ir 192)	10
Cesium-135 (Cs 135)	10	Iridium-194 (Ir 194)	100
Cesium-136 (Cs 136)	10	Iron-52 (Fe 52)	10
Cesium-137 (Cs 137)	10	Iron-55 (Fe 55)	100

Radioactive Material	MicroCuries	Radioactive Material	MicroCuries
Chlorine-36 (Cl 36)	10	Iron-59 (Fe 59)	10
Chlorine-38 (Cl 38)	10	Krypton-85 (Kr 85)	100
Chromium-51 (Cr 51)	1,000	Krypton-87 (Kr 87)	10
Cobalt-57 (Co 57)	100	Lanthanum-140 (La 140)	10
Cobalt-58m (Co 58m)	10	Lutetium-177 (Lu 177)	100
Cobalt-58 (Co 58)	10	Manganese-52 (Mn 52)	10
Cobalt-60 (Co 60)	1	Manganese-54 (Mn 54)	10
Copper-64 (Cu 64)	100	Manganese-56 (Mn 56)	10
Dysprosium-165 (Dy 165)	10	Mercury-197m (Hg 197m)	100
Dysprosium-166 (Dy 166)	100	Mercury-197 (Hg 197)	100
Erbium-169 (Er 169)	100	Mercury-203 (Hg 203)	10
Erbium-171 (Er 171)	100	Molybdenum-99 (Mo 99)	100
Europium-152(Eu152)9.2h	100	Neodymium-147 (Nd 147)	100
Europium-152(Eu152)13yr	1	Neodymium-149 (Nd 149)	100
Europium-154 (Eu 154)	1	Nickel-59 (Ni 59)	100
Europium-155 (Eu 155)	10	Nickel-63 (Ni 63)	10
Fluorine-18 (F 18)	1,000	Nickel-65 (Ni 65)	100
Gadolinium-153 (Gd 153)	10	Niobium-93m (Nb 93m)	10
Gadolinium-159 (Gd 159)	100	Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10	Strontium 92 (Sr 92)	10
Osmium-185 (Os 185)	10	Sulphur-35 (S 35)	100
Osmium-191m (Os 191m)	100	Tantalum-182 (Ta 182)	10
Osmium-191 (Os 191)	100	Technetium-96 (Tc 96)	10
Osmium-193 (Os 193)	100	Technetium-97m (Tc 97m)	100
Palladium-103 (Pd 103)	100	Technetium-97 (Tc 97)	100
Palladium-109 (Pd 109)	100	Technetium-99m (Tc 99m)	100
Phosphorus-32 (P 32)	10	Technetium-99 (Tc 99)	10
Platinum-191 (Pt 191)	100	Tellurium-125m (Te 125m)	10
Platinum-193m (Pt 193m)	100	Tellurium-127m (Te 127m)	10
Platinum-193 (Pt 193)	100	Tellurium-127 (Te 127)	100
Platinum-197m (Pt 197m)	100	Tellurium-129m (Te 129m)	10
Platinum-197 (Pt 197)	100	Tellurium-129 (Te 129)	100
Polonium-210 (Po 210)	0.1	Tellurium-131m (Te 131m)	10
Potassium-42 (K 42)	10	Tellurium-132 (Te 132)	10
Potassium-43 (K 43)	10	Terbium-160 (Tb 160)	10
Praseodymium-142(Pr142)	100	Thallium-200 (Tl 200)	100
Praseodymium-143(Pr143)	100	Thallium-201 (Tl 201)	100
Promethium-147 (Pm 147)	10	Thallium-202 (Tl 202)	100
Promethium-149 (Pm 149)	10	Thallium-204 (Tl 204)	10
Rhenium-186 (Re 186)	100	Thulium-170 (Tm 170)	10
Rhenium-188 (Re 188)	100	Thulium-171 (Tm 171)	10
Rhodium-103m (Rh 103m)	100	Tin-113 (Sn 113)	10
Rhodium-105 (Rh 105)	100	Tin-125 (Sn 125)	10
Rubidium-81 (Rb 81)	10	Tungsten-181 (W 181)	10
Rubidium-86 (Rb 86)	10	Tungsten-185 (W 185)	10
Rubidium-87 (Rb 87)	10	Tungsten-187 (W 187)	100
Ruthenium-97 (Ru 97)	100	Vanadium-48 (V 48)	10
Ruthenium-103 (Ru 103)	10	Xenon-131m (Xe 131m)	1,000
Ruthenium-105 (Ru 105)	10	Xenon-133 (Xe 133)	100

Radioactive Material	MicroCuries	Radioactive Material	MicroCuries
Ruthenium-106 (Ru 106)	1	Xenon-135 (Xe 135)	100
Samarium-151 (Sm 151)	10	Ytterbium-175 (Yb 175)	100
Samarium-153 (Sm 153)	100	Yttrium-87 (Y 87)	10
Scandium-46 (Sc 46)	10	Yttrium-88 (Y 88)	10
Scandium-47 (Sc 47)	100	Yttrium-90 (Y 90)	10
Scandium-48 (Sc 48)	10	Yttrium-91 (Y 91)	10
Selenium-75 (Se 75)	10	Yttrium-92 (Y 92)	100
Silicon-31 (Si 31)	100	Yttrium-93 (Y 93)	100
Silver-105 (Ag 105)	10	Zinc-65 (Zn 65)	10
Silver-110m (Ag 110m)	1	Zinc-69m (Zn 69m)	100
Silver-111 (Ag 111)	100	Zinc-69 (Zn 69)	1,000
Sodium-22 (Na 22)	10	Zirconium-93 (Zr 93)	10
Sodium-24 (Na 24)	10	Zirconium-95 (Zr 95)	10
Strontium-85 (Sr 85)	10	Zirconium-97 (Zr 97)	10
Strontium-89 (Sr 89)	1	Any radioactive material not listed above other than alpha emitting radioactive material	0.1
Strontium 90 (Sr 90)	0.1		
Strontium 91 (Sr 91)	10		

NOTE: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above by 37.

SCHEDULE C. LIMITS FOR BROAD LICENSES *(C.10)*

RADIOACTIVE MATERIAL	COL I CURIES*	COL II CURIES**	RADIOACTIVE MATERIAL	COL I CURIES*	COL II CURIES**
Antimony-122	1	0.01	Gallium-72	10	0.1
Antimony-124	1	0.01	Germanium-71	100	1
Antimony-125	1	0.01	Gold-198	10	0.1
Arsenic-73	10	0.1	Gold-199	10	0.1
Arsenic-74	1	0.01	Hafnium-181	1	0.01
Arsenic-76	1	0.01	Holmium-166	10	0.1
Arsenic-77	10	0.1	Hydrogen-3	100	1
Barium-131	10	0.1	Indium-113m	100	1
Barium-140	1	0.01	Indium-114m	1	0.01
Beryllium-7	10	0.1	Indium-115m	100	1
Bismuth-210	0.1	0.001	Indium-115	1	0.01
Bromine-82	10	0.1	Iodine-125	0.1	0.001
Cadmium-109	1	0.01	Iodine-126	0.1	0.001
Cadmium-115m	1	0.01	Iodine-129	0.1	0.001
Cadmium-115	10	0.1	Iodine-131	0.1	0.001
Calcium-45	1	0.01	Iodine-132	10	0.1
Calcium-47	10	0.1	Iodine-133	1	0.01
Carbon-14	100	1	Iodine-134	10	0.1
Cerium-141	10	0.1	Iodine-135	1	0.01
Cerium-143	10	0.1	Iridium-192	1	0.01
Cerium-144	0.1	0.001	Iridium-194	10	0.1
Cesium-131	100	1	Iron-55	10	0.1
Cesium-134m	100	1	Iron-59	1	0.01
Cesium-134	0.1	0.001	Krypton-85	100	1
Cesium-135	1	0.01	Krypton-87	10	0.1
Cesium-136	10	0.1	Lanthanum-140	1	0.01

RADIOACTIVE MATERIAL	COL I CURIES*	COL II CURIES**	RADIOACTIVE MATERIAL	COL I CURIES*	COL II CURIES**
Cesium-137	0.1	0.001	Lutetium-177	10	0.1
Chlorine-36	1	0.01	Manganese-52	1	0.01
Chlorine-38	100	1	Manganese-54	1	0.01
Chromium-51	100	1	Manganese-56	10	0.1
Cobalt-57	10	0.1	Mercury-197m	10	0.1
Cobalt-58m	100	1	Mercury-197	10	0.1
Cobalt-58	1	0.01	Mercury-203	1	0.01
Cobalt-60	0.1	0.001	Molybdenum-99	10	0.1
Copper-64	10	0.1	Neodymium-147	10	0.1
Dysprosium-165	100	1	Neodymium-149	10	0.1
Dysprosium-166	10	0.1	Nickel-59	10	0.1
Erbium-169	10	0.1	Nickel-63	1	0.01
Erbium-171	10	0.1	Nickel-65	10	0.1
Europium-152(9.2h	10	0.1	Niobium-93m	1	0.01
Europium-152(13y)	0.1	0.001	Niobium-95	1	0.01
Europium-154	0.1	0.001	Niobium-97	100	1
Europium-155	1	0.01	Osmium-185	1	0.01
Fluorine-18	100	1	Osmium-191m	100	1
Gadolinium-153	1	0.01	Osmium-191	10	0.1
Gadolinium-159	10	0.1	Osmium-193	10	0.1
Palladium-103	10	0.1	Technetium-96	10	0.1
Palladium-109	10	0.1	Technetium-97m	10	0.1
Phosphorus-32	1	0.01	Technetium-97	10	0.1
Platinum-191	10	0.1	Technetium-99m	100	1
Platinum-193m	100	1	Technetium-99	1	0.01
Platinum-193	10	0.1	Tellurium-125m	1	0.01
Platinum 197m	100	1	Tellurium-127m	1	0.01
Platinum-197	10	0.1	Tellurium-127	10	0.1
Polonium-210	0.01	0.0001	Tellurium-129m	1	0.01
Potassium-42	1	0.01	Tellurium-129	100	1
Praseodymium-142	10	0.1	Tellurium-131m	10	0.1
Praseodymium-143	10	0.1	Tellurium-132	1	0.01
Promethium-147	1	0.01	Terbium-160	1	0.01
Promethium-149	10	0.1	Thallium-200	10	0.1
Radium-226	0.01	0.0001	Thallium-201	10	0.1
Rhenium-186	10	0.1	Thallium-202	10	0.1
Rhenium-188	10	0.1	Thallium-204	1	0.01
Rhodium-103m	1,000	10	Thulium-170	1	0.01
Rhodium-105	10	0.1	Thulium-171	1	0.01
Rubidium-86	1	0.01	Tin-113	1	0.01
Rubidium-87	1	0.01	Tin-125	1	0.01
Ruthenium-97	100	1	Tungsten-181	1	0.01
Ruthenium-103	1	0.01	Tungsten-185	1	0.01
Ruthenium-105	10	0.1	Tungsten-187	10	0.1
Ruthenium-106	0.1	0.001	Vanadium-48	1	0.01
Samarium-151	1	0.01	Xenon-131m	1,000	10
Samarium-153	10	0.1	Xenon-133	100	1
Scandium-46	1	0.01	Xenon-135	100	1
Scandium-47	10	0.1	Ytterbium-175	10	0.1

RADIOACTIVE MATERIAL	COL I CURIES*	COL II CURIES**	RADIOACTIVE MATERIAL	COL I CURIES*	COL II CURIES**
Scandium-48	1	0.01	Yttrium-90	1	0.01
Selenium-75	1	0.01	Yttrium-91	1	0.01
Silicon-31	10	0.1	Yttrium-92	10	0.1
Silver-105	1	0.01	Yttrium-93	1	0.01
Silver-110m	0.1	0.001	Zinc-65	1	0.01
Silver-111	10	0.1	Zinc-69m	10	0.1
Sodium-22	0.1	0.001	Zinc-69	100	1
Sodium-24	1	0.01	Zirconium-93	1	0.01
Strontium-85m	1,000	10	Zirconium-95	1	0.01
Strontium-85	1	0.01	Zirconium-97	1	0.01
Strontium-89	1	0.01	Any radioactive material other than source material, special nuclear material or alpha emitting radioactive material not listed above.	0.1	0.001
Strontium-90	0.01	0.0001			
Strontium-91	10	0.1			
Strontium-92	10	0.1			
Sulphur-35	10	0.1			
Tantalum-182	1	0.01			

* Type B Specific license ** Type C Specific license

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

SCHEDULE D. QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (curies)	Radioactive Material	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000	Krypton-85	1	6,000,000
Americium-241	0.001	2	Lead-210	0.01	8
Americium-242	0.001	2	Manganese-56	0.01	60,000
Americium-243	0.001	2	Mercury-203	0.01	10,000
Antimony-124	0.01	4,000	Molybdenum-99	0.01	30,000
Antimony-126	0.01	6,000	Neptunium-237	0.001	2
Barium-133	0.01	10,000	Nickel-63	0.01	20,000
Barium-140	0.01	30,000	Niobium-94	0.01	300
Bismuth-207	0.01	5,000	Phosphorus-32	0.5	100
Bismuth-210	0.01	600	Phosphorus-33	0.5	1,000
Cadmium-109	0.01	1,000	Polonium-210	0.01	10
Cadmium-113	0.01	80	Potassium-42	0.01	9,000
Calcium-45	0.01	20,000	Promethium-145	0.01	4,000
Californium-252	0.001	9 (20 mg)	Promethium-147	0.01	4,000
Carbon-14 (NonCO_2)	0.01	50,000	Radium-226	0.001	100
Cerium-141	0.01	10,000	Ruthenium-106	0.01	200
Cerium-144	0.01	300	Samarium-151	0.01	4,000
Cesium-134	0.01	2,000	Scandium-46	0.01	3,000
Cesium-137	0.01	3,000	Selenium-75	0.01	10,000

Radioactive Material	Release Fraction	Quantity (curies)	Radioactive Material	Release Fraction	Quantity (curies)
Chlorine-36	0.5	100	Silver-110m	0.01	1,000
Chromium-51	0.01	300,000	Sodium-22	0.01	9,000
Cobalt-60	0.001	5,000	Sodium-24	0.01	10,000
Copper-64	0.01	200,000	Strontium-89	0.01	3,000
Curium-242	0.001	60	Strontium-90	0.01	90
Curium-243	0.001	3	Sulphur-35	0.5	900
Curium-244	0.001	4	Technetium-99	0.01	10,000
Curium-245	0.001	2	Technetium-99m	0.01	400,000
Europium-152	0.01	500	Tellurium-127m	0.01	5,000
Europium-154	0.01	400	Tellurium-129m	0.01	5,000
Europium-155	0.01	3,000	Terbium-160	0.01	4,000
Gadolinium-153	0.01	5,000	Thulium-170	0.01	4,000
Germanium-68	0.01	2,000	Tin-113	0.01	10,000
Gold-198	0.01	30,000	Tin-123	0.01	3,000
Hafnium-172	0.01	400	Tin-126	0.01	1,000
Hafnium-181	0.01	7,000	Titanium-44	0.01	100
Holmium-166m	0.01	100	Vanadium-48	0.01	7,000
Hydrogen-3	0.5	20,000	Xenon-133	1	900,000
Indium-114m	0.01	1,000	Yttrium-91	0.01	2,000
Iodine-125	0.5	10	Zinc-65	0.01	5,000
Iodine-131	0.5	10	Zirconium-93	0.01	400
Iridium-192	0.001	40,000	Zirconium-95	0.01	5,000
Iron-55	0.01	40,000			
Iron-59	0.01	7,000			
Any other beta-gamma emitter	0.01	10,000	Irradiated material, solid noncombustible	0.001	10,000
Mixed fission products	0.01	1,000	Mixed radioactive waste, beta-gamma	0.01	1,000
Mixed corrosion products	0.01	10,000	Packaged mixed waste, beta-gamma	0.001	10,000
Contaminated equipment beta-gamma	0.001	10,000	Any other alpha emitter	0.001	2
			Contaminated equipment alpha	0.0001	20
Irradiated material, any form other than solid noncombustible	0.01	1,000	Packaged waste, alpha	0.0001	20
			Combinations of radioactive materials listed above		

APPENDIX A.
GENERAL PROVISIONS

A. Purpose.

The regulations in this Part set out fees charged for licensing and registration services rendered by the Maine Center for Disease Control and Prevention, Radiation Control Program (the Agency), as authorized under 22 MRSA Section 680 of Maine's Radiation Protection Act.

B. Scope.

Except for persons who apply for or hold the permits, licenses, or approvals exempted in Part C, the regulations in this section apply to a person who is:

1. An applicant for or holder of a specific radioactive material license, NARM material, source material, or special nuclear material license issued pursuant to Part C of these rules;

2. An applicant for or holder of specific approval of shipping containers issued pursuant to Part L of these rules;

3. An applicant for or holder of a specific approval of sealed sources and devices containing radioactive material, NARM material, source material, or special nuclear material;

4. Required to have routine and non-routine safety and safeguards inspections of activities licensed pursuant to the requirements of these rules; or

5. An applicant for or holder of a license, approval, determination, or other authorization issued by the Agency pursuant to these rules.

C. Definitions. As used in this Part:

1. Materials license means a radioactive, NARM, or a source material license issued pursuant to Part C of these rules.

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

3. Inspection means:

   a. Routine inspections designed to evaluate the licensee's activities within the context of the licensee having primary responsibility for protection of the public and environment.

   b. Non-routine inspections in response or reaction to an incident, allegation, follow-up to inspection deficiencies or inspections to determine implementation of safety issues. A non-routine or reactive inspection has the same purpose as the routine inspection.

4. State agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the State of Maine, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the State.

D. Exemptions.

1. No application fees, annual fees, amendment fees, or inspection fees shall be required for:

   a. A license authorizing the export only of a production or utilization facility.

   b. A license authorizing the export only or import only of radioactive material, source material or special nuclear material.

2. A license authorizing the use of source material as shielding only in devices and containers, provided, however, that all other licensed radioactive material, source material, or special nuclear material in the device or container will be subject to the fees prescribed in Table 1 of this Appendix.

E. Payment of fees

1. Application fees. Each application for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be accepted for filing or processed prior to payment of the full amount specified. Applications for which no remittance is received may be returned to the applicant. All application fees will be charged irrespective of the Agency's disposition of the application or withdrawal of the application.

2. Full cost. For each application on which the review charges are based on full costs and the application has been pending with the Agency for six months or longer, the first bill for accumulated costs will be sent and will include all of the applicable review time and contractual costs expended. Thereafter, each applicant will be billed at six-month intervals or when the review is completed, whichever is earlier. Each bill will identify the applications and the costs related to each.

3. Non-routine inspection fees. Non-routine inspection fees are payable upon notification by the Agency. Inspection costs will include preparation time, time on site and documentation time and any associated contractual service costs but will exclude the time involved by the staff in the processing and issuance of a notice of violation or civil penalty.

4. Annual fees. A license fee based upon the type of license, number of sources and/or gauges shall be assessed on an annual basis. The licensee has until June 1st of the billing year or 60 days from the postmark date of the radioactive materials license annual fees invoice , whichever is later, to submit payment in full, unless special arrangements are made with the Agency. Failure to pay the annual fee by the due date will result in a penalty not to exceed 9 percent of the unpaid fee compounded monthly. Failure to remit full payment within six months could, at the Agency’s discretion, result in the initiation of license termination procedures.

5. Method of payment. Fee payments shall be by check, draft, or money order made payable to the Treasurer, State of Maine.

F. Average cost per professional staff-hour. Fees for permits, licenses, amendments, renewals, special projects and inspections will be calculated based upon the full costs for the review.

TABLE 1 to Appendix A

RADIOACTIVE MATERIALS SPECIFIC LICENSE AND INSPECTION FEE SCHEDULE

LICENSE CATEGORY	APPLICATION	ANNUAL	NON-ROUTINE INSPECTION
1. SPECIAL NUCLEAR MATERIAL			
A. Sealed sources in devices	$500.00	$1200.00[5]	$1,300.00
B. Pacemakers	$500.00	$350.00	$800.00
C. Other except critical	$690.00	$3,800.00	$800.00
D. Termination	$500.00		
2. SOURCE MATERIAL			
A. Shielding	$110.00	$450.00	$350.00
B. Water treatment wastes	$800.00	$1,100.00	$1,300.00
C. Other	$790.00	$8,100.00	$1,500.00
D. Termination	$500.00	Full Cost	
3. RADIOACTIVE MATERIAL, NATURALLY OCCURRING RADIOACTIVE MATERIAL OR ACCELERATOR PRODUCED MATERIAL			
A. Processing or manufacturing for commercial distribution			
1. Broad Scope A	$8,000.00	$20,000.00	$2,100.00
2. Broad Scope B	$7,000.00	$15,000.00	$2,100.00
3. Broad Scope C	$6,000.00	$12,000.00	$2,100.00
4. Other	$1,300.00	$4,875.00	$2,000.00
B. Radiopharmaceuticals, reagent kits, sources and devices			
1. Processing, manufacturing and distribution. This category includes nuclear pharmacies.	$6,000.00	$6,750.00	$1,900.00
2. Cyclotron for processing, manufacturing and distribution.	$6,500.00	$6,100.00	$1,900.00
3. Distribution only	$2,000.00	$4350.00	$1,200.00
C. Sealed sources for irradiation			
1. Fixed, self shielded	$1,500.00	$2,325.00	$690.00
2. Exposed source < 10,000 Ci.	$3,000.00	$6,350.00	$1,300.00
3. Exposed source > 10,000 Ci.	$8,000.00	$31,400.00	$1,400.00
D. Distribution to persons exempt (NARM)			
1. Device review required	$2,500.00	$6,600.00	$690.00
2. No device review required	$3,000.00	$7,450.00	$690.00
E. Distribution to persons generally licensed			
1. SSD review required	$2,500.00	$3,300.00	$690.00
2. No SSD review required	$1,900.00	$1,250.00	$690.00
F. Research and development, no commercial distribution			
1. Broad Scope A	$3,300.00	$8,500.00	$1,200.00
2. Broad Scope B	$2,500.00	$7,000.00	$1,200.00
3. Broad Scope C	$2,300.00	$5,500.00	$1,200.00
4. Other	$1,500.00	$3,250.00	$930.00
G. Services for other licensees	$2,000.00	$3,400.00	$690.00
H. Industrial radiography	$4,000.00	$8,400.00	$2,500.00
I. All other radioactive and NARM, except 4A through 8D			
1. Portable gauges	$700.00	$1,000.00[5]	$1,200.00
2. Fixed gauges	$700.00	$1,000.00[5]	$1,200.00
3. X-ray fluorescence	$700.00	$1,000.00[5]	$1,200.00
4. Laboratory services	$700.00	$1,000.00	$1,200.00
5. Storage only	$500.00	$800.00	$1,200.00

LICENSE CATEGORY	APPLICATION	ANNUAL	NON-ROUTINE INSPECTION
6. In-vitro laboratories	$500.00	$1,000.00	$1,200.00
7. Gas chromatographs	$500.00	$800.00	$1,200.00
8. Other	$500.00	$1,100.00	$1,200.00
4. WASTE DISPOSAL SERVICES			
A. Packaging or repackaging	$2,800.00	$7,000.00	$1,600.00
B. Transfer to another person	$2,500.00	$5,000.00	$2,100.00
C. Incineration or other treatment	$500 + full cost	$14,100.00	
5. WELL LOGGING			
A. Well logging and tracer studies	$3,400.00	$4,850.00	$800.00
B. Field flooding tracer studies	$500.00 + full cost	$5,000.00	$1,200.00
6. NUCLEAR LAUNDRIES	$8,000.00	$17,700.00	$1,900.00
7. MEDICAL (HUMAN) USE			
A. Broad scope	$5,000.00	$17,250.00	$1,800.00
B. Other Medical Use			
1. G.100 - Use of unsealed radioactive material for uptake, dilution, and excretion studies-written directive not required	$1,000.00	$2,500.00	$1,500.00
2. G.200 - Use of unsealed radioactive material for imaging and localization studies-written directive not required	$1,000.00	$2,500.00[6]	$1,500.00
3. G.300 - Use of unsealed radioactive material - written directive required	$1,000.00	$2,500.00[6]	$1,500.00
4. G.400 - Manual brachytherapy	$1,000.00	$2,500.00[6]	$1,500.00
5. G.500 - Sealed sources for diagnosis	$1,000.00	$2,500.00[6]	$1,500.00
6. G.600 - Sealed source(s) in a device for therapy-teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit	$3,400.00	$8,500.00[6]	$1,900.00
7. G.1000 - Other medical uses of RAM or radiation from RAM	$2,000.00	$4,500.00[6]	$1,900.00
8. CIVIL DEFENSE ACTIVITIES	$580.00	$1,275.00	$690.00
9. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION			
A. Devices, for commercial dist.	$4,000.00	$10,400.00	
B. Devices, single applicant	$4,000.00	$10,400.00	
C. Sources, for commercial dist.	$2,500.00	$7,300.00	
D. Sources, single applicant	$750.00	$1,200.00	
10. GENERAL LICENSE REGISTRATION			
A. Submission of form HHE-860		$200.00	$1,200.00
B. Submission of form HHE-861 (facility)		$200.00	$1,200.00
C. Submission of form HHE-862 (device)		$200.00	$1,200.00
D. Submission of form HHE-863 (facility)		$200.00	$1,200.00
E. Submission of form HHE-867		$200.00	$1,200.00
11. RECIPROCITY		$1,800.00	

TABLE 1 to Appendix A

1. Types of material license fees - Separate charges as shown in the schedule will be assessed for applications for new licenses and approvals, issuance of new licenses and approvals, and amendments to existing licenses and approvals. The following guidelines apply to these charges:

   a. Application fees - Applications for materials licenses and approvals must be accompanied by the prescribed application fee for each category, except that applications for licenses covering more than one fee category of special nuclear material or source material to be used at the same location, must be accompanied by the prescribed application fee for the highest fee category. When a license or approval has expired, the application fee for each category shall be due, except for licenses covering more than one fee category of special nuclear material or source material for use at the same location, in which case the application fee for the highest category applies.

   b. License/approval fees - For new licenses and approvals issued in fee Categories 1D, 2C, 4C, and 5B, the recipient shall pay the license or approval fee for each category, as determined by the Agency in accordance with Part E of this Appendix except that a license covering more than one fee category of special nuclear material in Categories 1A through 1D or source material in fee Categories 2A through 2C must pay a license fee for the highest fee category assigned to the license.

   c. Amendment fees - Applications for amendments must be accompanied by the minimum amendment fee of $150. The Agency will compute the final amendment fee based upon actual costs, but not more than $1,000., and the applicant will be billed at the completion of the licensing action.

2. Material license fees will not be charged for orders issued by the Agency pursuant to Part B.8 nor for amendments resulting specifically from such orders. However, fees will be charged for approvals issued pursuant to a specific exemption provision of the Agency's regulations regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

3. Types of inspections - Separate charges as shown in this schedule will be the maximum amount assessed for each non-routine inspection, which is performed. The amount that will be charged to the licensee will be based on the staff time and contractual costs expended by the Agency.

4. A licensee who is authorized to use licensed radioactive materials at multiple locations that are not immediately adjacent, or on the same campus, will be assessed an additional 25% of their annual fee for multiple sites. This does not apply to broad scope licensees.

5. The following scale of additional fees will be added to the stated annual fee as applicable from the licensed quantity. If a licensee is authorized for use under fee categories 1.A, 3.I.1, and/or 3.I.3 the total number of gauges authorized under all types are cumulative. If more than one of the remaining fee categories also applies to a licensee only the highest fee will be charged.

License Category	1-4 gauges	5 to 9 gauges	10 gauges plus
1.A.	0	$ 500.00	$ 1000.00
3.I.1.	0	$ 500.00	$ 1000.00
3.I.3.	0	$ 500.00	$ 1000.00
License Category	**1-10 gauges**	**11 to 20 gauges**	**21 gauges plus**
3.I.2.	0	$ 500.00	$ 1000.00

6. The license fee categories 7.B.2 through 7.B.7 will be charged the stated fee if any of the categories are authorized singly. There will be no charge for a 7.B.1 authorization if the licensee holds a license for 7.B.2 through 7.B.7. If multiple categories are authorized an additional fee of $1,000 per category will be added to the annual fee of the highest fee category.

APPENDIX B.

NATURALLY OCCURRING OR ACCELERATOR PRODUCED RADIOACTIVE MATERIAL (NARM)

Examples of naturally occurring radioactive materials. (Naturally occurring radioactive material is any material of natural origin that emits radiation spontaneously, excluding uranium, thorium, and the tailings produced in their extraction)

Hydrogen-3	Indium-115	Lead-210
Beryllium-7	Lanthanum-138	Lead-212
Beryllium-10	Cerium-142	Bismuth-210
Carbon-14	Neodymium-144	Bismuth-212
Sodium-22	Samarium-147	Polonium-210
Silicon-32	Samarium-148	Radon-220
Phosphorus-32	Samarium-149	Radon-222
Phosphorus-33	Gadolinium-152	Radium-224
Sulfur-35	Hafnium-174	Radium-226
Chlorine-36	Lutetium-176	Radium-228
Chlorine-39	Rhenium-187	Actinium-227
Potassium-40	Platinum-190	Actinium-228
Vanadium-50	Platinum-192	Protoactinium-231
Rubidium-87	Lead-204	

Examples of accelerator-produced radioactive materials. (Accelerator- produced radioactive material is any material made radioactive (emits radiation spontaneously) by a particle accelerator)

Carbon-11	Zinc-62	Iodine-124
Nitrogen-13	Gallium-66	Iodine-125*
Oxygen-15	Gallium--67	Iodine-126
Fluorine-18	Germanium-68	Xenon-127
Sodium-22	Arsenic-73	Cesium-131
Magnesium-28	Selenium-73	Promethium-145
Aluminum-28	Bromine-77	Dysprosium-157
Phosphorus-33	Krypton-77	Osmium-190
Argon-37	Krypton-81	Iridium-190
Potassium-43	Rubidium-81	Iridium-190ml
Scandium-49	Rubidium-82	Platinum-193m
Manganese-52	Rubidium-84	Gold-195
Iron-52	Strontium-82	Mercury-197
Cobalt-57	Strontium-87m	Thallium-199
Cobalt-58	Yttrium-87	Thallium-201
Copper-62	Technetium-97m	Lead-203
Copper-67	Indium-111	Bismuth-204
Zinc-62	Iodine-123	

* Excludes Iodine-125 as radioactive material, which requires licensing by either the U.S. Nuclear Regulatory Commission or an Agreement State.

APPENDIX C.

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This Appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

B. Financial Test

1. To pass the financial test, the parent company must meet the criteria of either paragraph 1.a or 2.a of this section:

   a. The parent company must have:

      (1) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

      (2) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

      (3) Tangible net worth of at least $10 million; and

      (4) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

   b. The parent company must have:

      (1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and

      (2) Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

(3) Tangible net worth of at least $10 million; and

(4) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

2. 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 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 auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. a. 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.

b. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in 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.

C. Parent Company Guarantee. The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

1. 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.

2. 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 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.

3. The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

4. 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 which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or State Agency.

APPENDIX D.

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section B of this Appendix. The terms of the self-guarantee are in Section C of this Appendix. This Appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

B. Financial Test

1. To pass the financial test, a company must meet all of the following criteria:

   a. Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)).

   b. Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof.

   c. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moody’s.

2. To pass the financial test, a company must meet all of the following additional requirements:

   a. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

   b. 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, yearend 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.

   c. 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 Section B.2. of this Appendix, 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.

C. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

1. The guarantee will remain in force unless the licensee sends notice of cancel certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

2. 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.

3. 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.

4. 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.

5. 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 Section B.1. of this Appendix.

6. 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.

APPENDIX E.

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*	Material	Microcurie*
Americium-241	0.01	Germanium-71	100
Antimony-122	100	Gold-198	100
Antimony-124	10	Gold-199	100
Antimony-125	10	Hafnium-181	10
Arsenic-73	100	Holmium-166	100
Arsenic-74	10	Hydrogen-3	1,000
Arsenic-76	10	Indium-113m	100
Arsenic-77	100	Indium-114m	10
Barium-131	10	Indium-115m	100
Barium-133	10	Indium-115	10
Barium-140	10	Iodine-125	1
Bismuth-210	1	Iodine-126	1
Bromine-82	10	Iodine-129	0.1
Cadmium-109	10	Iodine-131	1
Cadmium-115m	10	Iodine-132	10
Cadmium-115	100	Iodine-133	1
Calcium-45	10	Iodine-134	10
Calcium-47	10	Iodine-135	10
Carbon-14	100	Iridium-192	10
Cerium-141	100	Iridium-194	100
Cerium-143	100	Iron-55	100
Cerium-144	1	Iron-59	10
Cesium-131	1,000	Krypton-85	100
Cesium-134m	100	Krypton-87	10
Cesium-134	1	Lanthanum-140	10
Cesium-135	10	Lutetium-177	100
Cesium-136	10	Manganese-52	10
Cesium-137	10	Manganese-54	10
Chlorine-36	10	Manganese-56	10
Chlorine-38	10	Mercury-197m	100
Chromium-51	1,000	Mercury-197	100
Cobalt-58m	10	Mercury-203	10
Cobalt-58	10	Molybdenum-99	100
Cobalt-60	1	Neodymium-147	100
Copper-64	100	Neodymium-149	100
Dysprosium-165	10	Nickel-59	100
Dysprosium-166	100	Nickel-63	10
Erbium-169	100	Nickel-65	100
Erbium-171	100	Niobium-93m	10
Europium-152 (9.2 h)	100	Niobium-95	10
Europium-152 (13 yr)	1	Niobium-97	10
Europium-154	1	Osmium-185	10
Europium-155	10	Osmium-191m	100
Florine-18	1,000	Osmium-191	100
Gadolinium-153	10	Osmium-193	100
Gadolinium-159	100	Palladium-103	100
Gallium-72	10	Palladium-109	100
Phosphorus-32	10	Technetium-97m	100

Material	Microcurie*	Material	Microcurie*
Platinum-191	100	Technetium-97	100
Platinum-193m	100	Technetium-99m	100
Platinum-193	100	Technetium-99	10
Platinum-197m	100	Tellurium-125m	10
Platinum-197	100	Tellurium-127m	10
Plutonium-239	0.01	Tellurium-127	100
Polonium-210	0.1	Tellurium-129m	10
Potassium-42	10	Tellurium-129	100
Praseodymium-142	100	Tellurium-131m	10
Praseodymium-143	100	Tellurium-132	10
Promethium-147	10	Terbium-160	10
Promethium-149	10	Thallium-200	100
Radium-226	0.01	Thallium-201	100
Rhenium-186	100	Thallium-202	100
Rhenium-188	100	Thallium-204	10
Rhodium-103m	100	Thorium (natural)**	100
Rhodium-105	100	Thulium-170	10
Rubidium-86	10	Thulium-171	10
Rubidium-87	10	Tin-113	10
Ruthenium-97	100	Tin-125	10
Ruthenium-103	10	Tungsten-181	10
Ruthenium-105	10	Tungsten-185	10
Ruthenium-106	1	Tungsten-187	100
Samarium-153	100	Uranium (natural)***	100
Scandium-46	10	Uranium-233	0.01
Scandium-47	100	Uranium-234	0.01
Scandium-48	10	Uranium-235	0.01
Selenium-75	10	Vanadium-48	10
Silicon-31	100	Xenon-131m	1,000
Silver-105	10	Xenon-133	100
Silver-110m	1	Xenon-135	100
Silver-111	100	Ytterbium-175	100
Sodium-22	1	Yttrium-90	10
Sodium-24	10	Yttrium-91	10
Strontium-85	10	Yttrium-92	100
Strontium-89	1	Yttrium-93	100
Strontium-90	0.1	Zinc-65	10
Strontium-91	10	Zinc-69m	100
Strontium-92	10	Zinc-69	1,000
Sulfur –35	100	Zirconium-93	10
Tantalum-182	10	Zirconium-95	10
Technetium-96	10	Zirconium-97	10

* To convert µCi to kBq, multiply the µCi value by 37.
** Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.
*** Based on alpha disintegration rate of U-238, U-234, and U-235.

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

* To convert μCi to kBq, multiply the □Ci value by 37.

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed 1 -- that is, unity.

PART D.

STANDARDS FOR PROTECTION AGAINST RADIATION

SUBPART A - GENERAL PROVISIONS

1001. Purpose.

A. Part D establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. This rule is issued pursuant to 22 M.R.S., Ch. 160, the Radiation Control Act.

B. The requirements of Part D are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part D. However, nothing in Part D shall be construed as limiting actions that may be necessary to protect health and safety.

1002. Scope. Except as specifically provided in other Parts of this rule, Part D applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part D do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with Part G, or to voluntary participation in medical research programs.

1003. Definitions. (See Part A)

1004. Units of radiation dose (See Part A)

1005. Units of radioactivity (See Part A)

1008. Implementation.

A. (Reserved)

B. (Reserved)

C. Any existing license or registration condition that is more restrictive than Part D remains in force until there is an amendment or renewal of the license or registration.

D. If a license or registration condition exempts a licensee or registrant from a provision of Part D in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of Part D.

E. If a license or registration condition cites provisions of Part D in effect prior to January 1, 1994, which do not correspond to any provisions of Part D, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

SUBPART B - RADIATION PROTECTION PROGRAMS

1101. 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 Part D. See D.2102 for record keeping 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 public doses that are as low as is reasonably achievable (ALARA).

C. The licensee or registrant shall periodically (at least annually), review the radiation protection program content and implementation.

D. To implement the ALARA requirements of D.1101.B and notwithstanding the requirements in D.1301, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to 10 CFR Part 50.34a of the USNRC regulations, 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 0.1mSv (10 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 D.2203 and promptly take appropriate corrective action to ensure against recurrence.

SUBPART C - OCCUPATIONAL DOSE LIMITS

1201. Occupational dose limits for adults.

A. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to D.1206, to the following dose limits:

(1) An annual limit, which is the more limiting of:

(a) The total effective dose equivalent (TEDE) being equal to 0.05 Sv (5 rem); or

(b) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(a) A lens dose equivalent of 0.15 Sv (15 rem), and

(b) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

B. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for

planned special exposures that the individual may receive during the current year and during the individual's lifetime. See D.1206.E.(1) and (2).

C. When the external exposure is determined by measurement with an external personal monitoring device, the assigned 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 NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

D. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See D.2106.

E. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

F. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See D.2104.E.

1202. Compliance with requirements for summation of external and internal doses.

A. If the licensee or registrant is required to monitor pursuant to both D.1502.A and B, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to D.1502.A or only pursuant to D.1502.B, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph B of this Section and the conditions in paragraphs C and D of this Section. Note: 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 (TEDE) limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation ALI for each radionuclide, or

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$ that is, $W_T H_{T,50}$, unit intake for any organ or tissue.

C. Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

D. Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. Note the intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

1203. Determination of external dose from airborne radioactive material.

A. Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose-equivalent, lens-dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

B. Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

1204. Determination of internal exposure.

A. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to D.1502, 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 D.1703, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

C. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

(1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

(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 (CEDE). See Appendix B.

D. If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in D.1204.A.(2) or (3), the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by D.2202 or D.2203. This delay permits the licensee or registrant 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 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 or registrant may disregard certain radionuclides in the mixture if:

(1) The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in D.6 and in complying with the monitoring requirements in D.1502.B, and

(2) The concentration of any radionuclide disregarded is fewer than 10 percent of its DAC, and

(3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

H. (1) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rem (0.05 Sv)

for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) When the ALI (and the associated DAC) is determined by the non-stochastic organ dose limit of 50 rem (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 Sv), (the stochastic ALI) is listed in parentheses in Table I of Appendix B to Part D. In this case, the licensee or registrant may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALIs, the licensee or registrant must also demonstrate that the limit in D.1201.A.(1)(b) is met.

1206. Planned special exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in D.1201 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.

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; and

(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 D.2104.B during the lifetime of the individual for each individual involved.

E. Subject to D.1201.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 D.1201.A in any year; and

(2) Five times the annual dose limits in D.1201.A during the individual's lifetime.

F. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with D.2105 and submits a written report in accordance with D.2204.

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 D.1201.A but shall be included in evaluations required by D.1206.D and E.

1207. Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in D.1201.

1208. 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 5 mSv (0.5 rem). See D.2106 for record keeping requirements.

B. The licensee or registrant shall make efforts to avoid substantial variation[1] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in D.1208.A.

C. The dose equivalent to an embryo/fetus shall be taken as the sum of:

(1) The deep-dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

D. If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.5 mSv (0.05 rem) of this dose, by the time the woman declares her pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with paragraph A of this section if the additional dose equivalent does not exceed) 5mSv (0.05 rem) during the remainder of the pregnancy.

SUBPART D - RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

1301. 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 1 mSv (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 Part G, from voluntary participation in medical research programs, and from the licensee's or

[1] The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

registrant's disposal of radioactive material into sanitary sewerage in accordance with D.2003[2], 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 Part G, does not exceed 0.02 mSv (0.002 rem) in any one hour.

B. If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

C. Notwithstanding paragraph A.(1) of this section, a licensee may permit visitors to an individual who cannot be released in accordance with Part G, to receive a radiation dose greater than 1 mSv (0.1 rem) if:

(1) The radiation dose received does not exceed 5 mSv (0.5 rem); and

(2) The authorized user, as defined in Part G, has determined before the visit that it is appropriate.

D. 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 5 mSv (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 D.1301.A; and

(2) The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and

(3) The procedures to be followed to maintain the dose ALARA.

E. In addition to the requirements of Part D, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

F. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

1302. 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 and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in D.1301.

B. A licensee or registrant shall show compliance with the annual dose limit in D.1301 by: D.1302.B(1)

[2] Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994 and met the previous requirements of 5 mSv (0.5 rem) in a year.

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(2) Demonstrating that:

(a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(b) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

C. Upon approval from the Agency, the licensee or registrant may adjust the effluent concentration values in 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.

1310. 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 D.1310.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 C.11.K.(4) and (5) of this rule, an Agreement State or the 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 C.11.K.(4) and (5) of this rule, an Agreement 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 fewer than 30 days;

(2) Sealed sources containing only radioactive material as a gas;

(3) Sealed sources containing 3.7 MBq (100 μCi) or fewer of beta or photon-emitting material or 370 kBq (10 μCi) or fewer 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 six 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 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.

(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 Part.

G. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to D.2208.

SUBPART E - RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

1401. General provisions and scope. The criteria in this subpart apply to the decommissioning of facilities licensed under Parts C, E, G, K, and N of this rule.

A. The criteria in this subpart do not apply to sites which have been decommissioned prior to the effective date of this rule.

B. After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

C. When calculating total effective dose equivalent 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 the completing the decommissioning process.

(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.

1402. Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that shall not exceed 10 mrem (0.10 mSv) per year, including that from groundwater sources of drinking water and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels, which are ALARA, must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

1403. Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

A. The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of D.1402. would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels, which are ALARA, must take into account consideration of any detriments, such as 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 the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 10 mrem (0.10 mSv) per year;

C. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

1) Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in Part C.8.F.

(2) Surety method, insurance or other guarantee method as described in Part C.8.F;

(3) A statement of intent in the case of State, or local Government licensees, as described in Part C.8.F; or

(4) 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 Parts C, D, and E, 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:

(i) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 10 mrem (0.10 mSv) TEDE per year;

(ii) Will be enforceable; and

(iii) 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 1403.D(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; and

E. Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(1) 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 100 mrem/yr (1 mSv/yr) value of paragraph E(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(b) Makes provisions for durable institutional controls; and

(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 D.1403.B. and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in paragraph C. of this section.

1404. Alternate criteria for license termination

A. The Agency may terminate a license using alternate criteria greater than the dose criterion of parts D.1402, D.1403.B, and D.1403.D, if the licensee:

(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit, 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 D.1403 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 to the Agency indicating the licensee's intent to decommission in accordance with Parts C, D, and E., 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.

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 D.2302.

SUBPART F - SURVEYS AND MONITORING

1501. General.

A. Each licensee or registrant shall make, or cause to be made, surveys that:

(1) Are necessary for the licensee or registrant to comply with Part D; and

(2) Are necessary under the circumstances to evaluate:

(a) The magnitude of radiation levels; and

(b) Concentrations or quantities of radioactive material; and

(c) The potential radiological hazards.

B. 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.

C. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with D.1201, with other applicable provisions of this rule, or with conditions specified in a license or 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.

D. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

1502. Conditions requiring individual monitoring of external and internal occupational dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D. As a minimum:

A. Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee 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 percent of the limits in D.1201.A; and

(2) Minors likely to receive, in one year from sources external to the body, a deep-dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of

1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 5 mSv (0.5 rem; and

(3) Declared pregnant women likely to receive during the entire pregnancy from sources external to the body, a deep-dose equivalent in excess of 1 mSv (0.1 rem; and

(4) Individuals entering a high or very high radiation area.

B. Each licensee or registrant shall monitor, to determine compliance with D.1204, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and

(2) Minors and declared pregnant women (during the entire pregnancy) likely to receive, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).

SUBPART G - CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

1601. 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 1 mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

(2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

B. In place of the controls required by D.1601.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 D.1601.A and C in a way that does not prevent individuals from leaving a high radiation area.

E. The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of

radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

(1) The packages do not remain in the area longer than three days; and

(2) The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

F. The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Part D and to operate within the ALARA provisions of the licensee's or registrant'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 D.1601 if the registrant has met all the specific requirements for access and control specified in other applicable Parts of this rule, such as, Part E for industrial radiography, Part F for x-rays in the healing arts, and Part I for particle accelerators.

1602. Control of access to very high radiation areas.

A. In addition to the requirements in D.1601, 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 5 Gy (500 rad) or more in one hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

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 D.1602.A if the registrant has met all the specific requirements for access and control specified in other applicable Parts of this rule, such as, Part E for industrial radiography, Part F for x-rays in the healing arts, and Part I for particle accelerators.

1603. Control of access to very high radiation areas -- irradiators.

A. Section D.1603 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section D.1603 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 5 Gy (500 rad) in one hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(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; and

(b) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 1 mSv (0.1 rem) in 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 1 mSv (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 D.1603.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 1 mSv (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 or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(a) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 1 mSv (0.1 rem) in 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 registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(4) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(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 D.1603.B(3) and (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 1 mSv (0.1 rem) in one hour.

(9) The entry control devices required in D.1603.B(1) shall be tested for proper functioning. See D.2109 for record keeping 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; and

(b) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(c) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(10) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(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, registrants, or applicants for licenses or registrations for sources of radiation within the purview of D.1603.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 D.1603.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 D.21.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 D.1603.B and C shall be established in such a way that no individual will be prevented from leaving the area.

SUBPART H - RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

1701. Use of process or other engineering controls. The licensee or registrant shall use, to the extent practicable, process or other engineering controls, such as, containment, decontamination or ventilation, to control the concentrations of radioactive material in air.

1702. Use of other controls.

A. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant 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; or

(2) Limitation of exposure times; or

(3) Use of respiratory protection equipment; or

(4) Other controls.

B. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

1703. Use of individual respiratory protection equipment.

A. If the licensee or registrant assigns or permits the use respiratory protection equipment to limit the intake of radioactive material pursuant to D.1702,

(1) Except as provided in D.1704.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 (NIOSH).

(2) If the licensee or registrant wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health, the licensee or registrant shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under

anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(3) The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(a) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses; Note: In those cases where air sampling is difficult or even impossible, the exposure can be calculated based upon the known chemicals and ventilation rates;

(b) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(c) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(d) Written procedures regarding respirator selection, fit testing, storage, issuance, maintenance, repair, testing of respirators, including testing for operability immediately prior to each use; quality assurance of respiratory protection equipment supervision and training of respirator users; monitoring, including air sampling and bioassays; breathing air quality, inventory and control, and recordkeeping; and limitations on periods of respirator use and relief from respirator use; and

(e) Determination by a physician that the individual user is medically fit to use the respiratory protection equipment; before.

(i) The initial fitting of a face sealing respirator;

(ii) Before the first field use of non-face sealing respirators, and

(iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

(f) Fit testing, with a fit factor ≥ 10 times the APF for negative pressure devices, and a fit factor ≥ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(4) 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.

(5) The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide for vision correction, adequate communication, low temperature work environments and the concurrent use of other safety or radiological

protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(6) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating 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.

(7) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed gas Association in publication G-7.1, "Commodity Specification for Air" 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)1(ii)(A) through (E). Grade D quality air criteria include:

(a) Oxygen content (v/v) of 19.5-23.5%;

(b) Hydrocarbon (condensed) content of 5 milligrams per cubic meter or air or fewer;

(c) Carbon Monoxide (CO) content of 10 ppm or fewer;

(d) Carbon Dioxide content of 1,000 ppm or fewer; and

(e) Lack of noticeable odor

(9) 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.

(10) 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.

1704. Further restrictions on the use of respiratory protection equipment. The Agency may impose restrictions in addition to the provisions of D.1702 and D.1703, and Appendix A of this Part, 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.

1705. 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 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.

SUBPART I - STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

1801. Security of stored sources of radiation. The licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in controlled or unrestricted areas.

1802. Control of sources of radiation not in storage

A. The licensee or registrant shall control and maintain constant surveillance of licensed or registered radioactive material that is in a controlled or unrestricted area and that is not in storage.

B. The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

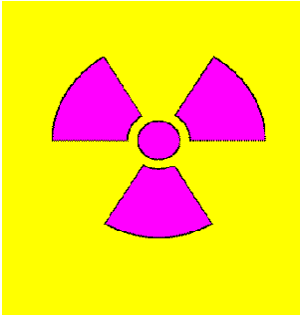
SUBPART J - PRECAUTIONARY PROCEDURES

1901. Caution Signs.

A. Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by D.27 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

(1) Cross-hatched area is to be magenta, or purple, or black, and
(2) The background is to be yellow.



B. Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of D.1901.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 Part D, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

1902. Posting requirements

A. Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "**CAUTION, RADIATION AREA**."

B. Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "**CAUTION, HIGH RADIATION AREA**" or "**DANGER, HIGH RADIATION AREA**."

C. Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "**GRAVE DANGER, VERY HIGH RADIATION AREA**."

D. Posting of airborne radioactivity areas. The licensee or registrant 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 or registered material is used or stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation

symbol and the words "**CAUTION, RADIOACTIVE MATERIAL(S)**" or "**DANGER, RADIOACTIVE MATERIAL(S)**."

1903. Exceptions to posting requirements.

A. A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of fewer than eight hours, if each of the following conditions is met:

(1) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part D; 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 D.1902 provided that the patient could be released from confinement pursuant to Part G of this rule.

C. 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.

D. Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under D.1902 if:

(1) Access to the room is controlled pursuant to G.604; 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 this part.

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.

1904. Labeling containers and radiation machines.

A. The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "**CAUTION, RADIOACTIVE MATERIAL**" or "**DANGER, RADIOACTIVE MATERIAL**." The label 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 or registrant 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.

1905. Exemptions to labeling requirements. A licensee or registrant is not required to label:

A. Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or

B. Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or

C. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part D; or

D. Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation[3]; or

E. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to 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.

1906. 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 L.2 and Appendix A of Part L of this rule, 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[5]/package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in A.2 of this rule; and

(2) Monitor the external surfaces of a labeled[4] 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 Part L of this rule; and

[3] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.
[4] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

(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 D.1906.B as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

D. The licensee or registrant shall immediately notify the final delivery carrier and the Agency by telephone and telegram, mailgram, or facsimile, when:

(1) Removable radioactive surface contamination exceeds the limits of Part L of this rule; or

(2) External radiation levels exceed the limits of Part L of this rule.

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.

F. Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of D.1906.B, but are not exempt from the monitoring requirement in D.1906.B for measuring radiation levels that ensures that the source is still properly lodged in its shield.

SUBPART K - WASTE DISPOSAL

2001. General requirements.

A. A licensee or registrant shall dispose of licensed or registered material only:

(1) By transfer to an authorized recipient as provided in D.2006, or in Part C of this rule, or to the U.S. Department of Energy; or

(2) By decay in storage; or

(3) By release in effluents within the limits in D.1301; or

(4) As authorized pursuant to D.2002, D.2003, D.2004, D.2005, or D.2008.

B. A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed pursuant to 10 CFR Part 61, Subpart B; or

(5) Storage until transferred to a storage or disposal facility authorized to receive the waste.

2002. 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 this rule, 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; and

B. An analysis and evaluation of pertinent information on the nature of the environment; and

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 Part D.

2003. Disposal by release into sanitary sewerage

A. A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble, or is readily dispersible biological material, in water; and

(2) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B; and

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(a) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

(b) The sum of the fractions for each radionuclide required by D.2003.A(3)(a) does not exceed unity; and

(4) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

B. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in D.2003.A.

2004. Treatment or disposal by incineration. A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the amounts and forms specified in D.2005 or as specifically approved by the Agency pursuant to D.2002.

2005. 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 fewer, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 1.85 kBq (0.05 μCi), or fewer, 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 D.2005.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 D.2108.

2006. Transfer for disposal and manifests.

A. The requirements of D.2006, Appendices D and G of this Part are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined, who ships low-level waste either directly or indirectly through a waste processor to a licensed low-level waste land disposal facility.

B. Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Section I of Appendix D.

C. Each shipment manifest shall include a certification by the waste generator as specified in Section III of Appendix D.

D. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section IV of Appendix D.

E. Any license shipping radioactive material intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61, Subpart B must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this

recorded manifest information to the intended consignee in accordance with Appendix D to this Part.

2007. Compliance with environmental and health protection regulations. Nothing in this Subpart relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to the Subpart.

2008. Disposal of certain radioactive material

A. Licensed material defined as;

(1) 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

(2) Any material that—

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

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

B. Any discrete source of naturally occurring radioactive material, other than source material, that—

(1) The NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(2) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

C. A licensed material, as defined in paragraphs a and b of this section, may be disposed of in accordance with 10 CFR 61, even though it is not defined as low-level radioactive waste. Therefore, any licensed radioactive material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR 61, Subpart B must meet the requirements of D.2006.

D. A licensee may dispose of radioactive material, as defined in paragraphs a and b of this section 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, P.L. 109-58.

SUBPART L - RECORDS

2101. General provisions.

A. Each licensee or registrant shall use the units (curie, rad, rem and roentgen) including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part D.

B. In the records required by this Part, the licensee may record quantities in the International System of Units (SI) in parentheses following each of the units specified in paragraph A. However, all quantities must be recorded as stated in paragraph A.

C. Notwithstanding the requirements of paragraph A of this section, when recording information on shipment manifests, as required in D.2006, information must be recorded in SI units or in SI units and units as specified in paragraph A above.

D. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep-dose equivalent, or committed effective dose equivalent.

2102. 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 D.2102.A(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by D.2102.A(2) for three years after the record is made.

2103. Records of surveys.

A. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by D.1501 and D.1906.B. The licensee or registrant shall retain these records for three years after the record is made.

B. The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

(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; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to D.1703.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.

C. Upon termination of the license or registration, the licensee or registrant shall permanently store records on HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

2104. 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 D.1502, 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; and

(3) All cumulative occupational radiation dose.

C. In complying with the requirements of D.2104.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; and

(2) Accept, as the record of cumulative radiation dose, an up-to-date Agency form HHE 835 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;

(3) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

D. The licensee or registrant shall record the exposure history, as required by D.2104.A, on Agency form HHE 835, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure.

(1) 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 HHE 835 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 HHE 835 or equivalent indicating the periods of time for which data are not available.

(2) Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the regulations in Part D in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on HHE 835 or equivalent before January 1, 1994, 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 D.1201.F. for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

F. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in D.2104 on HHE 835 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing HHE 835 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 HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

2105. Records of planned special exposures.

A. For each use of the provisions of D.1206 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.

B. The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

C. Upon termination of the license or registration, the licensee or registrant shall permanently store records on HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

2106. Records of individual monitoring results.

A. Record keeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to D.1502, 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 D.1202;

(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 D.1204.C;

(5) The total effective dose equivalent when required by D.1202; and

(6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

B. Record-keeping frequency. The licensee or registrant shall make entries of the records specified in D.2106.A at intervals not to exceed one year.

C. Record-keeping format. The licensee or registrant shall maintain the records specified in D.2106.A on HHE-840, in accordance with the instructions for HHE-840, or in clear and legible records containing all the information required by HHE-840.

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 licensee or registrant shall permanently store records on HHE-835 or equivalent, or shall make provision with the Agency for transfer to the Agency.

2107. Records of dose to individual members of the public.

A. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See D.1301.

B. The licensee or registrant shall retain the records required by D.2107.A until the Agency terminates each pertinent license or registration requiring the record.

2108. Records of waste disposal.

A. Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to D.2002, D.2003, D.2004, or D.2006, of this rule, and disposal by burial in soil, including burials authorized before January 28, 1981.[5]

B. The licensee or registrant shall retain the records required by D.2108.A until the Agency terminates each pertinent license or registration requiring the record.

2109. Records of testing entry control devices for very high radiation areas.

A. Each licensee or registrant shall maintain records of tests made pursuant to D.1603.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 D.2109.A for three years after the record is made.

2110. Form of records. Each record required by Part D shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[5] A previous U.S. Nuclear Regulatory Commission rule (10 CFR 20.304) authorized burial of small quantities of licensed materials in soil before January 28, 1981, without specific NRC authorization.

2111. Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by D.1310 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for five years after the records are made.

SUBPART M - REPORTS

2201. 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 or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

(2) Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in 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 D.2201.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; and

(3) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

(4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(5) Actions that have been taken, or will be taken, to recover the source of radiation; and

(6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

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.

D. The licensee or registrant shall prepare any report filed with the Agency pursuant to D.2201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

2202. Notification of incidents.

A. Immediate notification. Notwithstanding 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 Sv (25 rem) or more; or

(b) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(c) A shallow-dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (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. Twenty-four 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 Sv (5 rem); or

(b) A lens-dose equivalent exceeding 0.15 Sv (15 rem); or

(c) A shallow-dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. The provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

C. The licensee or registrant shall prepare each report filed with the Agency pursuant to D.2202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

D. Licensees or registrants shall make the reports required by D.2202.A and B to the Agency by telephone, telegram, mailgram, or facsimile to the Agency.

E. The provisions of D.2202 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to D.2204.

2203. Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

A. Reportable events. In addition to the notification required by D.2202, 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 D.2202; or

(2) Doses in excess of any of the following:

(a) The occupational dose limits for adults in D.1201;

(b) The occupational dose limits for a minor in D.1207;

(c) The limits for an embryo/fetus of a declared pregnant woman in D.1208;

(d) The limits for an individual member of the public in D.1301;

(e) Any applicable limit in the license or registration; or

(3) Levels of radiation or concentrations of radioactive material in:

(a) A restricted area in excess of applicable limits in the license or registration; or

(b) An unrestricted area in excess of 10 times the applicable limit set forth in Part D or in the license or registration, whether or not involving exposure of any individual in excess of the limits in D.1301; 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 D.2203.A shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(a) Estimates of each individual's dose; and

(b) The levels of radiation and concentrations of radioactive material involved; and

(c) The cause of the elevated exposures, dose rates, or concentrations; and

(d) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

(2) Each report filed pursuant to D.2203.A. shall include for each individual exposed: the name, Social Security number, and date of birth. With respect to the limit for the embryo/fetus in D.13, 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 part of the report and must be clearly labeled "**Privacy Act Information: Not For Public Disclosure**."

C. All licensees or registrants who make reports pursuant to D.2203.A shall submit the report in writing to the Agency.

2204. Reports of planned special exposures. The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with D.1206, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Sec. D.2105.

2205. Reports to individuals of exceeding dose limits. When a licensee is required, pursuant to D.2203, D.2204, or D.2206 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 report on his or her exposure data included in 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.

2206. Reports of individual monitoring.

A. This section applies to each person licensed or registered by the Agency to:

(1) Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts C and E of this rule; or

(2) Possess or use at any time, for processing or manufacturing for distribution pursuant to Part C or G of this rule, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000.

[a] The Agency may require as a license condition, or by rule, regulation, or order, 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 D.2206.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 D.1502 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 HHE-840 or equivalent or electronic media containing all the information required by HHE-840.

C. The licensee or registrant shall file the report required by D.2206.B, covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Agency.

2207. 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 paragraphs (a) through (e) of this section for each type of transaction.

A. Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

B. Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the 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 Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

D. Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported; and

(7) The disassemble date of the source.

E. Each Licensee who disposes of nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source;

(5) The date of disposal; and

(6) The method of disposal.

F. The reports discussed in paragraphs A through E of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computer-readable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with follow up by facsimile or mail.

G. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 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 paragraphs A through E of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

H. Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tacked sources to the National Source Tracking System by November 15, 2007. 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 November 30, 2007. The information may be submitted by using any of the methods identified by paragraph F(1) through F(4) of this section. 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.

2208. Notifications and reports to individuals.

A. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in J.4 of this rule.

B. When a licensee or registrant is required pursuant to D.2203 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 J.4.A of this rule.

2209. Reports of leaking or contaminated sealed sources. The licensee or registrant shall file a report within five days with the Agency if the test for leakage or contamination required pursuant to D.1310 indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

2301. Vacating premises. Each specific licensee or registrant shall, no fewer 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 activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.

2302. 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 D.1402 and D.1403, 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 D.1403.

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.

2304. Minimization of contamination. 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.

APPENDIX A

ASSIGNED PROTECTION FACTORS FOR RESPIRATOR[A]

	Operating Mode	Assigned Protection Factors
I. Air purifying respirators (Particulate[b] only)[c]		
Filtering faceplate disposable[d] ------	Negative pressure----------	([d])
Facepiece, half[e]----------	Negative pressure----------	10
Facepiece, full----------	Negative pressure----------	100
Facepiece, half----------	Powered air-purifying respirators-	50
Facepiece, full----------	Powered air-purifying respirators-	1000
Helmet/hood----------	Powered air-purifying respirators-	1000
Facepiece, loose fitting----------	Powered air-purifying respirators-	25
II. Atmosphere supplying respirators (Particulate, gases, and vapors[f)]		
1: Air-line respirator:		10
Facepiece, half----------	Demand----------	50
Facepiece, half[e]----------	Continuous flow----------	50
Facepiece, half----------	Pressure demand----------	100
Facepiece, full----------	Demand----------	1000
Facepiece, full----------	Continuous flow----------	1000
Facepiece, full----------	Pressure demand----------	1000
Helmet/hood----------	Continuous flow----------	25
Facepiece, loose fitting----------	Continuous flow----------	([g])
Suit----------	Continuous flow----------	
2: Self-contained breathing apparatus (SCBA):		
Facepiece, full----------	Demand----------	[h]100
Facepiece, full----------	Pressure demand----------	[i]10,000
Facepiece, full----------	Demand, recirculating----------	[h]100
Facepiece, full----------	Positive pressure recirculating---	[i]10,000
III. Combination respirators: Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operations as listed above	

[a-i] See the following pages for footnotes.

Appendix A.

a. These assigned protection factors apply only in respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations. Radioactive contaminants for which the concentration values in Table 1, column 3 of Appendix B to Part D are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

b. Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF =100 must be equipped with particulate filters that area at least 99 percent efficient. Air purifying respirators with APF >100 must be equipped with particulate filters that area at least 99.97 percent efficient.

c. The licensee may apply to the Agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

d. Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in D.1703 and 10 CFR Part 20, Appendix A. apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

e. Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.

f. The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one0third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

g. No NIOSH approval schedule is currently available for 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., D.24).

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.

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

1. 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 mm, 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 fewer than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6 x 10-2 or 0.06, 6E+2 represents 6 x 102 or 600, and 6E+0 represents 6 x 100 or 6.

2. Table I, Occupational values

Note that the columns in Table I of this Appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this Appendix are the annual intakes of given radionuclide by Reference Man which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep-dose equivalent to the whole body of 0.05 Sv (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, W_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of W_T are listed under the definition of weighting factor in Part D.3. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $W_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract, stomach, small intestine, upper large intestine, and lower large intestine, are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;
St. wall = stomach wall;
Blad wall = bladder wall; and
Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 Sv (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep-dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the non-stochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, (intake (in ∏Ci) of each radionuclide/ALI_{ns}) < 1.0. If there is an external deep-dose equivalent contribution of Hd, then this sum must be less than 1 - (H_d/50), instead of < 1.0.

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in mCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute) = [ALI/2.4 x 10^9] mCi/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 D.7. 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.

3. Table II, Effluent Concentrations

The columns in Table II of this Appendix captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of D.15. The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.5 mSv (0.05 rem).

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.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 1 mSv (0.1 rem) limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml), which is the annual water intake of Reference Man.

Note 2 of this Appendix provides groupings of radionuclides, which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

4. Table III, Releases to Sewers

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in D.35. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3 x 106 (ml). The factor of 7.3 x 106 (ml) is composed of a factor of 7.3 x 105 (ml), the annual water intake by Reference Man, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a Reference Man during a year, would result in a committed effective dose equivalent of 5 mSv (0.5 rem).

LIST OF ELEMENTS

Name	Symbol	Atomic number	Name	Symbol	Atomic Number
Actinium	Ac	89	Molybdenum	Mo	42
Aluminum	Al	13	Neodymium	Nd	60
Americium	Am	95	Neptunium	Np	93
Antimony	Sb	51	Nickel	Ni	28
Argon	Ar	18	Niobium	Nb	41
Arsenic	As	33	Nitrogen	N	7
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Oxygen	O	8
Berkelium	Bk	97	Palladium	Pd	46
Beryllium	Be	4	Phosphorus	P	15
Bismuth	Bi	83	Platinum	Pt	78
Bromine	Br	35	Plutonium	Pu	94
Cadmium	Cd	48	Polonium	Po	84
Calcium	Ca	20	Potassium	K	19
Californium	Cf	98	Praseodymium	Pr	59
Carbon	C	6	Promethium	Pm	61
Cerium	Ce	58	Protactinium	Pa	91
Cesium	Cs	55	Radium	Ra	88
Chlorine	Cl	17	Radon	Rn	86
Chromium	Cr	24	Rhenium	Re	75
Cobalt	Co	27	Rhodium	Rh	45
Copper	Cu	29	Rubidium	Rb	37
Curium	Cm	96	Ruthenium	Ru	44
Dysprosium	Dy	66	Samarium	Sm	62
Einsteinium	Es	99	Scandium	Sc	21
Erbium	Er	68	Selenium	Se	34
Europium	Eu	63	Silicon	Si	14
Fermium	Fm	100	Silver	Ag	47
Fluorine	F	9	Sodium	Na	11
Francium	Fr	87	Strontium	Sr	38
Gadolinium	Gd	64	Sulfur	S	16
Gallium	Ga	31	Tantalum	Ta	73
Germanium	Ge	32	Technetium	Tc	43
Gold	Au	79	Tellurium	Te	52
Hafnium	Hf	72	Terbium	Tb	65
Holmium	Ho	67	Thallium	Tl	81
Hydrogen	H	1	Thorium	Th	90
Indium	In	49	Thulium	Tm	69
Iodine	I	53	Tin	Sn	50
Iridium	Ir	77	Titanium	Ti	22
Iron	Fe	26	Tungsten	W	74
Krypton	Kr	36	Uranium	U	92
Lanthanum	La	57	Vanadium	V	23
Lead	Pb	82	Xenon	Xe	54
Lutetium	Lu	71	Ytterbium	Yb	70
Magnesium	Mg	12	Yttrium	Y	39
Manganese	Mn	25	Zinc	Zn	30
Mendelevium	Md	101	Zirconium	Zr	40
Mercury	Hg	80			

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	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 T2) Submersion1: Use above values as HT and T2 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 7Be	1E+3	2E+2	6E-8	2E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 7Be	-	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	Submersion	-	-	4E-6	2E-8	-	-
8	Oxygen-15	Submersion	-	-	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
		W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
		Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14	Silicon-32	D, see 31Si	2E+3	2E+2	1E-7	3E-10	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see 31Si	-	1E+2	5E-8	2E-10	-	-
		Y, see 31Si	-	5E+0	2E-9	7E-12	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn2+, S3+, Mg2+, Fe3+, Bi3+, and lanthanides	-	4E+2	2E-7	5E-10	-	-
15	Phosphorus-33	D, see 32P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see 32P	-	3E+3	1E-6	4E-9	-	-
16	Sulfur-35	Vapor	1E+4	6E-6	2E-8	-	-	
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
			LLI wall (8E+3)	-	-	-	1E-4	1E-3
		W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu,	6E+3					

		Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	-	2E+3	9E-7	3E-9	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-
17	Chlorine-38[2]	D, see 36Cl	2E+4	4E+4	2E-5	6E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
		W, see 36Cl	-	5E+4	2E-5	6E-8	-	-
17	Chlorine-39[2]	D, see 36Cl	2E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 36Cl	-	6E+4	2E-5	8E-8	-	-
18	Argon-37	Submersion1	-	-	1E+0	6E-3	-	-
18	Argon-39	Submersion1	-	-	2E-4	8E-7	-	-
18	Argon-41	Submersion1	-	-	3E-6	1E-8	-	-
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19	Potassium-44[2]	D, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
19	Potassium-45[2]	D, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	-	-	-
			Bone surf (4E+3)	Bone surf (4E+3)	-	5E-9	6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Scandium-49[2]	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	3E+1	1E-8	4E-11	-	-
		Y, SrTi0	-	6E+0	2E-9	8E-12	-	-
22	Titanium-45	D, see 44Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see 44Ti	-	4E+4	1E-5	5E-8	-	-
		Y, see 44Ti	-	3E+4	1E-5	4E-8	-	-
23	Vanadium-47[2]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
23	Vanadium-48	D, see 47V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
		W, see 47V	-	6E+2	3E-7	9E-10	-	-
23	Vanadium-49	D, see 47V	7E+4	3E+4	1E-5	-	-	-
			LLI wall (9E+4)	Bone surf (3E+4)	-	5E-8	1E-3	1E-2
		W, see 47V	-	2E+4	8E-6	2E-8	-	-
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
		Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24	Chromium-49[2]	D, see 48Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see 48Cr	-	1E+5	4E-5	1E-7	-	-
		Y, see 48Cr	-	9E+4	4E-5	1E-7	-	-
24	Chromium-51	D, see 48Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see 48Cr	-	2E+4	1E-5	3E-8	-	-
		Y, see 48Cr	-	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	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
25	Manganese-52m[2]	D, see 51Mn	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 51Mn	-	1E+5	4E-5	1E-7	-	-
25	Manganese-52	D, see 51Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see 51Mn	-	9E+2	4E-7	1E-9	-	-
25	Manganese-53	D, see 51Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
			-	Bone surf (2E+4)	-	3E-8	-	-
		W, see 51Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see 51Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see 51Mn	-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see 51Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see 51Mn	-	2E+4	9E-6	3E-8	-	-
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26	Iron-55	D, see 52Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see 52Fe	-	4E+3	2E-6	6E-9	-	-
26	Iron-59	D, see 52Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see 52Fe	-	5E+2	2E-7	7E-10	-	-
26	Iron-60	D, see 52Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see 52Fe	-	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 55Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see 55Co	4E+2	2E+2	8E-8	3E-10	-	-
27	Cobalt-57	W, see 55Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see 55Co	4E+3	7E+2	3E-7	9E-10	-	-
27	Cobalt-58m	W, see 55Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see 55Co	-	6E+4	3E-5	9E-8	-	-
27	Cobalt-58	W, see 55Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see 55Co	1E+3	7E+2	3E-7	1E-9	-	-
27	Cobalt-60m[2]	W, see 55Co	1E+6	4E+6	2E-3	6E-6	-	-
			St wall (1E+6)	-	-	-	2E-2	2E-1
		Y, see 55Co	-	3E+6	1E-3	4E-6	-	-
27	Cobalt-60	W, see 55Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see 55Co	2E+2	3E+1	1E-8	5E-11	-	-
27	Cobalt-612	W, see 55Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see 55Co	2E+4	6E+4	2E-5	8E-8	-	-
27	Cobalt-62m[2]	W, see 55Co	4E+4	2E+5	7E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see 55Co	-	2E+5	6E-5	2E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	-	1E+3	5E-7	2E-9	-	-
		Vapor	-	1E+3	5E-7	2E-9	-	-
28	Nickel-57	D, see 56Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see 56Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	6E+3	3E-6	9E-9	-	-
28	Nickel-59	D, see 56Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see 56Ni	-	7E+3	3E-6	1E-8	-	-
		Vapor	-	2E+3	8E-7	3E-9	-	-
28	Nickel-63	D, see 56Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see 56Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	8E+2	3E-7	1E-9	-	-
28	Nickel-65	D, see 56Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see 56Ni	-	3E+4	1E-5	4E-8	-	-
		Vapor	-	2E+4	7E-6	2E-8	-	-
28	Nickel-66	D, see 56Ni	4E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see 56Ni	-	6E+2	3E-7	9E-10	-	-
		Vapor	-	3E+3	1E-6	4E-9	-	-
29	Copper-60[2]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, sulfides, halides,						

		and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-
29	Copper-61	D, see 60Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 60Cu	-	4E+4	2E-5	6E-8	-	-
		Y, see 60Cu	-	4E+4	1E-5	5E-8	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
29	Copper-64	D, see 60Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 60Cu	-	2E+4	1E-5	3E-8	-	-
		Y, see 60Cu	-	2E+4	9E-6	3E-8	-	-
29	Copper-67	D, see 60Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see 60Cu	-	5E+3	2E-6	7E-9	-	-
		Y, see 60Cu	-	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 65Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see 65Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see 65Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see 65Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68[2]	D, see 65Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 65Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70[2]	D, see 65Ga	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		W, see 65Ga	-	2E+5	8E-5	3E-7	-	-
31	Gallium-72	D, see 65Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see 65Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-73	D, see 65Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see 65Ga	-	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 66Ge	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, see 66Ge	-	1E+5	4E-5	1E-7	-	-
32	Germanium-68	D, see 66Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see 66Ge	-	1E+2	4E-8	1E-10	-	-
32	Germanium-69	D, see 66Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see 66Ge	-	8E+3	3E-6	1E-8	-	-
32	Germanium-71	D, see 66Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see 66Ge	-	4E+4	2E-5	6E-8	-	-
32	Germanium-75[2]	D, see 66Ge	4E+4	8E+4	3E-5	1E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see 66Ge	-	8E+4	4E-5	1E-7	-	-
32	Germanium-77	D, see 66Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see 66Ge	-	6E+3	2E-6	8E-9	-	-
32	Germanium-78[2]	D, see 66Ge	2E+4	2E+4	9E-6	3E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see 66Ge	-	2E+4	9E-6	3E-8	-	-
33	Arsenic-69[2]	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
33	Arsenic-70[2]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	6E-5	6E-4
33	Arsenic-78[2]	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34	Selenium-70[2]	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
		W, oxides, hydroxides,						

		carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
34	Selenium-73m[2]	D, see 70Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see 70Se	3E+4	1E+5	6E-5	2E-7	-	-
34	Selenium-73	D, see 70Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see 70Se	-	2E+4	7E-6	2E-8	-	-
34	Selenium-75	D, see 70Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see 70Se	-	6E+2	3E-7	8E-10	-	-
34	Selenium-79	D, see 70Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see 70Se	-	6E+2	2E-7	8E-10	-	-
34	Selenium-81m[2]	D, see 70Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see 70Se	2E+4	7E+4	3E-5	1E-7	-	-
34	Selenium-81[2]	D, see 70Se	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		W, see 70Se	-	2E+5	1E-4	3E-7	-	-
34	Selenium-83[2]	D, see 70Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see 70Se	3E+4	1E+5	5E-5	2E-7	-	-
35	Bromine-74m[2]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-
35	Bromine-74[2]	D, see 74mBr	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 74mBr	-	8E+4	4E-5	1E-7	-	-
35	Bromine-75[2]	D, see 74mBr	3E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 74mBr	-	5E+4	2E-5	7E-8	-	-
35	Bromine-76	D, see 74mBr	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see 74mBr	-	4E+3	2E-6	6E-9	-	-
35	Bromine-77	D, see 74mBr	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see 74mBr	-	2E+4	8E-6	3E-8	-	-
35	Bromine-80m	D, see 74mBr	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see 74mBr	-	1E+4	6E-6	2E-8	-	-
35	Bromine-80[2]	D, see 74mBr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 74mBr	-	2E+5	9E-5	3E-7	-	-
35	Bromine-82	D, see 74mBr	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see 74mBr	-	4E+3	2E-6	5E-9	-	-
35	Bromine-83	D, see 74mBr	5E+4	6E+4	3E-5	9E-8	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see 74mBr	-	6E+4	3E-5	9E-8	-	-
35	Bromine-84[2]	D, see 74mBr	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see 74mBr	-	6E+4	3E-5	9E-8	-	-
36	Krypton-74[2]	Submersion1	-	-	3E-6	1E-8	-	-
36	Krypton-76	Submersion1	-	-	9E-6	4E-8	-	-
36	Krypton-77[2]	Submersion1	-	-	4E-6	2E-8	-	-
36	Krypton-79	Submersion1	-	-	2E-5	7E-8	-	-
36	Krypton-81	Submersion1	-	-	7E-4	3E-6	-	-
36	Krypton-83m[2]	Submersion1	-	-	1E-2	5E-5	-	-
36	Krypton-85m	Submersion1	-	-	2E-5	1E-7	-	-
36	Krypton-85	Submersion1	-	-	1E-4	7E-7	-	-
36	Krypton-87[2]	Submersion1	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion1	-	-	2E-6	9E-9	-	-
37	Rubidium-79[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
37	Rubidium-81m[2]	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88[2]	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
37	Rubidium-89[2]	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
38	Strontium-80[2]	D, all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and SrTi0	-	1E+4	5E-6	2E-8	-	-
38	Strontium-81[2]	D, see 80Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see 80Sr	2E+4	8E+4	3E-5	1E-7	-	-
38	Strontium-82	D, see 80Sr	3E+2	4E+2	2E-7	6E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		Y, see 80Sr	2E+2	9E+1	4E-8	1E-10	-	-
38	Strontium-83	D, see 80Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see 80Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m[2]	D, see 80Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see 80Sr	-	8E+5	4E-4	1E-6	-	-
38	Strontium-85	D, see 80Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see 80Sr	-	2E+3	6E-7	2E-9	-	-
38	Strontium-87m	D, see 80Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see 80Sr	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see 80Sr	6E+2	8E+2	4E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see 80Sr	5E+2	1E+2	6E-8	2E-10	-	-
38	Strontium-90	D, see 80Sr	3E+1	2E+1	8E-9	-	-	-
			Bone surf (4E+1)	Bone surf (2E+1)	-	3E-11	5E-7	5E-6
		Y, see 80Sr	-	4E+0	2E-9	6E-12	-	-
38	Strontium-91	D, see 80Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see 80Sr	-	4E+3	1E-6	5E-9	-	-
38	Strontium-92	D, see 80Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see 80Sr	-	7E+3	3E-6	9E-9	-	-
39	Yttrium-86m[2]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39	Yttrium-86	W, see 86mY	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see 86mY	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-87	W, see 86mY	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see 86mY	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-88	W, see 86mY	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see 86mY	-	2E+2	1E-7	3E-10	-	-
39	Yttrium-90m	W, see 86mY	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see 86mY	-	1E+4	5E-6	2E-8	-	-
39	Yttrium-90	W, see 86mY	4E+2	7E+2	3E-7	9E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see 86mY	-	6E+2	3E-7	9E-10	-	-
39	Yttrium-91m[2]	W, see 86mY	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see 86mY	-	2E+5	7E-5	2E-7	-	-
39	Yttrium-91	W, see 86mY	5E+2	2E+2	7E-8	2E-10	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see 86mY	-	1E+2	5E-8	2E-10	-	-
39	Yttrium-92	W, see 86mY	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see 86mY	-	8E+3	3E-6	1E-8	-	-
39	Yttrium-93	W, see 86mY	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see 86mY	-	2E+3	1E-6	3E-9	-	-
39	Yttrium-94[2]	W, see 86mY	2E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, see 86mY	-	8E+4	3E-5	1E-7	-	-
39	Yttrium-95[2]	W, see 86mY	4E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see 86mY	-	1E+5	6E-5	2E-7	-	-
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
		Y, carbide	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-88	D, see 86Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see 86Zr	-	5E+2	2E-7	7E-10	-	-
		Y, see 86Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-89	D, see 86Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see 86Zr	-	2E+3	1E-6	3E-9	-	-
		Y, see 86Zr	-	2E+3	1E-6	3E-9	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
40	Zirconium-93	D, see 86Zr	1E+3	6E+0	3E-9	-	-	-
			Bone surf (3E+3)	Bone surf (2E+1)	-	2E-11	4E-5	4E-4
		W, see 86Zr	-	2E+1	1E-8	-	-	-
			-	Bone surf (6E+1)	-	9E-11	-	-
		Y, see 86Zr	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	9E-11	-	-
40	Zirconium-95	D, see 86Zr	1E+3	1E+2	5E-8	-	2E-5	2E-4
			-	Bone surf (3E+2)	-	4E-10	-	-
		W, see 86Zr	-	4E+2	2E-7	5E-10	-	-
		Y, see 86Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-97	D, see 86Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see 86Zr	-	1E+3	6E-7	2E-9	-	-
		Y, see 86Zr	-	1E+3	5E-7	2E-9	-	-
41	Niobium-88[2]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41	Niobium-89[2]	W, see 88Nb (66 min)	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see 88Nb	-	4E+4	2E-5	5E-8	-	-
41	Niobium-89	W, see 88Nb (122 min)	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see 88Nb	-	2E+4	6E-6	2E-8	-	-
41	Niobium-90	W, see 88Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see 88Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-93m	W, see 88Nb	9E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+4)	-	-	-	2E-4	2E-3
		Y, see 88Nb	-	2E+2	7E-8	2E-10	-	-
41	Niobium-94	W, see 88Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see 88Nb	-	2E+1	6E-9	2E-11	-	-
41	Niobium-95m	W, see 88Nb	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see 88Nb	-	2E+3	9E-7	3E-9	-	-
41	Niobium-95	W, see 88Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see 88Nb	-	1E+3	5E-7	2E-9	-	-
41	Niobium-96	W, see 88Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see 88Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-97[2]	W, see 88Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see 88Nb	-	7E+4	3E-5	1E-7	-	-
41	Niobium-98[2]	W, see 88Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see 88Nb	-	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	2E+3	5E+3	2E-6	6E-9	-	-
42	Molybdenum-93m	D, see 90Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see 90Mo	4E+3	1E+4	6E-6	2E-8	-	-
42	Molybdenum-93	D, see 90Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see 90Mo	2E+4	2E+2	8E-8	2E-10	-	-
42	Molybdenum-99	D, see 90Mo	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 90Mo	1E+3	1E+3	6E-7	2E-9	-	-
42	Molybdenum-101[2]	D, see 90Mo	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see 90Mo	-	1E+5	6E-5	2E-7	-	-
43	Technetium-93m[2]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43	Technetium-93	D, see 93mTc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see 93mTc	-	1E+5	4E-5	1E-7	-	-
43	Technetium-94m[2]	D, see 93mTc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see 93mTc	-	6E+4	2E-5	8E-8	-	-
43	Technetium-94	D, see 93mTc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see 93mTc	-	2E+4	1E-5	3E-8	-	-
43	Technetium-95m	D, see 93mTc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see 93mTc	-	2E+3	8E-7	3E-9	-	-
43	Technetium-95	D, see 93mTc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 93mTc	-	2E+4	8E-6	3E-8	-	-
43	Technetium-96m[2]	D, see 93mTc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see 93mTc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-96	D, see 93mTc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see 93mTc	-	2E+3	9E-7	3E-9	-	-

Table I Occupational Values | Table II Effluent Concentrations | Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
43	Technetium-97m	D, see 93mTc	5E+3	7E+3	3E-6	-	6E-5	6E-4
			-	St wall (7E+3)	-	1E-8	-	-
		W, see 93mTc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see 93mTc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see 93mTc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see 93mTc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see 93mTc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see 93mTc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see 93mTc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see 93mTc	4E+3	5E+3	2E-6	-	6E-5	6E-4
			-	St wall (6E+3)	-	8E-9	-	-
		W, see 93mTc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101[2]	D, see 93mTc	9E+4	3E+5	1E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, see 93mTc	-	4E+5	2E-4	5E-7	-	-
43	Technetium-104[2]	D, see 93mTc	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see 93mTc	-	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 94Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see 94Ru	-	1E+4	5E-6	2E-8	-	-
		Y, see 94Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-103	D, see 94Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see 94Ru	-	1E+3	4E-7	1E-9	-	-
		Y, see 94Ru	-	6E+2	3E-7	9E-10	-	-
44	Ruthenium-105	D, see 94Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see 94Ru	-	1E+4	6E-6	2E-8	-	-
		Y, see 94Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-106	D, see 94Ru	2E+2	9E+1	4E-8	1E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		W, see 94Ru	-	5E+1	2E-8	8E-11	-	-
		Y, see 94Ru	-	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 99mRh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see 99mRh	-	2E+3	9E-7	3E-9	-	-
		Y, see 99mRh	-	2E+3	8E-7	3E-9	-	-
45	Rhodium-100	D, see 99mRh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see 99mRh	-	4E+3	2E-6	6E-9	-	-
		Y, see 99mRh	-	4E+3	2E-6	5E-9	-	-
45	Rhodium-101m	D, see 99mRh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see 99mRh	-	8E+3	4E-6	1E-8	-	-
		Y, see 99mRh	-	8E+3	3E-6	1E-8	-	-
45	Rhodium-101	D, see 99mRh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see 99mRh	-	8E+2	3E-7	1E-9	-	-
		Y, see 99mRh	-	2E+2	6E-8	2E-10	-	-
45	Rhodium-102m	D, see 99mRh	1E+3	5E+2	2E-7	7E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		W, see 99mRh	-	4E+2	2E-7	5E-10	-	-
		Y, see 99mRh	-	1E+2	5E-8	2E-10	-	-
45	Rhodium-102	D, see 99mRh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see 99mRh	-	2E+2	7E-8	2E-10	-	-
		Y, see 99mRh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m[2]	D, see 99mRh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see 99mRh	-	1E+6	5E-4	2E-6	-	-
		Y, see 99mRh	-	1E+6	5E-4	2E-6	-	-
45	Rhodium-105	D, see 99mRh	4E+3	1E+4	5E-6	2E-8	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see 99mRh	-	6E+3	3E-6	9E-9	-	-
		Y, see 99mRh	-	6E+3	2E-6	8E-9	-	-
45	Rhodium-106m	D, see 99mRh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see 99mRh	-	4E+4	2E-5	5E-8	-	-
		Y, see 99mRh	-	4E+4	1E-5	5E-8	-	-
45	Rhodium-107[2]	D, see 99mRh	7E+4	2E+5	1E-4	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 99mRh	-	3E+5	1E-4	4E-7	-	-
		Y, see 99mRh	-	3E+5	1E-4	3E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
46	Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	-	1E+3	5E-7	2E-9	-	-
		Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46	Palladium-101	D, see 100Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see 100Pd	-	3E+4	1E-5	5E-8	-	-
		Y, see 100Pd	-	3E+4	1E-5	4E-8	-	-
46	Palladium-103	D, see 100Pd	6E+3	6E+3	3E-6	9E-9	-	-
			LLI wall (7E+3)	-	-	-	1E-4	1E-3
		W, see 100Pd	-	4E+3	2E-6	6E-9	-	-
		Y, see 100Pd	-	4E+3	1E-6	5E-9	-	-
46	Palladium-107	D, see 100Pd	3E+4	2E+4	9E-6	-	-	-
			LLI wall (4E+4)	Kidneys (2E+4)	-	3E-8	5E-4	5E-3
		W, see 100Pd	-	7E+3	3E-6	1E-8	-	-
		Y, see 100Pd	-	4E+2	2E-7	6E-10	-	-
46	Palladium-109	D, see 100Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		W, see 100Pd	-	5E+3	2E-6	8E-9	-	-
		Y, see 100Pd	-	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 102Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see 102Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see 102Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104m[2]	D, see 102Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
		W, see 102Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see 102Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104[2]	D, see 102Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see 102Ag	-	1E+5	6E-5	2E-7	-	-
		Y, see 102Ag	-	1E+5	6E-5	2E-7	-	-
47	Silver-105	D, see 102Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
		W, see 102Ag	-	2E+3	7E-7	2E-9	-	-
		Y, see 102Ag	-	2E+3	7E-7	2E-9	-	-
47	Silver-106m	D, see 102Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
		W, see 102Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see 102Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-106[2]	D, see 102Ag	6E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	9E-4	9E-3
		W, see 102Ag	-	2E+5	9E-5	3E-7	-	-
		Y, see 102Ag	-	2E+5	8E-5	3E-7	-	-
47	Silver-108m	D, see 102Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
		W, see 102Ag	-	3E+2	1E-7	4E-10	-	-
		Y, see 102Ag	-	2E+1	1E-8	3E-11	-	-
47	Silver-110m	D, see 102Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
		W, see 102Ag	-	2E+2	8E-8	3E-10	-	-
		Y, see 102Ag	-	9E+1	4E-8	1E-10	-	-
47	Silver-111	D, see 102Ag	9E+2	2E+3	6E-7	-	-	-
			LLI wall (1E+3)	Liver (2E+3)	-	2E-9	2E-5	2E-4
		W, see 102Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see 102Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-112	D, see 102Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see 102Ag	-	1E+4	4E-6	1E-8	-	-
		Y, see 102Ag	-	9E+3	4E-6	1E-8	-	-
47	Silver-115[2]	D, see 102Ag	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see 102Ag	-	9E+4	4E-5	1E-7	-	-
		Y, see 102Ag	-	8E+4	3E-5	1E-7	-	-
48	Cadmium-104[2]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
48	Cadmium-107	D, see 104Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
		W, see 104Cd	-	6E+4	2E-5	8E-8	-	-
		Y, see 104Cd	-	5E+4	2E-5	7E-8	-	-
48	Cadmium-109	D, see 104Cd	3E+2	4E+1	1E-8	-	-	-
			Kidneys (4E+2)	Kidneys (5E+1)	-	7E-11	6E-6	6E-5
		W, see 104Cd	-	1E+2	5E-8	-	-	-
			-	Kidneys (1E+2)	-	2E-10	-	-
		Y, see 104Cd	-	1E+2	5E-8	2E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
48	Cadmium-113m	D, see 104Cd	2E+1	2E+0	1E-9	-	-	-
			Kidneys (4E+1)	Kidneys (4E+0)	-	5E-12	5E-7	5E-6
		W, see 104Cd	-	8E+0	4E-9	-	-	-
			-	Kidneys (1E+1)	-	2E-11	-	-
		Y, see 104Cd	-	1E+1	5E-9	2E-11	-	-
48	Cadmium-113	D, see 104Cd	2E+1	2E+0	9E-10	-	-	-
			Kidneys (3E+1)	Kidneys (3E+0)	-	5E-12	4E-7	4E-6
		W, see 104Cd	-	8E+0	3E-9	-	-	-
			-	Kidneys (1E+1)	-	2E-11	-	-
		Y, see 104Cd	-	1E+1	6E-9	2E-11	-	-
48	Cadmium-115m	D, see 104Cd	3E+2	5E+1	2E-8	-	4E-6	4E-5
			-	Kidneys (8E+1)	-	1E-10	-	-
		W, see 104Cd	-	1E+2	5E-8	2E-10	-	-
		Y, see 104Cd	-	1E+2	6E-8	2E-10	-	-
48	Cadmium-115	D, see 104Cd	9E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
		W, see 104Cd	-	1E+3	5E-7	2E-9	-	-
		Y, see 104Cd	-	1E+3	6E-7	2E-9	-	-
48	Cadmium-117m	D, see 104Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see 104Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see 104Cd	-	1E+4	6E-6	2E-8	-	-
48	Cadmium-117	D, see 104Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see 104Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see 104Cd	-	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 109In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	(69.1 min)	W, see 109In	-	6E+4	2E-5	8E-8	-	-
49	Indium-110	D, see 109In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
	(4.9 h)	W, see 109In	-	2E+4	8E-6	3E-8	-	-
49	Indium-111	D, see 109In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see 109In	-	6E+3	3E-6	9E-9	-	-
49	Indium-112[2]	D, see 109In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see 109In	-	7E+5	3E-4	1E-6	-	-
49	Indium-113m[2]	D, see 109In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see 109In	-	2E+5	8E-5	3E-7	-	-
49	Indium-114m	D, see 109In	3E+2	6E+1	3E-8	9E-11	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		W, see 109In	-	1E+2	4E-8	1E-10	-	-
49	Indium-115m	D, see 109In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 109In	-	5E+4	2E-5	7E-8	-	-
49	Indium-115	D, see 109In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see 109In	-	5E+0	2E-9	8E-12	-	-
49	Indium-116m[2]	D, see 109In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see 109In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m[2]	D, see 109In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see 109In	-	4E+4	2E-5	6E-8	-	-
49	Indium-1172	D, see 109In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see 109In	-	2E+5	9E-5	3E-7	-	-
49	Indium-119m[2]	D, see 109In	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, see 109In	-	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 110Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
		W, see 110Sn	-	3E+5	1E-4	4E-7	-	-
50	Tin-113	D, see 110Sn	2E+3	1E+3	5E-7	2E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see 110Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-117m	D, see 110Sn	2E+3	1E+3	5E-7	-	-	-
			LLI wall (2E+3)	Bone surf (2E+3)	-	3E-9	3E-5	3E-4
		W, see 110Sn	-	1E+3	6E-7	2E-9	-	-
50	Tin-119m	D, see 110Sn	3E+3	2E+3	1E-6	3E-9	-	-
			LLI wall					

			(4E+3)	-	-	-	6E-5	6E-4
		W, see 110Sn	-	1E+3	4E-7	1E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
50	Tin-121m	D, see 110Sn	3E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see 110Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-121	D, see 110Sn	6E+3	2E+4	6E-6	2E-8	-	-
			LLI wall (6E+3)	-	-	-	8E-5	8E-4
		W, see 110Sn	-	1E+4	5E-6	2E-8	-	-
50	Tin-123m[2]	D, see 110Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
		W, see 110Sn	-	1E+5	6E-5	2E-7	-	-
50	Tin-123	D, see 110Sn	5E+2	6E+2	3E-7	9E-10	-	-
			LLI wall (6E+2)	-	-	-	9E-6	9E-5
		W, see 110Sn	-	2E+2	7E-8	2E-10	-	-
50	Tin-125	D, see 110Sn	4E+2	9E+2	4E-7	1E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see 110Sn	-	4E+2	1E-7	5E-10	-	-
50	Tin-126	D, see 110Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
		W, see 110Sn	-	7E+1	3E-8	9E-11	-	-
50	Tin-127	D, see 110Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see 110Sn	-	2E+4	8E-6	3E-8	-	-
50	Tin-128[2]	D, see 110Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see 110Sn	-	4E+4	1E-5	5E-8	-	-
51	Antimony-115[2]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51	Antimony-116m[2]	D, see 115Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see 115Sb	-	1E+5	6E-5	2E-7	-	-
51	Antimony-1162	D, see 115Sb	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 115Sb	-	3E+5	1E-4	5E-7	-	-
51	Antimony-117	D, see 115Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see 115Sb	-	3E+5	1E-4	4E-7	-	-
51	Antimony-118m	D, see 115Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see 115Sb	5E+3	2E+4	9E-6	3E-8	-	-
51	Antimony-119	D, see 115Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see 115Sb	2E+4	3E+4	1E-5	4E-8	-	-
51	Antimony-120[2] (16 min)	D, see 115Sb	1E+5	4E+5	2E-4	6E-7	-	-
			St wall (2E+5)	-	-	-	2E-3	2E-2
		W, see 115Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120 (5.76 d)	D, see 115Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see 115Sb	9E+2	1E+3	5E-7	2E-9	-	-
51	Antimony-122	D, see 115Sb	8E+2	2E+3	1E-6	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see 115Sb	7E+2	1E+3	4E-7	2E-9	-	-
51	Antimony-124m[2]	D, see 115Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see 115Sb	2E+5	6E+5	2E-4	8E-7	-	-
51	Antimony-124	D, see 115Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see 115Sb	5E+2	2E+2	1E-7	3E-10	-	-
51	Antimony-125	D, see 115Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see 115Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m[2]	D, see 115Sb	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see 115Sb	-	2E+5	8E-5	3E-7	-	-
51	Antimony-126	D, see 115Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see 115Sb	5E+2	5E+2	2E-7	7E-10	-	-
51	Antimony-127	D, see 115Sb	8E+2	2E+3	9E-7	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see 115Sb	7E+2	9E+2	4E-7	1E-9	-	-
51	Antimony-128[2] (10.4 min)	D, see 115Sb	8E+4	4E+5	2E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see 115Sb	-	4E+5	2E-4	6E-7	-	-
51	Antimony-128 (9.01 h)	D, see 115Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see 115Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see 115Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see 115Sb	-	9E+3	4E-6	1E-8	-	-
51	Antimony-130[2]	D, see 115Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3

		W, see 115Sb	-	8E+4	3E-5	1E-7	-	-

			Table I Occupational Values	Table II Effluent Concentrations		Table III Releases to Sewers		
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
51	Antimony-131[2]	D, see 115Sb	1E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (4E+4)	-	6E-8	2E-4	2E-3
		W, see 115Sb	-	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 116Te	5E+2	2E+2	8E-8	-	-	-
			Bone surf (7E+2)	Bone surf (4E+2)	-	5E-10	1E-5	1E-4
		W, see 116Te	-	4E+2	2E-7	6E-10	-	-
52	Tellurium-121	D, see 116Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see 116Te	-	3E+3	1E-6	4E-9	-	-
52	Tellurium-123m	D, see 116Te	6E+2	2E+2	9E-8	-	-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	8E-10	1E-5	1E-4
		W, see 116Te	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-123	D, see 116Te	5E+2	2E+2	8E-8	-	-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	7E-10	2E-5	2E-4
		W, see 116Te	-	4E+2	2E-7	-	-	-
			-	Bone surf (1E+3)	-	2E-9	-	-
52	Tellurium-125m	D, see 116Te	1E+3	4E+2	2E-7	-	-	-
			Bone surf (1E+3)	Bone surf (1E+3)	-	1E-9	2E-5	2E-4
		W, see 116Te	-	7E+2	3E-7	1E-9	-	-
52	Tellurium-127m	D, see 116Te	6E+2	3E+2	1E-7	-	9E-6	9E-5
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see 116Te	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-127	D, see 116Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 116Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see 116Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see 116Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129[2]	D, see 116Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see 116Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see 116Te	3E+2	4E+2	2E-7	-	-	-
			Thyroid (6E+2)	Thyroid (1E+3)	-	2E-9	8E-6	8E-5
		W, see 116Te	-	4E+2	2E-7	-	-	-
			-	Thyroid (9E+2)	-	1E-9	-	-
52	Tellurium-131[2]	D, see 116Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	8E-5	8E-4
		W, see 116Te	-	5E+3	2E-6	-	-	-
			-	Thyroid (1E+4)	-	2E-8	-	-
52	Tellurium-132	D, see 116Te	2E+2	2E+2	9E-8	-	-	-
			Thyroid (7E+2)	Thyroid (8E+2)	-	1E-9	9E-6	9E-5
		W, see 116Te	-	2E+2	9E-8	-	-	-
			-	Thyroid (6E+2)	-	9E-10	-	-
52	Tellurium-133m[2]	D, see 116Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid (6E+3)	Thyroid (1E+4)	-	2E-8	9E-5	9E-4
		W, see 116Te	-	5E+3	2E-6	-	-	-
			-	Thyroid (1E+4)	-	2E-8	-	-
52	Tellurium-133[2]	D, see 116Te	1E+4	2E+4	9E-6	-	-	-
			Thyroid (3E+4)	Thyroid (6E+4)	-	8E-8	4E-4	4E-3
		W, see 116Te	-	2E+4	9E-6	-	-	-
			-	Thyroid (6E+4)	-	8E-8	-	-
52	Tellurium-134[2]	D, see 116Te	2E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (5E+4)	-	7E-8	3E-4	3E-3
		W, see 116Te	-	2E+4	1E-5	-	-	-
			-	Thyroid (5E+4)	-	7E-8	-	-
53	Iodine-120m[2]	D, all compounds	1E+4	2E+4	9E-6	3E-8	-	-
			Thyroid					

			(1E+4)	-	-	-	2E-4	2E-3
53	Iodine-120[2]	D, all compounds	4E+3	9E+3	4E-6	-	-	-
			Thyroid	Thyroid				
			(8E+3)	(1E+4)	-	2E-8	1E-4	1E-3

			Table I			Table II		Table III
			Occupational Values			Effluent Concentrations		Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				Monthly Average
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
53	Iodine-121	D, all compounds	1E+4	2E+4	8E-6	-	-	-
			Thyroid	Thyroid				
			(3E+4)	(5E+4)	-	7E-8	4E-4	4E-3
53	Iodine-123	D, all compounds	3E+3	6E+3	3E-6	-	-	-
			Thyroid	Thyroid				
			(1E+4)	(2E+4)	-	2E-8	1E-4	1E-3
53	Iodine-124	D, all compounds	5E+1	8E+1	3E-8	-	-	-
			Thyroid	Thyroid				
			(2E+2)	(3E+2)	-	4E-10	2E-6	2E-5
53	Iodine-125	D, all compounds	4E+1	6E+1	3E-8	-	-	-
			Thyroid	Thyroid				
			(1E+2)	(2E+2)	-	3E-10	2E-6	2E-5
53	Iodine-126	D, all compounds	2E+1	4E+1	1E-8	-	-	-
			Thyroid	Thyroid				
			(7E+1)	(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	-	-	-
			Thyroid	Thyroid				
			(2E+1)	(3E+1)	-	4E-11	2E-7	2E-6
53	Iodine-130	D, all compounds	4E+2	7E+2	3E-7	-	-	-
			Thyroid	Thyroid				
			(1E+3)	(2E+3)	-	3E-9	2E-5	2E-4
53	Iodine-131	D, all compounds	3E+1	5E+1	2E-8	-	-	-
			Thyroid	Thyroid				
			(9E+1)	(2E+2)	-	2E-10	1E-6	1E-5
53	Iodine-132m[2]	D, all compounds	4E+3	8E+3	4E-6	-	-	-
			Thyroid	Thyroid				
			(1E+4)	(2E+4)	-	3E-8	1E-4	1E-3
53	Iodine-132	D, all compounds	4E+3	8E+3	3E-6	-	-	-
			Thyroid	Thyroid				
			(9E+3)	(1E+4)	-	2E-8	1E-4	1E-3
53	Iodine-133	D, all compounds	1E+2	3E+2	1E-7	-	-	-
			Thyroid	Thyroid				
			(5E+2)	(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	Thyroid				
			(3E+3)	(4E+3)	-	6E-9	3E-5	3E-4
54	Xenon-120[2]	Submersion1	-	-	1E-5	4E-8	-	-
54	Xenon-121[2]	Submersion1	-	-	2E-6	1E-8	-	-
54	Xenon-122	Submersion1	-	-	7E-5	3E-7	-	-
54	Xenon-123	Submersion1	-	-	6E-6	3E-8	-	-
54	Xenon-125	Submersion1	-	-	2E-5	7E-8	-	-
54	Xenon-127	Submersion1	-	-	1E-5	6E-8	-	-
54	Xenon-129m	Submersion1	-	-	2E-4	9E-7	-	-
54	Xenon-131m	Submersion1	-	-	4E-4	2E-6	-	-
54	Xenon-133m	Submersion1	-	-	1E-4	6E-7	-	-
54	Xenon-133	Submersion1	-	-	1E-4	5E-7	-	-
54	Xenon-135m[2]	Submersion1	-	-	9E-6	4E-8	-	-
54	Xenon-135	Submersion1	-	-	1E-5	7E-8	-	-
54	Xenon-138[2]	Submersion1	-	-	4E-6	2E-8	-	-
55	Cesium-125[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	-	-
			St wall					
			(9E+4)	-	-	-	1E-3	1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	-	-
			St wall					
			(1E+5)	-	-	-	1E-3	1E-2
55	Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cesium-134m	D, all compounds	1E+5	1E+5	6E-5	2E-7	-	-
			St wall					
			(1E+5)	-	-	-	2E-3	2E-2
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cesium-135m[2]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138[2]	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
			St wall					

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
			(3E+4)	-	-	-	4E-4	4E-3
56	Barium-126[2]	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m[2]	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
			St wall (5E+5)	-	-	-	7E-3	7E-2
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139[2]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
56	Barium-141[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131[2]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57	Lanthanum-132	D, see 131La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see 131La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-135	D, see 131La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see 131La	-	9E+4	4E-5	1E-7	-	-
57	Lanthanum-137	D, see 131La	1E+4	6E+1	3E-8	-	2E-4	2E-3
			-	Liver (7E+1)	-	1E-10	-	-
		W, see 131La	-	3E+2	1E-7	-	-	-
			-	Liver (3E+2)	-	4E-10	-	-
57	Lanthanum-138	D, see 131La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see 131La	-	1E+1	6E-9	2E-11	-	-
57	Lanthanum-140	D, see 131La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see 131La	-	1E+3	5E-7	2E-9	-	-
57	Lanthanum-141	D, see 131La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see 131La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-142[2]	D, see 131La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 131La	-	3E+4	1E-5	5E-8	-	-
57	Lanthanum-143[2]	D, see 131La	4E+4	1E+5	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see 131La	-	9E+4	4E-5	1E-7	-	-
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see 134Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see 134Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see 134Ce	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see 134Ce	-	4E+3	2E-6	5E-9	-	-
58	Cerium-137	W, see 134Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see 134Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see 134Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see 134Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see 134Ce	2E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see 134Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see 134Ce	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 134Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see 134Ce	2E+2	3E+1	1E-8	4E-11	-	-
			LLI wall (3E+2)	-	-	-	3E-6	3E-5
		Y, see 134Ce	-	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 136Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see 136Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-138m	W, see 136Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see 136Pr	-	4E+4	2E-5	6E-8	-	-

59	Praseodymium-139	W, see 136Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see 136Pr	-	1E+5	5E-5	2E-7	-	-

			Table I Occupational Values	Table II Effluent Concentrations		Table III Releases to Sewers		
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
59	Praseodymium-142m[2]	W, see 136Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see 136Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-142	W, see 136Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see 136Pr	-	2E+3	8E-7	3E-9	-	-
59	Praseodymium-143	W, see 136Pr	9E+2	8E+2	3E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 136Pr	-	7E+2	3E-7	9E-10	-	-
59	Praseodymium-144[2]	W, see 136Pr	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see 136Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-145	W, see 136Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see 136Pr	-	8E+3	3E-6	1E-8	-	-
59	Praseodymium-147[2]	W, see 136Pr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		Y, see 136Pr	-	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 136Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see 136Nd	-	5E+3	2E-6	7E-9	-	-
60	Neodymium-139m	W, see 136Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see 136Nd	-	1E+4	6E-6	2E-8	-	-
60	Neodymium-139[2]	W, see 136Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see 136Nd	-	3E+5	1E-4	4E-7	-	-
60	Neodymium-141	W, see 136Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see 136Nd	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see 136Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 136Nd	-	8E+2	4E-7	1E-9	-	-
60	Neodymium-149[2]	W, see 136Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see 136Nd	-	2E+4	1E-5	3E-8	-	-
60	Neodymium-151[2]	W, see 136Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see 136Nd	-	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 141Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see 141Pm	-	7E+2	3E-7	1E-9	-	-
61	Promethium-144	W, see 141Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see 141Pm	-	1E+2	5E-8	2E-10	-	-
61	Promethium-145	W, see 141Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see 141Pm	-	2E+2	8E-8	3E-10	-	-
61	Promethium-146	W, see 141Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see 141Pm	-	4E+1	2E-8	6E-11	-	-
61	Promethium-147	W, see 141Pm	4E+3	1E+2	5E-8	-	-	-
			LLI wall (5E+3)	Bone surf (2E+2)	-	3E-10	7E-5	7E-4
		Y, see 141Pm	-	1E+2	6E-8	2E-10	-	-
61	Promethium-148m	W, see 141Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see 141Pm	-	3E+2	1E-7	5E-10	-	-
61	Promethium-148	W, see 141Pm	4E+2	5E+2	2E-7	8E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see 141Pm	-	5E+2	2E-7	7E-10	-	-
61	Promethium-149	W, see 141Pm	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 141Pm	-	2E+3	8E-7	2E-9	-	-
61	Promethium-150	W, see 141Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see 141Pm	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see 141Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see 141Pm	-	3E+3	1E-6	4E-9	-	-
62	Samarium-141m[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141/[2]	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
62	Samarium-142[2]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E2	1E-11	-	-	-
			Bone surf (3E+1)	Bone surf (6E-2)	-	9E-14	3E-7	3E-6
62	Samarium-147	W, all compounds	2E+1	4E2	2E-11	-	-	-
			Bone surf (3E+1)	Bone surf (7E-2)	-	1E-13	4E-7	4E-6
62	Samarium-151	W, all compounds	1E+4	1E+2	4E-8	-	-	-
			LLI wall (1E+4)	Bone surf (2E+2)	-	2E-10	2E-4	2E-3
62	Samarium-153	W, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
62	Samarium-155[2]	W, all compounds	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[2]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[2]	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64	Gadolinium-146	D, see 145Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see 145Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see 145Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see 145Gd	-	4E+3	1E-6	5E-9	-	-
64	Gadolinium-148	D, see 145Gd	1E+1	8E+3	3E-12	-	-	-
			Bone surf (2E+1)	Bone surf (2E+2)	-	2E-14	3E-7	3E-6
		W, see 145Gd	-	3E-2	1E-11	-	-	-
			-	Bone surf (6E-2)	-	8E-14	-	-
64	Gadolinium-149	D, see 145Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see 145Gd	-	2E+3	1E-6	3E-9	-	-
64	Gadolinium-151	D, see 145Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4
			-	Bone surf (6E+2)	-	9E-10	-	-
		W, see 145Gd	-	1E+3	5E-7	2E-9	-	-
64	Gadolinium-152	D, see 145Gd	2E+1	1E-2	4E-12	-	-	-
			Bone surf (3E+1)	Bone surf (2E-2)	-	3E-14	4E-7	4E-6
		W, see 145Gd	-	4E-2	2E-11	-	-	-
64	Gadolinium-153	D, see 145Gd	5E+3	Bone surf 1E+2	6E-8	-	6E-5	6E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		W, see 145Gd	-	6E+2	2E-7	8E-10	-	-
64	Gadolinium-159	D, see 145Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see 145Gd	-	6E+3	2E-6	8E-9	-	-
65	Terbium-147[2]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
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
67	Holmium-155[2]	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Holmium-157[2]	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159[2]	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m[2]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162[2]	W, all compounds	5E+5	2E+6	1E-3	3E-6	-	-
			St wall (8E+5)	-	-	-	1E-2	1E-1
67	Holmium-164m[2]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164[2]	W, all compounds	2E+5	6E+5	3E-4	9E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (9E+2)	-	-	-	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
			LLI wall (E+3)	-	-	-	2E-5	2E-4
69	Thulium-162[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (2E+3)-	-	-	3E-5	3E-4	
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-
			LLI wall (1E+4)	Bone surf (6E+2)	-	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
70	Ytterbium-162[2]	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		Y, oxides, hydroxides, and fluorides	-	3E+5	1E-4	4E-7	-	-
70	Ytterbium-166	W, see 162Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		Y, see 162Yb	-	2E+3	8E-7	3E-9	-	-
70	Ytterbium-167[2]	W, see 162Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
		Y, see 162Yb	-	7E+5	3E-4	1E-6	-	-
70	Ytterbium-169	W, see 162Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
		Y, see 162Yb	-	7E+2	3E-7	1E-9	-	-

Table I Occupational Values | Table II Effluent Concentrations | Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
70	Ytterbium-175	W, see 162Yb	3E+3	4E+3	1E-6	5E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see 162Yb	-	3E+3	1E-6	5E-9	-	-
70	Ytterbium-177[2]	W, see 162Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
		Y, see 162Yb	-	5E+4	2E-5	6E-8	-	-
70	Ytterbium-178[2]	W, see 162Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		Y, see 162Yb	-	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 169Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
		Y, see 169Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-171	W, see 169Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
		Y, see 169Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-172	W, see 169Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
		Y, see 169Lu	-	1E+3	5E-7	2E-9	-	-
71	Lutetium-173	W, see 169Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
			-	Bone surf (5E+2)	-	6E-10	-	-
		Y, see 169Lu	-	3E+2	1E-7	4E-10	-	-
71	Lutetium-174m	W, see 169Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall (3E+3)	Bone surf (3E+2)	-	5E-10	4E-5	4E-4
		Y, see 169Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see 169Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see 169Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see 169Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see 169Lu	-	2E+4	9E-6	3E-8	-	-
71	Lutetium-176	W, see 169Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
			-	Bone surf (1E+1)	-	2E-11	-	-
		Y, see 169Lu	-	8E+0	3E-9	1E-11	-	-
71	Lutetium-177m	W, see 169Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
		Y, see 169Lu	-	8E+1	3E-8	1E-10	-	-
71	Lutetium-177	W, see 169Lu	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see 169Lu	-	2E+3	9E-7	3E-9	-	-
71	Lutetium-178m2	W, see 169Lu	5E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	8E-4	8E-3
		Y, see 169Lu	-	2E+5	7E-5	2E-7	-	-
71	Lutetium-178[2]	W, see 169Lu	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see 169Lu	-	1E+5	5E-5	2E-7	-	-
71	Lutetium-179	W, see 169Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see 169Lu	-	2E+4	6E-6	3E-8	-	-
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72	Hafnium-172	D, see 170Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
		W, see 170Hf	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
72	Hafnium-173	D, see 170Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see 170Hf	-	1E+4	5E-6	2E-8	-	-
72	Hafnium-175	D, see 170Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
			-	Bone surf (1E+3)	-	1E-9	-	-
		W, see 170Hf	-	1E+3	5E-7	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table II Effluent Concentrations Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table III Releases to Sewers Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table II Effluent Concentrations Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table III Releases to Sewers Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
72	Hafnium-177m[2]	D, see 170Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see 170Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see 170Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
			-	Bone surf (2E+0)	-	3E-12	-	-
		W, see 170Hf	-	5E+0	2E-9	-	-	-
			-	Bone surf (9E+0)	-	1E-11	-	-
72	Hafnium-179m	D, see 170Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
			-	Bone surf (6E+2)	-	8E-10	-	-
		W, see 170Hf	-	6E+2	3E-7	8E-10	-	-
72	Hafnium-180m	D, see 170Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see 170Hf	-	3E+4	1E-5	4E-8	-	-
72	Hafnium-181	D, see 170Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see 170Hf	-	4E+2	2E-7	6E-10	-	-
72	Hafnium-182m[2]	D, see 170Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see 170Hf	-	1E+5	6E-5	2E-7	-	-
72	Hafnium-182	D, see 170Hf	2E+2	8E-1	3E-10	-	-	-
			Bone surf (4E+2)	Bone surf (2E+0)	-	2E-12	5E-6	5E-5
		W, see 170Hf	-	3E+0	1E-9	-	-	-
			-	Bone surf (7E+0)	-	1E-11	-	-
72	Hafnium-183[2]	D, see 170Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see 170Hf	-	6E+4	2E-5	8E-8	-	-
72	Hafnium-184	D, see 170Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see 170Hf	-	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 172Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see 172Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-174[2]	W, see 172Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see 172Ta	-	9E+4	4E-5	1E-7	-	-
73	Tantalum-175	W, see 172Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see 172Ta	-	1E+4	6E-6	2E-8	-	-
73	Tantalum-176	W, see 172Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see 172Ta	-	1E+4	5E-6	2E-8	-	-
73	Tantalum-177	W, see 172Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see 172Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-178	W, see 172Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see 172Ta	-	7E+4	3E-5	1E-7	-	-
73	Tantalum-179	W, see 172Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see 172Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see 172Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see 172Ta	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-180	W, see 172Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see 172Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m[2]	W, see 172Ta	2E+5	5E+5	2E-4	8E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
		Y, see 172Ta	-	4E+5	2E-4	6E-7	-	-
73	Tantalum-182	W, see 172Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see 172Ta	-	1E+2	6E-8	2E-10	-	-
73	Tantalum-183	W, see 172Ta	9E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see 172Ta	-	1E+3	4E-7	1E-9	-	-
73	Tantalum-184	W, see 172Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see 172Ta	-	5E+3	2E-6	7E-9	-	-
73	Tantalum-185[2]	W, see 172Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see 172Ta	-	6E+4	3E-5	9E-8	-	-
73	Tantalum-186[2]	W, see 172Ta	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, see 172Ta	-	2E+5	9E-5	3E-7	-	-
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74	Tungsten-179[2]	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74	Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4

74	Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
75	Rhenium-177[2]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-
75	Rhenium-178[2]	D, see 177Re	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see 177Re	-	3E+5	1E-4	4E-7	-	-
75	Rhenium-181	D, see 177Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see 177Re	-	9E+3	4E-6	1E-8	-	-
75	Rhenium-182	D, see 177Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
(12.7 h)		W, see 177Re	-	2E+4	6E-6	2E-8	-	-
75	Rhenium-182	D, see 177Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
(64.0 h)		W, see 177Re	-	2E+3	9E-7	3E-9	-	-
75	Rhenium-184m	D, see 177Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see 177Re	-	4E+2	2E-7	6E-10	-	-
75	Rhenium-184	D, see 177Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see 177Re	-	1E+3	6E-7	2E-9	-	-
75	Rhenium-186m	D, see 177Re	1E+3	2E+3	7E-7	-	-	-
			St wall (2E+3)	St wall (2E+3)	-	3E-9	2E-5	2E-4
		W, see 177Re	-	2E+2	6E-8	2E-10	-	-
75	Rhenium-186	D, see 177Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see 177Re	-	2E+3	7E-7	2E-9	-	-
75	Rhenium-187	D, see 177Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
			-	St wall (9E+5)	-	1E-6	-	-
		W, see 177Re	-	1E+5	4E-5	1E-7	-	-
75	Rhenium-188m[2]	D, see 177Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see 177Re	-	1E+5	6E-5	2E-7	-	-
75	Rhenium-188	D, see 177Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see 177Re	-	3E+3	1E-6	4E-9	-	-
75	Rhenium-189	D, see 177Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see 177Re	-	4E+3	2E-6	6E-9	-	-
76	Osmium-180[2]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	-	5E+5	2E-4	7E-7	-	-
		Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-	-
76	Osmium-181[2]	D, see 180Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 180Os	-	5E+4	2E-5	6E-8	-	-
		Y, see 180Os	-	4E+4	2E-5	6E-8	-	-
76	Osmium-182	D, see 180Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see 180Os	-	4E+3	2E-6	6E-9	-	-
		Y, see 180Os	-	4E+3	2E-6	6E-9	-	-
76	Osmium-185	D, see 180Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see 180Os	-	8E+2	3E-7	1E-9	-	-
		Y, see 180Os	-	8E+2	3E-7	1E-9	-	-
76	Osmium-189m	D, see 180Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see 180Os	-	2E+5	9E-5	3E-7	-	-
		Y, see 180Os	-	2E+5	7E-5	2E-7	-	-
76	Osmium-191m	D, see 180Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 180Os	-	2E+4	8E-6	3E-8	-	-
		Y, see 180Os	-	2E+4	7E-6	2E-8	-	-
76	Osmium-191	D, see 180Os	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	3E-5	3E-4
		W, see 180Os	-	2E+3	7E-7	2E-9	-	-
		Y, see 180Os	-	1E+3	6E-7	2E-9	-	-
76	Osmium-193	D, see 180Os	2E+3	5E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		W, see 180Os	-	3E+3	1E-6	4E-9	-	-
		Y, see 180Os	-	3E+3	1E-6	4E-9	-	-
76	Osmium-194	D, see 180Os	4E+2	4E+1	2E-8	6E-11	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		W, see 180Os	-	6E+1	2E-8	8E-11	-	-
		Y, see 180Os	-	8E+0	3E-9	1E-11	-	-
77	Iridium-182[2]	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-

Table I Occupational Values	Table II Effluent Concentrations	Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
77	Iridium-184	D, see 182Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see 182Ir	-	3E+4	1E-5	5E-8	-	-
		Y, see 182Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-185	D, see 182Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see 182Ir	-	1E+4	5E-6	2E-8	-	-
		Y, see 182Ir	-	1E+4	4E-6	1E-8	-	-
77	Iridium-186	D, see 182Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see 182Ir	-	6E+3	3E-6	9E-9	-	-
		Y, see 182Ir	-	6E+3	2E-6	8E-9	-	-
77	Iridium-187	D, see 182Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see 182Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see 182Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-188	D, see 182Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see 182Ir	-	4E+3	1E-6	5E-9	-	-
		Y, see 182Ir	-	3E+3	1E-6	5E-9	-	-
77	Iridium-189	D, see 182Ir	5E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	7E-5	7E-4
		W, see 182Ir	-	4E+3	2E-6	5E-9	-	-
		Y, see 182Ir	-	4E+3	1E-6	5E-9	-	-
77	Iridium-190m[2]	D, see 182Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see 182Ir	-	2E+5	9E-5	3E-7	-	-
		Y, see 182Ir	-	2E+5	8E-5	3E-7	-	-
77	Iridium-190	D, see 182Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see 182Ir	-	1E+3	4E-7	1E-9	-	-
		Y, see 182Ir	-	9E+2	4E-7	1E-9	-	-
77	Iridium-192m	D, see 182Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see 182Ir	-	2E+2	9E-8	3E-10	-	-
		Y, see 182Ir	-	2E+1	6E-9	2E-11	-	-
77	Iridium-192	D, see 182Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see 182Ir	-	4E+2	2E-7	6E-10	-	-
		Y, see 182Ir	-	2E+2	9E-8	3E-10	-	-
77	Iridium-194m	D, see 182Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
		W, see 182Ir	-	2E+2	7E-8	2E-10	-	-
		Y, see 182Ir	-	1E+2	4E-8	1E-10	-	-
77	Iridium-194	D, see 182Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see 182Ir	-	2E+3	9E-7	3E-9	-	-
		Y, see 182Ir	-	2E+3	8E-7	3E-9	-	-
77	Iridium-195m	D, see 182Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see 182Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see 182Ir	-	2E+4	9E-6	3E-8	-	-
77	Iridium-195	D, see 182Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 182Ir	-	5E+4	2E-5	7E-8	-	-
		Y, see 182Ir	-	4E+4	2E-5	6E-8	-	-
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	-	-
			LLI wall (3E+4)	-	-	-	4E-5	4E-4
78	Platinum-193	D, all compounds	4E+4	2E+4	1E-5	3E-8	-	-
			LLI wall (5E+4)	-	-	-	6E-4	6E-3
78	Platinum-195m	D, all compounds	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
78	Platinum-197m[2]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Platinum-199[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
		Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79	Gold-194	D, see 193Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see 193Au	-	5E+3	2E-6	8E-9	-	-
		Y, see 193Au	-	5E+3	2E-6	7E-9	-	-
79	Gold-195	D, see 193Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see 193Au	-	1E+3	6E-7	2E-9	-	-
		Y, see 193Au	-	4E+2	2E-7	6E-10	-	-
79	Gold-198m	D, see 193Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see 193Au	-	1E+3	5E-7	2E-9	-	-
		Y, see 193Au	-	1E+3	5E-7	2E-9	-	-

Table I Occupational Values	Table II Effluent Concentrations	Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
79	Gold-198	D, see 193Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see 193Au	-	2E+3	8E-7	3E-9	-	-
		Y, see 193Au	-	2E+3	7E-7	2E-9	-	-
79	Gold-199	D, see 193Au	3E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see 193Au	-	4E+3	2E-6	6E-9	-	-
		Y, see 193Au	-	4E+3	2E-6	5E-9	-	-
79	Gold-200m	D, see 193Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see 193Au	-	3E+3	1E-6	4E-9	-	-
		Y, see 193Au	-	2E+4	1E-6	3E-9	-	-
79	Gold-200[2]	D, see 193Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see 193Au	-	8E+4	3E-5	1E-7	-	-
		Y, see 193Au	-	7E+4	3E-5	1E-7	-	-
79	Gold-201[2]	D, see 193Au	7E+4	2E+5	9E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see 193Au	-	2E+5	1E-4	3E-7	-	-
		Y, see 193Au	-	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 193mHg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 193mHg	-	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 193mHg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
		W, see 193mHg	-	1E+2	5E-8	2E-10	-	-
80	Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
		Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
		D, see 193mHg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
		W, see 193mHg	-	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 193mHg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
		W, see 193mHg	-	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 193mHg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
		W, see 193mHg	-	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 193mHg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see 193mHg	-	9E+3	4E-6	1E-8	-	-
80	Mercury-199m[2]	Vapor	-	8E+4	3E-5	1E-7	-	-
		Organic D	6E+4	2E+5	7E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		D, see 193mHg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
		W, see 193mHg	-	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 193mHg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		W, see 193mHg	-	1E+3	5E-7	2E-9	-	-
81	Thallium-194m[2]	D, all compounds	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
81	Thallium-194[2]	D, all compounds	3E+5	6E+5	2E-4	8E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
81	Thallium-195[2]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198m[2]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81	Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Lead-195m[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-199[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3

Table I Occupational Values	Table II Effluent Concentrations	Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E1	2E1	1E-10	-	-	-
			Bone surf (1E+0)	Bone surf (4E-1)	-	6E-13	1E-8	1E-7
82	Lead-211[2]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1	3E+1	1E-8	5E-11	-	-
			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 200Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see 200Bi	-	4E+4	2E-5	5E-8	-	-
83	Bismuth-202[2]	D, see 200Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see 200Bi	-	8E+4	3E-5	1E-7	-	-
83	Bismuth-203	D, see 200Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
		W, see 200Bi	-	6E+3	3E-6	9E-9	-	-
83	Bismuth-205	D, see 200Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
		W, see 200Bi	-	1E+3	5E-7	2E-9	-	-
83	Bismuth-206	D, see 200Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see 200Bi	-	9E+2	4E-7	1E-9	-	-
83	Bismuth-207	D, see 200Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see 200Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-210m	D, see 200Bi	4E+1	5E+0	2E-9	-	-	-
			Kidneys (6E+1)	Kidneys (6E+0)	-	9E-12	8E-7	8E-6
		W, see 200Bi	-	7E-1	3E-10	9E-13	-	-
83	Bismuth-210	D, see 200Bi	8E+2	2E+2	1E-7	-	1E-5	1E-4
			-	Kidneys				
			-	(4E+2)	-	5E-10	-	-
		W, see 200Bi	-	3E+1	1E-8	4E-11	-	-
83	Bismuth-212[2]	D, see 200Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see 200Bi	-	3E+2	1E-7	4E-10	-	-
83	Bismuth-213[2]	D, see 200Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see 200Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-214[2]	D, see 200Bi	2E+4	8E+2	3E-7	1E-9	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see 200Bi	-	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 203Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see 203Po	-	7E+4	3E-5	1E-7	-	-
84	Polonium-207	D, see 203Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see 203Po	-	3E+4	1E-5	4E-8	-	-
84	Polonium-210	D, see 203Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see 203Po	-	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 WLM)	3E-8 (or 0.33 WL)	1E-10	-	-
87	Francium-222[2]	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223[2]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0	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

	Table I Occupational Values	Table II Effluent Concentrations	Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
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 224Ac	5E+1	3E-1	1E-10	-	-	-
			LLI wall (5E+1)	Bone surf (5E-1)	-	7E-13	7E-7	7E-6
		W, see 224Ac	-	6E-1	3E-10	9E-13	-	-
		Y, see 224Ac	-	6E-1	3E-10	9E-13	-	-
89	Actinium-226	D, see 224Ac	1E+2	3E+0	1E-9	-	-	-
			LLI wall (1E+2)	Bone surf (4E+0)	-	5E-12	2E-6	2E-5
		W, see 224Ac	-	5E+0	2E-9	7E-12	-	-
		Y, see 224Ac	-	5E+0	2E-9	6E-12	-	-
89	Actinium-227	D, see 224Ac	2E-1	4E-4	2E-13	-	-	-
			Bone surf (4E-1)	Bone surf (8E-4)	-	1E-15	5E-9	5E-8
		W, see 224Ac	-	2E-3	7E-13	-	-	-
			Bone surf -	(3E-3)	-	4E-15	-	-
		Y, see 224Ac	-	4E-3	2E-12	6E-15	-	-
89	Actinium-228	D, see 224Ac	2E+3	9E+0	4E-9	-	3E-5	3E-4
			-	Bone surf (2E+1)	-	2E-11	-	-
		W, see 224Ac	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
		Y, see 224Ac	-	4E+1	2E-8	6E-11	-	-
90	Thorium-226[2]	W, all compounds except those given for Y	5E+3	2E+2	6E-8	2E-10	-	-
			St wall (5E+3)	-	-	-	7E-5	7E-4
		Y, oxides and hydroxides	-	1E+2	6E-8	2E-10	-	-
90	Thorium-227	W, see 226Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
		Y, see 226Th	-	3E-1	1E-10	5E-13	-	-
90	Thorium-228	W, see 226Th	6E+0	1E-2	4E-12	-	-	-
			Bone surf (1E+1)	Bone surf (2E-2)	-	3E-14	2E-7	2E-6
		Y, see 226Th	-	2E-2	7E-12	2E-14	-	-
90	Thorium-229	W, see 226Th	6E-1	9E-4	4E-13	-	-	-
			Bone surf (1E+0)	Bone surf (2E-3)	-	3E-15	2E-8	2E-7
		Y, see 226Th	-	2E-3	1E-12	-	-	-
			-	Bone surf (3E-3)	-	4E-15	-	-
90	Thorium-230	W, see 226Th	4E+0	6E-3	3E-12	-	-	-
			Bone surf (9E+0)	Bone surf (2E-2)	-	2E-14	1E-7	1E-6
		Y, see 226Th	-	2E-2	6E-12	-	-	-
			-	Bone surf (2E-2)	-	3E-14	-	-
90	Thorium-231	W, see 226Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see 226Th	-	6E+3	3E-6	9E-9	-	-
90	Thorium-232	W, see 226Th	7E-1	1E-3	5E-13	-	-	-
			Bone surf (2E+0)	Bone surf (3E-3)	-	4E-15	3E-8	3E-7
		Y, see 226Th	-	3E-3	1E-12	-	-	-
			-	Bone surf (4E-3)	-	6E-15	-	-
90	Thorium-234	W, see 226Th	3E+2	2E+2	8E-8	3E-10	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		Y, see 226Th	-	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	-	-

Table I	Table II	Table III
Occupational Values	Effluent Concentrations	Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
91	Protactinium-228	W, see 227Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
		Y, see 227Pa	-	1E+1	5E-9	2E-11	-	-
91	Protactinium-230	W, see 227Pa	6E+2	5E+0	2E-9	7E-12	-	-
			Bone surf (9E+2)	-	-	-	1E-5	1E-4
		Y, see 227Pa	-	4E+0	1E-9	5E-12	-	-
91	Protactinium-231	W, see 227Pa	2E-1	2E-3	6E-13	-	-	-
			Bone surf (5E-1)	Bone surf (4E-3)	-	6E-15	6E-9	6E-8
		Y, see 227Pa	-	4E-3	2E-12	-	-	-
			-	Bone surf (6E-3)	-	8E-15	-	-
91	Protactinium-232	W, see 227Pa	1E+3	2E+1	9E-9	-	2E-5	2E-4
			-	Bone surf (6E+1)	-	8E-11	-	-
		Y, see 227Pa	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	1E-10	-	-
91	Protactinium-233	W, see 227Pa	1E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		Y, see 227Pa	-	6E+2	2E-7	8E-10	-	-
91	Protactinium-234	W, see 227Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see 227Pa	-	7E+3	3E-6	9E-9	-	-
92	Uranium-230	D, UF, UOF, UO(NO)	4E+0	4E-1	2E-10	-	-	-
			Bone surf (6E+0)	Bone surf (6E-1)	-	8E-13	8E-8	8E-7
		W, UO, UF, UCl	-	4E-1	1E-10	5E-13	-	-
		Y, UO, UO	-	3E-1	1E-10	4E-13	-	-
92	Uranium-231	D, see 230U	5E+3	8E+3	3E-6	1E-8	-	-
			LLI wall (4E+3)	-	-	-	6E-5	6E-4
		W, see 230U	-	6E+3	2E-6	8E-9	-	-
		Y, see 230U	-	5E+3	2E-6	6E-9	-	-
92	Uranium-232	D, see 230U	2E+0	2E-1	9E-11	-	-	-
			Bone surf (4E+0)	Bone surf (4E-1)	-	6E-13	6E-8	6E-7
		W, see 230U	-	4E-1	2E-10	5E-13	-	-
		Y, see 230U	-	8E-3	3E-12	1E-14	-	-
92	Uranium-233	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	7E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-234[3]	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	7E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-235[3]	D, see 230U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-236	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-237	D, see 230U	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see 230U	-	2E+3	7E-7	2E-9	-	-
		Y, see 230U	-	2E+3	6E-7	2E-9	-	-
92	Uranium-238[3]	D, see 230U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	1E-12	-	-
		Y, see 230U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-239[2]	D, see 230U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		W, see 230U	-	2E+5	7E-5	2E-7	-	-
		Y, see 230U	-	2E+5	6E-5	2E-7	-	-
92	Uranium-240	D, see 230U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see 230U	-	3E+3	1E-6	4E-9	-	-
		Y, see 230U	-	2E+3	1E-6	3E-9	-	-

	Table I Occupational Values	Table II Effluent Concentrations	Table III Releases to Sewers

Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
92	Uranium-natural[3]	D, see 230U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see 230U	-	8E-1	3E-10	9E-13	-	-
		Y, see 230U	-	5E-2	2E-11	9E-14	-	-
93	Neptunium-232[2]	W, all compounds	1E+5	2E+3	7E-7	-	2E-3	2E-2
			-	Bone surf (5E+2)	-	6E-9	-	-
93	Neptunium-233[2]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Neptunium-235	W, all compounds	2E+4	8E+2	3E-7	-	-	-
			LLI wall (2E+4)	Bone surf (1E+3)	-	2E-9	3E-4	3E-3
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0	2E-2	9E-12	-	-	-
			Bone surf (6E+0)	Bone surf (5E-2)	-	8E-14	9E-8	9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3	3E+1	1E-8	-	-	-
			Bone surf (4E+3)	Bone surf (7E+1)	-	1E-10	5E-5	5E-4
93	Neptunium-237	W, all compounds	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	1E-14	2E-8	2E-7
93	Neptunium-238	W, all compounds	1E+3	6E+1	3E-8	-	2E-5	2E-4
			-	Bone surf (2E+2)	-	2E-10	-	-
93	Neptunium-239	W, all compounds	2E+3	2E+3	9E-7	3E-9	-	-
			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	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235[2]	W, see 234Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see 234Pu	-	3E+6	1E-3	3E-6	-	-
94	Plutonium-236	W, see 234Pu	2E+0	2E-2	8E-12	-	-	-
			Bone surf (4E+0)	Bone surf (4E-2)	-	5E-14	6E-8	6E-7
		Y, see 234Pu	-	4E-2	2E-11	6E-14	-	-
94	Plutonium-237	W, see 234Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see 234Pu	-	3E+3	1E-6	4E-9	-	-
94	Plutonium-238	W, see 234Pu	9E-1	7E-3	3E-12	-	-	-
			Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	8E-12	2E-14	-	-
94	Plutonium-239	W, see 234Pu	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-240	W, see 234Pu	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-241	W, see 234Pu	4E+1	3E-1	1E-10	-	-	-
			Bone surf (7E+1)	Bone surf (6E-1)	-	8E-13	1E-6	1E-5
		Y, see 234Pu	-	8E-1	3E-10	-	-	-
			-	Bone surf (1E+0)	-	1E-12	-	-
94	Plutonium-242	W, see 234Pu	8E-1	7E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-243	W, see 234Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see 234Pu	-	4E+4	2E-5	5E-8	-	-
94	Plutonium-244	W, see 234Pu	8E-1	7E-3	3E-12	-	-	-
			Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see 234Pu	-	2E-2	7E-12	-	-	-
			-	Bone surf (2E-2)	-	2E-14	-	-
94	Plutonium-245	W, see 234Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see 234Pu	-	4E+3	2E-6	6E-9	-	-
94	Plutonium-246	W, see 234Pu	4E+2	3E+2	1E-7	4E-10	-	-
			LLI wall (4E+2)	-	-	-	6E-6	6E-5
		Y, see 234Pu	-	3E+2	1E-7	4E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
95	Americium-237[2]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238[2]	W, all compounds	4E+4	3E+3	1E-6	-	5E-4	5E-3
			-	Bone surf (6E+3)	-	9E-9	-	-
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242m	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (9E+1)	-	1E-10	-	-
95	Americium-243	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-244m[2]	W, all compounds	6E+4	4E+3	2E-6	-	-	-
			St wall (8E+4)	Bone surf (7E+3)	-	1E-8	1E-3	1E-2
95	Americium-244	W, all compounds	3E+3	2E+2	8E-8	-	4E-5	4E-4
			-	Bone surf (3E+2)	-	4E-10	-	-
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m[2]	W, all compounds	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
95	Americium-246[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1	6E-1	2E-10	-	-	-
			Bone surf (8E+1)	Bone surf (6E-1)	-	9E-13	1E-6	1E-5
96	Curium-241	W, all compounds	1E+3	3E+1	1E-8	-	2E-5	2E-4
			-	Bone surf (4E+1)	-	5E-11	-	-
96	Curium-242	W, all compounds	3E+1	3E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	4E-13	7E-7	7E-6
96	Curium-243	W, all compounds	1E+0	9E-3	4E-12	-	-	-
			Bone surf (2E+0)	Bone surf (2E-2)	-	2E-14	3E-8	3E-7
96	Curium-244	W, all compounds	1E+0	1E-2	5E-12	-	-	-
			Bone surf (3E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
96	Curium-245	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-246	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-247	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-248	W, all compounds	2E-1	2E-3	7E-13	-	-	-
			Bone surf (4E-1)	Bone surf (3E-3)	-	4E-15	5E-9	5E-8
96	Curium-249[2]	W, all compounds	5E+4	2E+4	7E-6	-	7E-4	7E-3
			-	Bone surf (3E+4)	-	4E-8	-	-
96	Curium-250	W, all compounds	4E-2	3E-4	1E-13	-	-	-
			Bone surf (6E-2)	Bone surf (5E-4)	-	8E-16	9E-10	9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
97	Berkelium-249	W, all compounds	2E+2	2E+0	7E-10	-	-	-
			Bone surf (5E+2)	Bone surf (4E+0)	-	5E-12	6E-6	6E-5
97	Berkelium-250	W, all compounds	9E+3	3E+2	1E-7	-	1E-4	1E-3
			-	Bone surf (7E+2)	-	1E-9	-	-
98	Californium-244[2]	W, all compounds except those given for Y	3E+4	6E+2	2E-7	8E-10	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
98	Californium-246	W, see 244Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see 244Cf	-	9E+0	4E-9	1E-11	-	-
98	Californium-248	W, see 244Cf	8E+0	6E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
		Y, see 244Cf	-	1E-1	4E-11	1E-13	-	-
98	Californium-249	W, see 244Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see 244Cf	-	1E-2	4E-12	-	-	-
			Bone surf -	(1E-2)	-	2E-14	-	-
98	Californium-250	W, see 244Cf	1E+0	9E-3	4E-12	-	-	-
			Bone surf (2E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
		Y, see 244Cf	-	3E-2	1E-11	4E-14	-	-
98	Californium-251	W, see 244Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see 244Cf	-	1E-2	4E-12	-	-	-
			Bone surf -	(1E-2)	-	2E-14	-	-
98	Californium-252	W, see 244Cf	2E+0	2E-2	8E-12	-	-	-
			Bone surf (5E+0)	Bone surf (4E-2)	-	5E-14	7E-8	7E-7
		Y, see 244Cf	-	3E-2	1E-11	5E-14	-	-
98	Californium-253	W, see 244Cf	2E+2	2E+0	8E-10	3E-12	-	-
			Bone surf (4E+2)	-	-	-	5E-6	5E-5
		Y, see 244Cf	-	2E+0	7E-10	2E-12	-	-
98	Californium-254	W, see 244Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
		Y, see 244Cf	-	2E-2	7E-12	2E-14	-	-
99	Einsteinium-250	W, all compounds	4E+4	5E+2	2E-7	-	6E-4	6E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-251	W, all compounds	7E+3	9E+2	4E-7	-	1E-4	1E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99	Einsteinium-254m	W, all compounds	3E+2	1E+1	4E-9	1E-11	-	-
			LLI wall (3E+2)	-	-	-	4E-6	4E-5
99	Einsteinium-254	W, all compounds	8E+0	7E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1	2E-1	7E-11	-	-	-
			Bone surf (4E+1)	Bone surf (2E-1)	-	3E-13	5E-7	5E-6
101	Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	-	1E-4	1E-3
			-	Bone surf (9E+1)	-	1E-10	-	-
101	Mendelevium-258	W, all compounds	3E+1	2E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	5E-13	6E-7	6E-6
-Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours Submersion[1]			-	2E+2	1E-7	1E-9	-	-
-Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours			-	2E-1	1E-10	1E-12	1E-8	1E-7
-Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known			-	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:

1. Submersion means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

2. These radionuclides have radiological half-lives of fewer than two 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 Ci/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See D.1203.)

3 For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see 20.1201(e)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) µCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

SA = 3.6E-7 curies/gram U U-depleted
SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)2] E-6 , enrichment > 0.72
where enrichment is the percentage by weight of U-235, expressed as percent.

NOTES:

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

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
If it is known that Ac-227-D and Cm-250-W are not present			-	7E-4	3E-13	-	-	-
If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present			-	7E-3	3E-12	-	-	-
If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W,								

Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present	-	7E-2	3E-11	-	-	-

	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
	Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
Atomic No. Radionuclide Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present	-	7E-1	3E-10	-	-	-
If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present	-	7E+0	3E-9	-	-	-
If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present	-	-	-	1E-14	-	-
If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present	-	-	-	1E-13	-	-
If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present	-	-	-	1E-12	-	-
If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present	-	-	-	-	1E-6	1E-5

NOTES:

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 μm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 μCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 μCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Example: If radionuclides "A," "B," and "C" are present in concentrations CA, CB, and CC, and if the applicable DACs are DACA, DACB, and DACC, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

APPENDIX C.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-11	1,000	Manganese-51	1,000
Carbon-14	100	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62m	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100
Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82m	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-92	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000
Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000	Niobium-88	1,000

* To convert μCi to kBq, multiply the μCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Niobium-89m (66 min)	1,000	Palladium-101	1,000
Niobium-89 (122 min)	1,000	Palladium-103	100
Niobium-90	100	Palladium-107	10
Niobium-93m	10	Palladium-109	100
Niobium-94	1	Silver-102	1,000
Niobium-95m	100	Silver-103	1,000
Niobium-95	100	Silver-104m	1,000
Niobium-96	100	Silver-104	1,000
Niobium-97	1,000	Silver-105	100
Niobium-98	1,000	Silver-106m	100
Molybdenum-90	100	Silver-106	1,000
Molybdenum-93m	100	Silver-108m	1
Molybdenum-93	10	Silver-110m	10
Molybdenum-99	100	Silver-111	100
Molybdenum-101	1,000	Silver-112	100
Technetium-93m	1,000	Silver-115	1,000
Technetium-93	1,000	Cadmium-104	1,000
Technetium-94m	1,000	Cadmium-107	1,000
Technetium-94	1,000	Cadmium-109	1
Technetium-96m	1,000	Cadmium-113m	0.1
Technetium-96	100	Cadmium-113	100
Technetium-97m	100	Cadmium-115m	10
Technetium-97	1,000	Cadmium-115	100
Technetium-98	10	Cadmium-117m	1,000
Technetium-99m	1,000	Cadmium-117	1,000
Technetium-99	100	Indium-109	1,000
Technetium-101	1,000	Indium-110m(69.1m)	1,000
Technetium-104	1,000	Indium-110 (4.9h)	1,000
Ruthenium-94	1,000	Indium-111	100
Ruthenium-97	1,000	Indium-112	1,000
Ruthenium-103	100	Indium-113m	1,000
Ruthenium-105	1,000	Indium-114m	10
Ruthenium-106	1	Indium-115m	1,000
Rhodium-99m	1,000	Indium-115	100
Rhodium-99	100	Indium-116m	1,000
Rhodium-100	100	Indium-117m	1,000
Rhodium-101m	1,000	Indium-117	1,000
Rhodium-101	10	Indium-119m	1,000
Rhodium-102m	10	Tin-110	100
Rhodium-102	10	Tin-111	1,000
Rhodium-103m	1,000	Tin-113	100
Rhodium-105	100	Tin-117m	100
Rhodium-106m	1,000	Tin-119m	100
Rhodium-107	1,000	Tin-121m	100
Palladium-100	100	Tin-121	1,000

* To convert μCi to kBq, multiply the μCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Tin-123m	1,000	Iodine-120m	1,000
Tin-123	10	Iodine-120	100
Tin-125	10	Iodine-121	1,000
Tin-126	10	Iodine-123	100
Tin-127	1,000	Iodine-124	10
Tin-128	1,000	Iodine-125	1
Antimony-115	1,000	Iodine-126	1
Antimony-116m	1,000	Iodine-128	1,000
Antimony-116	1,000	Iodine-129	1
Antimony-117	1,000	Iodine-130	10
Antimony-118m	1,000	Iodine-131	1
Antimony-119	1,000	Iodine-132m	100
Antimony-120 (16m)	1,000	Iodine-132	100
Antimony-120 (5.76d)	100	Iodine-133	10
Antimony-122	100	Iodine-134	1,000
Antimony-124m	1,000	Iodine-135	100
Antimony-124	10	Xenon-120	1,000
Antimony-125	100	Xenon-121	1,000
Antimony-126m	1,000	Xenon-122	1,000
Antimony-126	100	Xenon-123	1,000
Antimony-127	100	Xenon-125	1,000
Antimony-128 (10.4m)	1,000	Xenon-127	1,000
Antimony-128 (9.O1h)	100	Xenon-129m	1,000
Antimony-129	100	Xenon-131m	1,000
Antimony-130	1,000	Xenon-133m	1,000
Antimony-131	1,000	Xenon-133	1,000
Tellurium-116	1,000	Xenon-135m	1,000
Tellurium-121m	10	Xenon-135	1,000
Tellurium-121	100	Xenon-138	1,000
Tellurium-123m	10	Cesium-125	1,000
Tellurium-123	100	Cesium-127	1,000
Tellurium-125m	10	Cesium-129	1,000
Tellurium-127m	10	Cesium-130	1,000
Tellurium-127	1,000	Cesium-131	1,000
Tellurium-129m	10	Cesium-132	100
Tellurium-129	1,000	Cesium-134m	1,000
Tellurium-131m	10	Cesium-134	10
Tellurium-131	100	Cesium-135m	1,000
Tellurium-132	10	Cesium-135	100
Tellurium-133m	100	Cesium-136	10
Tellurium-133	1,000	Cesium-137	10
Tellurium-134	1,000	Cesium-138	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-144	10
Barium-131	100	Promethium-145	10
Barium-133m	100	Promethium-146	1
Barium-133	100	Promethium-147	10
Barium-135m	100	Promethium-148m	10
Barium-139	1,000	Promethium-148	10
Barium-140	100	Promethium-149	100
Barium-141	1,000	Promethium-150	1,000
Barium-142	1,000	Promethium-151	100
Lanthanum-131	1,000	Samarium-141m	1,000
Lanthanum-132	100	Samarium-141	1,000
Lanthanum-135	1,000	Samarium-142	1,000
Lanthanum-137	10	Samarium-145	100
Lanthanum-138	100	Samarium-146	1
Lanthanum-140	100	Samarium-147	100
Lanthanum-141	100	Samarium-151	10
Lanthanum-142	1,000	Samarium-153	100
Lanthanum-143	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100
Cerium-143	100	Europium-150 (12.62h)	100
Cerium-144	1	Europium-150 (34.2y)	1
Praseodymium-136	1,000	Europium-152m	100
Praseodymium-137	1,000	Europium-152	1
Praseodymium-138m	1,000	Europium-154	1
Praseodymium-139	1,000	Europium-155	10
Praseodymium-142m	1,000	Europium-156	100
Praseodymium-142	100	Europium-157	100
Praseodymium-143	100	Europium-158	1,000
Praseodymium-144	1,000	Gadolinium-145	1,000
Praseodymium-145	100	Gadolinium-146	10
Praseodymium-147	1,000	Gadolinium-147	100
Neodymium-136	1,000	Gadolinium-148	0.001
Neodymium-138	100	Gadolinium-149	100
Neodymium-139m	1,000	Gadolinium-151	10
Neodymium-139	1,000	Gadolinium-152	100
Neodymium-141	1,000	Gadolinium-153	10
Neodymium-147	100	Gadolinium-159	100
Neodymium-149	1,000		
Neodymium-151	1,000		

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Terbium-147	1,000	Ytterbium-167	1,000
Terbium-149	100	Ytterbium-169	100
Terbium-150	1,000	Ytterbium-175	100
Terbium-151	100	Ytterbium-177	1,000
Terbium-153	1,000	Ytterbium-178	1,000
Terbium-154	100	Lutetium-169	100
Terbium-155	1,000	Lutetium-170	100
Terbium-156m (5.Oh)	1,000	Lutetium-171	100
Terbium-156m (24.4h)	1,000	Lutetium-172	100
Terbium-156	100	Lutetium-173	10
Terbium-157	10	Lutetium-174m	10
Terbium-158	1	Lutetium-174	10
Terbium-160	10	Lutetium-176m	1,000
Terbium-161	100	Lutetium-176	100
Dysprosium-155	1,000	Lutetium-177m	10
Dysprosium-157	1,000	Lutetium-177	100
Dysprosium-159	100	Lutetium-178m	1,000
Dysprosium-165	1,000	Lutetium-178	1,000
Dysprosium-166	100	Lutetium-179	1,000
Holmium-155	1,000	Hafnium-170	100
Holmium-157	1,000	Hafnium-172	1
Holmium-159	1,000	Hafnium-173	1,000
Holmium-161	1,000	Hafnium-175	100
Holmium-162m	1,000	Hafnium-177m	1,000
Holmium-162	1,000	Hafnium-178m	0.1
Holmium-164m	1,000	Hafnium-179m	10
Holmium-164	1,000	Hafnium-180m	1,000
Holmium-166m	1	Hafnium-181	10
Holmium-166	100	Hafnium-182m	1,000
Holmium-167	1,000	Hafnium-182	0.1
Erbium-161	1,000	Hafnium-183	1,000
Erbium-165	1,000	Hafnium-184	100
Erbium-169	100	Tantalum-172	1,000
Erbium-171	100	Tantalum-173	1,000
Erbium-172	100	Tantalum-174	1,000
Thulium-162	1,000	Tantalum-175	1,000
Thulium-166	100	Tantalum-176	100
Thulium-167	100	Tantalum-177	1,000
Thulium-170	10	Tantalum-178	1,000
Thulium-171	10	Tantalum-179	100
Thulium-172	100	Tantalum-180m	1,000
Thulium-173	100	Tantalum-180	100
Thulium-175	1,000	Tantalum-182m	1,000
Ytterbium-162	1,000	Tantalum-182	10
Ytterbium-166	100	Tantalum-183	100
		Tantalum-184	100
		Tantalum-185	1,000

* To convert μCi to kBq, multiply the μCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Tantalum-186	1,000	Iridium-195m	1,000
Tungsten-176	1,000	Iridium-195	1,000
Tungsten-177	1,000	Platinum-186	1,000
Tungsten-178	1,000	Platinum-188	100
Tungsten-179	1,000	Platinum-189	1,000
Tungsten-181	1,000	Platinum-191	100
Tungsten-185	100	Platinum-193m	100
Tungsten-187	100	Platinum-193	1,000
Tungsten-188	10	Platinum-195m	100
Rhenium-177	1,000	Platinum-197m	1,000
Rhenium-178	1,000	Platinum-197	100
Rhenium-181	1,000	Platinum-199	1,000
Rhenium-182 (12.7h)	1,000	Platinum-200	100
Rhenium-182 (64.Oh)	100	Gold-193	1,000
Rhenium-184m	10	Gold-194	100
Rhenium-184	100	Gold-195	10
Rhenium-186m	10	Gold-198m	100
Rhenium-186	100	Gold-198	100
Rhenium-187	1,000	Gold-199	100
Rhenium-188m	1,000	Gold-200m	100
Rhenium-188	100	Gold-200	1,000
Rhenium-189	100	Gold-201	1,000
Osmium-180	1,000	Mercury-193m	100
Osmium-181	1,000	Mercury-193	1,000
Osmium-182	100	Mercury-194	1
Osmium-185	100	Mercury-195m	100
Osmium-189m	1,000	Mercury-195	1,000
Osmium-191m	1,000	Mercury-197m	100
Osmium-191	100	Mercury-197	1,000
Osmium-193	100	Mercury-199m	1,000
Osmium-194	1	Mercury-203	100
Iridium-182	1,000	Thallium-194m	1,000
Iridium-184	1,000	Thallium-194	1,000
Iridium-185	1,000	Thallium-195	1,000
Iridium-186	100	Thallium-197	1,000
Iridium-187	1,000	Thallium-198m	1,000
Iridium-188	100	Thallium-198	1,000
Iridium-189	100	Thallium-199	1,000
Iridium-190m	1,000	Thallium-200	1,000
Iridium-190	100	Thallium-201	1,000
Iridium-192 (73.8d)	1	Thallium-202	100
Iridium-192m (1.4m)	10	Thallium-204	100
Iridium-194m	10	Lead-195m	1,000
Iridium-194	100	Lead-198	1,000

* To convert µCi to kBq, multiply the µCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Lead-199	1,000	Thorium-226	10
Lead-200	100	Thorium-227	0.01
Lead-201	1,000	Thorium-228	0.001
Lead-202m	1,000	Thorium-229	0.001
Lead-202	10	Thorium-230	0.001
Lead-203	1,000	Thorium-231	100
Lead-205	100	Thorium-232	100
Lead-209	1,000	Thorium-234	10
Lead-210	0.01	Thorium-natural	100
Lead-211	100	Protactinium-227	10
Lead-212	1	Protactinium-228	1
Lead-214	100	Protactinium-230	0.1
Bismuth-200	1,000	Protactinium-231	0.001
Bismuth-201	1,000	Protactinium-232	1
Bismuth-202	1,000	Protactinium-233	100
Bismuth-203	100	Protactinium-234	100
Bismuth-205	100	Uranium-230	0.01
Bismuth-206	100	Uranium-231	100
Bismuth-207	10	Uranium-232	0.001
Bismuth-210m	0.1	Uranium-233	0.001
Bismuth-210	1	Uranium-234	0.001
Bismuth-212	10	Uranium-235	0.001
Bismuth-213	10	Uranium-236	0.001
Bismuth-214	100	Uranium-237	100
Polonium-203	1,000	Uranium-238	100
Polonium-205	1,000	Uranium-239	1,000
Polonium-207	1,000	Uranium-240	100
Polonium-210	0.1	Uranium-natural	100
Astatine-207	100	Neptunium-232	100
Astatine-211	10	Neptunium-233	1,000
Radon-220	1	Neptunium-234	100
Radon-222	1	Neptunium-235	100
Francium-222	100	Neptunium-236 (1.15E+5)	0.001
Francium-223	100	Neptunium-236 (22.5h)	1
Radium-223	0.1	Neptunium-237	0.001
Radium-224	0.1	Neptunium-238	10
Radium-225	0.1	Neptunium-239	100
Radium-226	0.1	Neptunium-240	1,000
Radium-227	1,000	Plutonium-234	10
Radium-228	0.1	Plutonium-235	1,000
Actinium-224	1	Plutonium-236	0.001
Actinium-225	0.01	Plutonium-237	100
Actinium-226	0.1		
Actinium-227	0.001		
Actinium-228	1		

* To convert μCi to kBq, multiply the μCi value by 37.

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Plutonium-238	0.001	Curium-247	0.001
Plutonium-239	0.001	Curium-248	0.001
Plutonium-240	0.001	Curium-249	1,000
Plutonium-241	0.01	Berkelium-245	100
Plutonium-242	0.001	Berkelium-246	100
Plutonium-243	1,000	Berkelium-247	0.001
Plutonium-244	0.001	Berkelium-249	0.1
Plutonium-245	100	Berkelium-250	10
Americium-237	1,000	Californium-244	100
Americium-238	100	Californium-246	1
Americium-239	1,000	Californium-248	0.01
Americium-240	100	Californium-249	0.001
Americium-241	0.001	Californium-250	0.001
Americium-242m	0.001	Californium-251	0.001
Americium-242	10	Californium-252	0.001
Americium-243	0.001	Californium-253	0.1
Americium-244m	100	Californium-254	0.001
Americium-244	10	Einsteinium-250	100
Americium-245	1,000	Einsteinium-251	100
Americium-246m	1,000	Einsteinium-253	0.1
Americium-246	1,000	Einsteinium-254m	1
Curium-238	100	Einsteinium-254	0.01
Curium-240	0.1	Fermium-252	1
Curium-241	1	Fermium-253	1
Curium-242	0.01	Fermium-254	10
Curium-243	0.001	Fermium-255	1
Curium-244	0.001	Fermium-257	0.01
Curium-245	0.001	Mendelevium-257	10
Curium-246	0.001	Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

NOTE: For purposes of D.1902(e), D.1905(a), and D.2201(a) where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

[1] The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to Part D, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 μCi). Values of 3.7 MBq (100 μCi) have been assigned for radionuclides having a radioactive half- life in excess of E+9 years, except rhenium, 37 MBq (1,000 μCi), to take into account their low specific activity.

APPENDIX D.

Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

I. Manifest

A. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable Agency Forms (or other equivalent NRC, Licensing State or Agreement State approved forms) HHE-846 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and HHE-847 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable Agency Form HHE-848 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). Agency Forms HHE-846 and HHE-846A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, Agency Forms HHE-847, HHE-847A, HHE-848 and HHE-848A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by Agency to comply with the manifesting requirements of this Part when they ship:

1. LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

2. LLW that is being returned to the licensee who is the waste generator or generator, as defined in this part; or

3. Radioactively contaminated material to a waste processor that becomes the processor's residual waste.

B. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this Appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

C. Agency Forms HHE-846, HHE-846A, HHE-847, HHE-847A, HHE-848 and HHE-848A, and the accompanying instructions, in hard copy, may be obtained from the Maine Radiation Control Program, Maine Center for Disease Control and Prevention, Department of Health and Human Services, 11 State House Station, Augusta, Maine 04333-0011.

D. This Appendix includes information requirements of the U.S. Department of Transportation, as codified in 49 CFR Part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this Appendix.

E. As used in this Appendix, the following definitions apply:

1. **Agency Forms HHE-846, HHE-846A, HHE-847, HHE-847A, HHE-848 and HHE-848A** are official Agency Forms referenced in this Appendix. Licensees need not use originals of these Agency Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information.

Upon agreement between the shipper and consignee, Agency Forms HHE-847 (and HHE-847A) and Agency Forms HHE-848 (and HHE-848A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

2. **Chemical description** means a description of the principal chemical characteristics of a low-level radioactive waste.

3. **Computer-readable medium** means that the regulatory Agency's computer can transfer the information from the medium into its memory.

4. **Consignee** means the designated receiver of the shipment of low-level radioactive waste.

5. **Decontamination facility** means a facility operating under a Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

6. **Disposal container** means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see high integrity container). Note that for some shipments, the disposal container may be the transport package.

7. **EPA identification number** means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR Part 263.

8. **Generator** means a licensee operating under a Commission or Agreement State license who:

   (a) Is a waste generator as defined in this part, or

   (b) Is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

9. **High integrity container** (HIC) means a container commonly designed to meet the structural stability requirements of section V of this Appendix, and to meet Department of Transportation requirements for a Type A package.

10. **Land disposal facility** means the land, buildings and structures, and equipment, which are intended to be used for the disposal of radioactive wastes. For purposes of this rule, a geologic repository is not considered a land disposal facility.

11. **Package** means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

12. **Physical description** means the items called for on Agency Form HHE-847 to describe a low-level radioactive waste.

13. **Residual waste** means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

14. **Shipper** means the licensed entity (i.e., the waste generator, waste collector, or waste processor) that offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

15. **Shipping paper** means Agency Form HHE-846 and, if required, Agency Form HHE-846A, which includes the information, required by DOT in 49 CFR Part 172.

16. **Uniform Low-Level Radioactive Waste Manifest** or uniform manifest means the combination of Agency Forms HHE-846, HHE-847, and, if necessary, HHE-848, and their respective continuation sheets as needed, or equivalent.

17. **Waste collector** means an entity, operating under a Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

18. **Waste description** means the physical, chemical and radiological description of a low-level radioactive waste as called for on Agency Form HHE-847.

19. **Waste generator** means an entity, operating under a Commission or Agreement State license, that

    (a) Possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and

    (b) Transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a waste generator if the transfer of low-level radioactive waste from its facility is defined as residual waste.

20. **Waste processor** means an entity, operating under a Commission or Agreement State license, the principal purpose of which is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

21. **Waste type** means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

II. Information requirements

A. General Information: The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment information: The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal container and waste information: The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The absorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to section V of this Appendix. Waste not meeting the structural stability requirements of section VI.B. of this Appendix must be identified.

D. Uncontainerized waste information: The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to section V. of this Appendix. Waste not meeting the structural stability requirements of section VI.B. of this Appendix must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-generator disposal container information: This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more generators (including waste generators) as defined in this part). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the

identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(d) The absorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in section VI.B. of this Appendix; and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

III. Certification: An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Agency. A collector in signing the certification is certifying that nothing has been done to the collected waste, which would invalidate the waste generator's certification.

IV. Control and tracking:

A. Any licensee or registrant who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee or registrant who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this Appendix. A licensee shall:

1. Prepare all wastes so that the waste is classified according to section V. of this Appendix and meets the waste characteristics requirements in section VI. of this Appendix;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater then Class C waste, in accordance with section V. of this Appendix;

3. Conduct a quality assurance program to assure compliance with sections V. and VI. of this Appendix (the program must include management evaluation of audits);

4. Prepare the Agency Uniform Low-Level Radioactive Waste Manifest as required by this Appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either

(a) receipt of the manifest precedes the LLW shipment or

(b) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

6. Include Agency Form HHE-846 (and Agency Form HHE-846A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Agency Form HHE-846;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by this rule; and

9. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with paragraph E of this Appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Agency Form HHE-846;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this Appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either:

(a) Receipt of the manifest precedes the LLW shipment or

(b) The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

4. Include Agency Form HHE-846 (and Agency Form HHE-846A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Agency Form HHE-846;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by this rule;

7. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with paragraph E of this section; and

8. Notify the shipper and the Agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

C. Any licensed waste processor that treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Agency Form HHE-846;

2. Prepare a new manifest that meets the requirements of this Appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph I.E. of this Appendix;

3. Prepare all wastes so that the waste is classified according to section V. of this Appendix and meets the waste characteristics requirements in section VI. of this Appendix;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with sections V. and VI. of this Appendix;

5. Conduct a quality assurance program to assure compliance with sections V. and VI. of this Appendix (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either:

   (a) Receipt of the manifest precedes the LLW shipment or

   (b) The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

7. Include Agency Forms HHE-846 (and Agency Forms HHE-846A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Agency Forms HHE-846;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by this rule;

10. For any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with paragraph E of this section; and

11. Notify the shipper and the Agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of Agency Forms HHE-846 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level

Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by this Appendix until the Agency terminates the license; and

3. Notify the shipper and the Agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

E. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the Agency. Each licensee who conducts a trace investigation shall file a written report with the Agency within two weeks of completion of the investigation.

V. Classification of waste

A. Classification of waste for near surface 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) the potential hazard of which 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 VI.A. of this Appendix. If Class A waste also meets the stability requirements set forth in VI.B. of this Appendix, 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 section VI of this Appendix.

(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 section VI of this Appendix.

(d) Waste that is not generally acceptable for near-surface disposal is waste for which form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this part, such waste must be disposed of in a geologic repository as defined in 10 CFR Part 60 unless proposals for disposal of such waste in a disposal site licensed pursuant to 10 CFR Part 61 are approved by the Nuclear Regulatory Commission.

3. Classification determined by long-lived radionuclides. If radioactive waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

(a) If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.

(b) If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.

(c) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.

(d) For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions.

Table 1

Radionuclide	Concentration curies per cubic meter
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic nuclides with half-life greater than 5 years	100[1]
Pu-241	3,500[1]
Cm-242	20,000[1]

[1] Units are nanocuries per gram.

4. Classification determined by short-lived radionuclides. If radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. However, as specified in paragraph A.6. of this section, if radioactive waste does not contain any nuclides listed in either Table 1 or 2, 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 nuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule

Table 2

Radionuclide	**Concentration, curies per cubic meter**		
	Col. 1	**Col. 2**	**Col. 3**
Total of all nuclides with less than 5 year half-life	700	([1])	([1])
H-3	40	([1])	([1])
Co-60	700	([1])	([1])
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

[1] 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 nuclides in Table 2 determine the waste to the Class C independent of these nuclides.

5. Classification determined by both long- and short-lived radionuclides. If radioactive waste contains a mixture of radionuclides, some of which are listed in Table 1, and some of which are listed in Table 2, classification shall be determined as follows:

(a) If the concentration of a nuclide listed in Table 1 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of nuclides listed in Table 2.

(b) If the concentration of a nuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1 but does not exceed the value in Table 1, the waste shall be Class C, provided the concentration of nuclides listed in Table 2 does not exceed the value shown in Column 3 of Table 2.

6. Classification of wastes with radio--0uclides other than those listed in Tables 1 and 2. If radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.

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 nuclide'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 50 Ci/m3. and Cs-137 in a concentration of 22 Ci/m3. Since the concentrations both exceed the values in Column 1, Table 2, 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 nanocuries per gram.

VI. Waste characteristics.

A. The following requirements are minimum requirements for all classes of waste and are intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

1. Waste must not be packaged for disposal in cardboard or fiberboard boxes.

2. Liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.

3. Solid waste containing liquid shall contain as little free standing and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1 percent of the volume.

4. Waste must not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

5. Waste must not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with paragraph A.7. of this section.

6. Waste must not be pyrophoric. Pyrophoric materials contained in waste shall be treated, prepared, and packaged to be nonflammable.

7. Waste in a gaseous form must be packaged at a pressure that does not exceed 1.5 atmospheres at 20º C. Total activity must not exceed 100 curies per container.

8. Waste containing hazardous, biological, pathogenic, or infectious material must be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

B. The requirements in this section are intended to provide stability of the waste. Stability is intended to ensure that the waste does not structurally degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1. Waste must have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2. Notwithstanding the provisions in VI.A.2 and 3, liquid wastes, or wastes containing liquid, must be converted into a form that contains as little free standing 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.

3. Void spaces within the waste and between the waste and its package must be reduced to the extent practicable.

VII. Labeling. Each package of waste must be clearly labeled to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with section V of this Appendix.

VIII. Maintenance of records, reports, and transfers.

A. Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the Agency.

B. Records which are required by the regulations in this Part or by license conditions must be maintained for a period specified by the appropriate regulations in this rule or by license condition. If a retention period is not otherwise specified, these records must be maintained and transferred to the officials specified in paragraph E of this section as a condition of license termination unless the Agency otherwise authorizes their disposition.

C. Records which must be maintained pursuant to this Part may be the original or a reproduced copy or a microform if this reproduced copy or microform 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. If there is a conflict between the Agency's regulations in this Part, license condition, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the longest retention period specified takes precedence.

E. Notwithstanding paragraphs A through D of this section, the licensee shall record the location and the quantity of radioactive wastes contained in the disposal site and transfer these records upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning Agency, the State governor and other State, local, and federal governmental agencies as designated by the Agency at the time of license termination.

F. Following receipt and acceptance of a shipment of radioactive waste, the licensee shall record the date of disposal of the waste, the location in the disposal site, the condition of the waste packages as received, any discrepancies between materials listed on the manifest and those received, and any evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and Agency regulations. The licensee shall briefly describe any repackaging operations of any of the waste packages 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 this section.

G. Each licensee shall comply with the safeguards reporting requirements of Part C of this rule if the quantities or activities of materials received or transferred exceed the limits of these sections. Inventory reports required by these sections are not required for materials after disposal.

H. Each licensee authorized to dispose of radioactive waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the Agency in order to update the information base for determining financial qualifications.

1. Each licensee authorized to dispose of waste materials received from other persons, pursuant to this part, shall submit annual reports to the Agency. Reports must be submitted by the end of the first calendar quarter of each year for the preceding year.
2. The reports shall include:

(a) Specification of the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in airborne effluents during the preceding year,

(b) The results of the environmental monitoring program,

(c) A summary of licensee disposal unit survey and maintenance activities,

(d) A summary, by waste class, of activities and quantities of radionuclides disposed of,

(e) Any instances in which observed site characteristics were significantly different from those described in the application for a license; and

(f) Any other information the Agency may require. If the quantities of radioactive materials released during the reporting period, monitoring results, or maintenance performed are significantly different from those expected in the materials previously reviewed as part of the licensing action, the report must cover this specifically.

J. Each licensee shall report in accordance with the requirements of Part C.

K. Any transfer of radioactive materials by the licensee is subject to the requirements in Part C.

APPENDIX E.

NATIONALLY TRACKED SOURCE THRESHOLDS

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

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.

APPENDIX F.

(Reserved)

APPENDIX G.

SPECIAL REQUIREMENTS INVOLVING LOW-LEVEL RADIOACTIVE WASTE

1. Definitions

A. As used in this Part D Appendix G, the following definitions apply:

(1) **Activity,** as it applies to reporting the radioactivity of waste requiring disposal, refers to the radioactivity of the waste at the time of disposal. If the State did not have access to a disposal facility for that year, the radioactivity of waste placed in storage for that year shall apply (this radioactivity may be calculated to December 31 of the appropriate calendar year).

(2) **Generators of low-level radioactive waste** or generators means any persons who produce or process waste, as defined in Part A, whether or not that waste is shipped off site.

(3) **Minimization plan** means the plan required of each licensee who generates waste requiring disposal, which identifies actions to allow for storage for decay of short-lived radioisotopes and actions to achieve source and volume minimization.

(3) **Mixed waste** means waste that also contain a hazardous component, regulated under subtitle C of the Resource Conservation and Recovery Act (RCRA).

(4) **Source minimization** means minimizing the volume and curie content of waste prior to its generation by such methods as: (1) avoiding unnecessary contamination of items during the use of radioactive materials; (2) carefully segregating waste from non-radioactive trash; (3) substituting non-radioactive isotopes or radioisotopes with shorter half-lives where practicable.

(5) **Storage** means the holding of waste for treatment or disposal.

(6) **Storage for decay** means a procedure in which waste that is authorized by the United States Nuclear Regulatory Commission to be stored at the site of generation for decay and ultimate disposal without regard to radioactivity.

(7) **Volume,** as it applies to reporting volumes of waste requiring disposal, refers to the required space for ultimate disposal at a waste disposal facility. If the State did not have access to a disposal facility for that year, the volume of waste to be disposed of that was placed in storage for that year shall apply.

(8) **Volume minimization** means treatment of waste after its generation in order to minimize the physical dimensions of the waste and the space required for disposal.

2. Low-level radioactive waste fund

A. An annual service fee and a compact fee assessment shall be billed by the Agency. These fees are pro-rated such that fifty percent of the fees is based on volume of waste generated and fifty percent is based on the activity of waste generated.

B. Exempted from the annual service fee of Part D. Appendix G.2.A. are the following:

(1) Waste that is authorized by the United States Nuclear Regulatory Commission for disposal without regard to radioactivity;

(2) Waste that is stored for decay;

(3) Radioactive waste or other material that is returned to vendor, including, but not limited to, sealed sources.

C. The annual service fee and compact fee assessment, as specified in Part D. Appendix G.2.A, are determined by data collected on the low-level radioactive waste surveys. These fees will be based on a pro-rata share of the previous years' waste generation.

D. Generators are subject to service fee assessments the year following a termination of their radioactive materials license.

3. Annual surveys of the low-level radioactive waste stream

A. Generators of low-level radioactive waste must annually file a low-level radioactive waste survey with the Agency.

B. The low-level radioactive waste survey will require information concerning the volume, activity, isotopic content, chemical form, physical state, packaging, storage for decay, and interim storage capacity of waste and mixed wastes.

C. Completed survey forms must be returned to the Agency within sixty days of the postmarked date.

D. Generators shall maintain copies of their survey forms for the preceding three calendar years.

4. Advance notification of transportation of low-level radioactive waste

A. The following reporting requirements are made in addition to the requirements of Parts D.38 and L.19.

B. Three working days prior to the transport of waste outside the confines of the generators' facility or other place of use or storage, or three working days prior to the delivery of any waste to a carrier for transport, each generator shall provide advance notification of such transport to the Agency.

C. Advance notification is required only for waste that is being shipped to a disposal facility.

D. The notification required by Part D Appendix G.4.C. shall contain the following information:

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

(2) A description of the waste contained in the shipment as required by the regulations of the U. S. Department of Transportation, 49 CFR 172.202 and 172.203;

(3) The point of origin of the shipment;

(4) The destination of the shipment and the seven day period during which arrival of the shipment is estimated to occur;

(5) A point of contact with a telephone number for current shipment information

E. The notification required by Part D Appendix G.4. shall be made in writing to the Agency. A notification delivered by mail must be postmarked seven days prior to the date that the shipment is scheduled to occur. A notification delivered by telephone facsimile or messenger, must be delivered to the Agency at least three working days prior to the date that the shipment is scheduled to occur. A copy of the notification shall be retained by the licensee for one year.

5. Waste minimization

A. Generators who generate waste requiring disposal at a rate in excess of 100 cubic feet per calendar year, must submit a waste minimization plan to the Agency on a biennial basis. The plan must include:

(1) A description of the facility and the process or service that generates the waste.

(2) Identification and characterization of the waste streams that result from the process or service.

(3) Analysis of the technical characterization of the waste stream to determine the practicability of source minimization and volume minimization.

(4) Declaration of goals for waste minimization efforts and an analysis of the successfulness of the current waste minimization effort.

B. A detailed existing waste minimization plan may be submitted for Agency approval to meet the requirements of Part D Appendix G.5.A.

6. Packaging and waste form

Packaging and waste form of waste for disposal will comply with the requirements of the licensed or registered receiving radioactive waste site or authority.

PART E.

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

SUBPART A – GENERAL PROVISIONS

1. Purpose.

A. The requirements in this Part establish radiation safety requirements and licensing and registration procedures for using sources of radiation for industrial radiography and for certification of industrial radiographers.

B. The requirements in this Part apply to licensees and registrants who possess sources of radiation for industrial radiography, including radiation machines, accelerators, and sealed radioactive sources.

C. Each licensee and registrant is responsible for ensuring compliance with this Part, license and registration conditions, and orders of the Agency.

D. Each licensee and registrant is also responsible for ensuring that radiographic personnel performing activities under a license or registration comply with this Part, license and registration conditions, and orders of the Agency.

2. Scope.

The requirements of this Part apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for those requirements clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by this Part.

3. Definitions. As used in this Part, the following definitions apply:

Annual refresher safety training means a review conducted or provided by the licensee for it employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

Associated equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g. guide tube, control tube, control (drive) cable, removable source stop, J tube and collimator when it is used as an exposure head).

Cabinet x-ray system means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system. The cabinet x-ray system is intended to:

(a) Contain at least that portion of a material being irradiated;

(b) Provide radiation attenuation; and

(c) Exclude personnel from its interior during generation of radiation.

Certifiable cabinet x-ray system means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 Code of Federal Regulations (CFR).

Certification identification (ID) card means the document issued by the Agency to individuals who have completed the requirements stated in E.16.B.

Certified cabinet x-ray system means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled on or after April 10, 1975, according to the provisions of 21 CFR 1020.40.

Certifying entity means an independent certifying organization whose certification program has been reviewed and found to meet the requirements in Appendix A of 10 CFR Part 34 for radioactive materials and/or equivalent requirements for x-ray, or an Agreement State meeting the same requirements.

Collimator means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

Control (drive) cable means the cable that is connected to the source assembly and used to drive the source to and from the exposure location to return it to the shielded position.

Control drive mechanism – see crank out device.

Control tube means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

Crank-out device means the drive cable, control tube, and drive mechanism used to move the sealed source to and from the shielded position to make an industrial radiographic exposure.

Enclosed radiography means industrial radiography conducted in an enclosed cabinet or room. Enclosed radiography includes shielded-room radiography.

Exposure head means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop).

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

Guide tube (Projection sheath) means a flexible or rigid tube (e.g. J tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The

guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

Hands-on experience mean experience in all of those areas considered to be directly involved in the radiography process. This is also known as on-the-job training. The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

Independent certifying organization means an independent organization that meets all of the criteria of Appendix A of 10 CFR Part 34 for radioactive materials, or comparable standards for x-ray.

Industrial radiography means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to produce radiographic images.

Lay-barge radiography means industrial radiography performed on any water vessel used for laying pipe.

Lock-out survey means a radiation survey performed to determine that a sealed source is in its fully shielded position before moving the radiographic exposure device or source changer to a different temporary job site or before securing the radiographic exposure device or source changer against unauthorized removal.

Offshore platform radiography means industrial radiography conducted from a platform over a body of water.

Permanent radiographic installation means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed and meets the criteria of E.12.

Personal supervision means supervision in which the radiographer trainer is physically present at the site where sources of radiation, associated equipment, and survey meters are being used, watching the performance of the radiographer assistant and in such proximity that immediate assistance can be given if required.

Pipeliner means a directional beam radiographic exposure device.

Practical examination means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

Radiation safety officer (RSO) for industrial radiography means an individual with responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of E.15.A of this section.

Radiographer means any individual who performs or who, in attendance at the site where a sealed source or sources are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Agency's regulations and conditions of the license or certificate of registration.

Radiographer's assistant means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.

Radiographer certification means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

Radiographic exposure device (also called a camera, or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

Radiographic operations means all activities associated with the presence of x-ray machines or radioactive sources in a radiographic exposure device during the use of the machine or device or transport (except when being transported by a common or contract transport). Radiographic operations include surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries.

Radiographic personnel means any radiographer or radiographer assistant.

Residential location means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

Shielded position means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

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 Part D of this rule. A shielded room is also known as a bay or bunker.

Source assembly (pigtail) means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

Source changer means a device designed and used for replacement of the sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

Underwater radiography means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

4. Exemptions.

A. Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this Part except for any applicable requirements of sections E.25. and E.30.

B. Industrial uses of hand-held light intensified imaging devices are exempt from the requirements in this section if the exposure level 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour (mrem/hr) (0.02 millisieverts per hour (mSv/hr)). Devices with exposure levels that exceed the 2 mrem/hr (0.02 mSv/hr) level shall meet the applicable requirements of this section, Part D or Part H, as applicable.

C. Radiation machines determined by the Agency to constitute a minimal threat to human health and safety in accordance with E.25. and E.30., as applicable, are exempt from the requirements in this section except for the requirements of paragraph 1 above.

D. Facilities that utilize radiation machines for industrial radiography at permanent radiographic installations only are exempt from the requirements of this section except for the requirements of E.25. and E.30., as applicable. Receipt, transfer, and disposal of sources of radiation and devices using depleted uranium (DU) for shielding. Each licensee and registrant shall make and maintain records in accordance with E.26, showing the receipt, transfer, and disposal of sources of radiation and devices using for shielding.

E. Receipt, transfer, and disposal of sources of radiation and devices using depleted uranium (DU) for shielding. Each licensee and registrant shall make and maintain records in accordance with E.26, showing the receipt, transfer, and disposal of sources of radiation and devices using for shielding.

SUBPART B - SPECIFIC LICENSING PROVISIONS

4. Application for a specific license.

A. A person may file an application for specific license for use of sealed sources in industrial radiography, on HHE Form 850I, Application for Radioactive Material License for Industrial Radiography, in accordance with the provisions of this Part.

B. Specific license for industrial radiography. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

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

(2) The applicant submits an adequate program for training radiographers and radiographer assistants that meet the requirements of E.16.

(a) The applicant demonstrates that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers.

(b) 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.

(c) The applicant submits operating and emergency procedures as described in E.17.

(d) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer assistant at intervals not to exceed six months as described E.16.G.

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

(g) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant describes the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application includes a description of the procedures to be followed. The description includes the:

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

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

(h) The applicant intends to perform in-house calibrations of survey instruments, the applicant describes methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in E.8.

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

(j) The applicant identifies the locations where all records required by this Part will be maintained.

SUBPART C - EQUIPMENT

5. Performance requirements for industrial radiography equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

A. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard's Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

B. 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 pursuant to the above referenced standard.

C. In addition to the requirements specified in paragraphs E.5.A. and E.5.B. the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

a. Chemical symbol and mass number of the radionuclide in the device;

b. Activity and the date on which this activity was last measured;

c. Model (or product code) and serial number of the sealed source;

d. Manufacturer's identity of the sealed source; and

e. Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71 and Part L of this rule.

(3) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

D. In addition to the requirements specified in paragraphs A, B, and C of this Section, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it

cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The radiographic exposure 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 to protect the source assembly from water, mud, sand or other foreign matter during storage and transportation.

(4) Each sealed source or source assembly must have attached to it or engraved in 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) Guide tubes 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 the kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during 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.

E. Notwithstanding paragraph A(1) of this section, equipment used in industrial radiographic operations need not comply with 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

6. Limits on external radiation levels from radiographic exposure devices, storage containers and source changers. The maximum exposure rate limits for radiographic exposure devices, storage containers and source changers are 2 millisieverts (200 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at 1 meter (approximately 3 feet) from any exterior surface with the sealed source in the shielded position.

7. Locking of radiographic exposure devices, storage containers and source changers.

A. Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked at all times (and if a keyed lock, with the key removed at all times) when not under the direct visual surveillance of a radiographer or radiographer's assistant except at permanent radiographic installations as stated in E.12. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

B. Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

C. Each radiographic exposure device, storage container, and source changer shall be locked and the key removed from any lock prior to being transported from one location and also prior to being stored at a given location.

D. Locking and permanent storage precautions.

(1) Radiographic exposure devices, source changers, and transport containers that contain sealed sources shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

(2) Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This section does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with all applicable sections of this Part and if the vehicle does not constitute a permanent storage location as described in this Part.

8. Radiation survey instruments.

A. Each licensee and registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material and radiation machines are present to make the radiation surveys required by this Part and by Part D. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 sievert (1 rem) per hour.

B. The licensee or registrant shall have each radiation survey instrument required under paragraph A of this section calibrated:

(1) At intervals not to exceed six months and after instrument servicing, except for battery changes;

(2) For linear scale instruments, at two points located approximately one-third and two-thirds of full scale; for logarithmic scale instruments, at mid-range of each

decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour; and

(3) So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

(4) By a person licensed or registered by the Agency, another Agreement State, or the NRC to perform such service;

(5) At energies appropriate for the licensee's or registrant's use;

C. 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.

D. Each licensee and registrant shall maintain records of the results of the instrument calibrations in accordance with E.26.C.

9. Leak testing and replacement of sealed sources.

A. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed only by persons authorized to do so by the Agency, the NRC or an Agreement State.

B. The opening, repair or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the NRC or an Agreement State.

C. Testing and recordkeeping requirements.

(1) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved by the Agency, the NRC or by an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcurie) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the NRC, or an Agreement State to perform the analysis.

(2) The licensee shall maintain records of the leak tests in accordance with E.29.

(3) Unless a sealed source is accompanied by a certificate from the transferor, that shows that it has been leak tested within six months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.

D. Any test conducted pursuant to paragraphs B and C of this section, which reveals the presence of 185 Bq (0.005 microcurie) or more of removable radioactive material, must be considered evidence that the sealed source is leaking. The licensee shall immediately

withdraw the equipment involved from use and shall have it to be decontaminated and repaired or disposed of, in accordance with Agency regulations. A report must be filed with the Agency within five days of any test with results that exceed the threshold in this subsection, describing the equipment involved, the test results, and the corrective action taken.

E. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the NRC or an Agreement State to perform the analysis. Should such testing reveal the presence of 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 shall not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with E.29. A report must be filed with the Agency – within five days of any test with results that exceed the threshold in this subsection, describing the equipment involved, the test results, and the corrective action taken.

10. Quarterly inventory.

A. Each licensee and 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 this license.

B. Each licensee and registrant shall maintain records of the inventory in accordance with E.30.

11. Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

A. Each radiographer shall perform visual and operational checks on radiation machines, survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

B. Each licensee and registrant shall have written procedures for:

(1) Inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired. All appropriate components shall be maintained in accordance with

manufacturers' specifications. Radiation machines, radiographic exposure devices, transport containers and source changers being stored are exempted from this requirement provided that each radiation machine, radiographic exposure device, transport container, or source changer is inspected and repaired prior to being returned to service. This inspection and maintenance program shall cover, as a minimum, the items listed in Appendix B of this Part; and

(2) Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

C. Records of equipment problems and of any maintenance performed under paragraphs A and B of this section must be made in accordance with E.32.

12. Permanent radiographic installations.

A. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

(1) An entrance control of the type described in Part D.1601.A(1) that reduces the radiation level upon entry into the area, or

(2) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated, when an attempt is made to enter the installation while the source is exposed.

B. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in paragraph A(1) of this section) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee implements the continuous surveillance requirements of E.21 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarm must be maintained in accordance with E.33.

13. Labeling, storage, and transportation.

A. The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e. magenta, purple or black on a yellow background, having a minimum diameter of 25 millimeters, and the wording:

CAUTION*
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES
(or "NAME OF COMPANY")

*_____or “DANGER”

B. The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part L and 10 CFR Part 71.

C. Locked radiographic exposure devices, source changers, and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner that will minimize danger from explosion or fire.

D. The licensee shall lock and physically secure the transport package containing licensed radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

E. The licensee’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 for temporary job site use.

F. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(a) Chemical symbol and mass number of the radionuclide in the device;

(b) Activity and the date on which this activity was last measured;

(c) Model (or product code) and serial number of the sealed source;

(d) Manufacturer’s identity of the sealed source; and

(e) Licensee's name, address, and telephone number.

SUBPART D - Radiation Safety Requirements

14. Conducting industrial radiographic operations.

A. Whenever radiography is performed at a location other than a permanent radiographic installation, the qualified radiographer must be accompanied by at least one other qualified radiographer or qualified radiographer assistant. This additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

B. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the Agency.

C. A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency.

D. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must notify the requesting person's radiation safety officer or the person responsible for safety matters for those that do not have a radiation safety officer, before taking any licensed material onto the location.

15. Radiation safety officer for industrial radiography.

The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and requirements in the daily operation of the licensee's or registrant's program.

A. The minimum qualifications, training, and experience for RSO's for industrial radiography are as follows:

(1) Possession of a high school diploma or a certificate of high school equivalency based on the GED test.

(2) Completion of the training and testing requirements of E.16;

(3) Two years of documented experience including knowledge of industrial radiographic operations; and

(4) Formal training in the establishment and maintenance of a radiation protection program.

B. The Agency will consider alternatives when the RSO has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

C. The specific duties and authorities of the RSO include, but are not limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part D, and reviewing them regularly to ensure that the procedures in use conform to current Part D procedures, conform to other Agency regulations (Parts A, E, & J) and to the license conditions or certificate of registration.

(2) Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Part D.2106; and

(5) Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

(6) Ensuring that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

(7) Investigating, determining the cause, taking steps to prevent the recurrence, and reporting to the Agency each:

(a) Known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this Part; and

(b) Theft or loss of a source(s) of radiation.

16. Requirements for qualifications of radiographic personnel.

A. Radiographer assistant. No licensee or registrant shall permit any individual to act as a radiographer assistant until the individual possesses the original or a copy of an Agency-issued radiography assistant status card or certification ID card.

(1) To obtain an Agency-issued radiography assistant status card, the licensee, registrant, or the individual must document to the Agency on Agency Form HHE-851 or equivalent that such individual has successfully completed a course of at least 40 hours on the applicable subjects outlined in E Appendix A. The course must be one accepted by the Agency, another agreement state, or the NRC.

(2) The radiographer assistant must carry a copy of the completed Agency Form HHE-851 listed above, in the interim period after submitting documentation to the Agency and before receiving a radiographer assistant status card. The copy of the completed HHE-851 that was submitted to the Agency may be used in lieu of the radiographer assistant status card for a period of 60 days from the date recorded by the radiographer assistant on the documentation.

(3) The individual shall notify the Agency by telephone, telegram, telefacsimile, electronic media transmission, or in writing of the need for a replacement radiographer assistant status card. The individual shall carry a copy of documentation of the request while performing industrial radiographic operations until a replacement radiographer assistant status card is received from the Agency.

B. Radiographer. No licensee or registrant shall permit any individual to act as a radiographer until the individual carries a valid radiographer certification. To obtain a radiographer certification, an individual must comply with the following:

(1) The licensee, registrant, or the individual must document to the Agency on Forms HHE-854 and HHE-856 or equivalent that such individual:

(a) Has completed the requirements of E.16.A(1);

(b) Has completed two months on-the-job training as a radiographer assistant supervised by one or more radiographers authorized on a license or certificate of registration;

(i) The radiographer assistant must carry a legible radiographer assistant status card in accordance with paragraph A of this section while obtaining the on-the-job training specified in (1)(b)(ii)-(vii) of this section.

(ii) The two months on-the-job training shall include at least 320 hours of active participation in radioactive materials industrial radiographic operations or one month, 160 hours, for active participation in x-ray industrial radiographic operations.

(iii) Individuals performing industrial radiography utilizing radioactive materials and x-ray machines must complete both segments three months (480 hours) of on-the-job training.

(iv) The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

(v) One year of documented experience or on-the-job training as authorized by another Agreement State or the NRC may be substituted for (1)(b)(ii) or (iii) of this section. The documentation must be submitted to the Agency on Form HHE-856 or equivalent.

(vi) The radiographer assistant shall be under the personal supervision of a radiographer whenever a radiographer assistant:

(a) Uses radiation machines, radiographic exposure devices, or associated equipment; or

(b) Performs radiation surveys required by E.19 to determine that the sealed source has returned to the shielded position after an exposure or the radiation machine has stopped producing radiation.

(vii) The personal supervision shall include the following.

(a) The radiographer’s physical presence at the site where the sources of radiation are being used;

(b) The availability of the radiographer to give immediate assistance if required; and

(c) The radiographer’s direct observation of the radiographer assistant’s performance of the operations referred to in this section.

(2) Has successfully completed within the last five years the appropriate Agency-administered examination prescribed in E.46 or the appropriate examination of another certifying entity that affords the same or comparable certification standards as those afforded by (1) and (3) of this section and E.46.; and

(3) Possesses a current certification ID card issued in accordance with E.46 or by another certifying entity that affords the same or comparable certification standards as those afforded by (1) and (2) of this Part and E.46.

(4) Reciprocal recognition by the Agency of an individual radiographer certification may be granted according to E.23:

(5) Once an individual has completed the requirements of paragraph 3 of this section, the licensee or registrant is not required to submit the documentation referenced in paragraph B.(1)(a) and (b) of this section.

C. In addition, the licensee or registrant may not permit any individual to act as a radiographer, radiographer assistant, or RSO until the individual has:

(1) Received copies of and demonstrated an understanding of the following by successful completion of a written or oral examination administered by the licensee or registrant covering this material:

(a) The requirements contained in this Part and the applicable requirements of Parts A, B, C, D, F, H, J, and L;

(b) The appropriate conditions of the license(s) and certificate(s) of registration;

(c) The licensee's or registrant's operating and emergency procedures; and

(2) Demonstrated competence in the use of sources of radiation, radiographic exposure devices, associated equipment, related handling tools, and radiation survey instruments that may be employed in industrial radiographic assignments by successful completion of a practical examination administered by the licensee or registrant covering such use.

D. Records of the administration of and the examinations required by C(1) of this section shall be made and maintained for Agency inspection in accordance with E.34.

E. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

F. Except as provided in paragraph D, the RSO or designee shall conduct an internal audit of the job performance of each radiographer and radiographer's assistant to ensure that the Agency's regulations, license or certificate of registration requirements, and the licensee's or registrants operating and emergency procedures are followed. The audit program must:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation during the six months since the last inspection, the radiographer or radiographer assistant must demonstrate knowledge of the training requirements of E.16.D. 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 RSO.

(4) In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

G. The licensee or registrant shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and audits of job performance in accordance with

H. The licensee or registrant training shall include the subjects covered in Appendix A of this Part.

17. Operating and emergency procedures. Operating and emergency procedures must include, as a minimum, instructions as outlined in Appendix C of this Part.

18. Personnel monitoring

A. The licensee or registrant may not permit any individual to act as a radiographer or radiographer assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter or an electronic personal dosimeter, an operating alarm ratemeter, and an individual monitoring device that meets the requirements of Part D.1501. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to 2 millisieverts (200 milliroentgens) and must be recharged at the start of each work shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(2) Each approved individual monitoring device must be assigned to and worn by only one individual.

(3) Individual monitoring devices must be replaced at least monthly. After replacement, each individual monitoring device must be returned to the supplier for processing as soon as possible or within 14 calendar days of the exchange date specified by the personnel monitoring supplier or as soon as practicable. In circumstances that make it impossible to return each individual monitoring

device within 14 calendar days, such circumstances must be documented and available for review by the Agency. If an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged shall be included in the records maintained in accordance with Subpart E of this Part.

B. Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each work shift (or day), and the accumulated doses for that day determined and recorded. The records must be maintained in accordance with Subpart E.

C. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with Subpart E. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

D. If an individual's pocket dosimeter is found to be off scale, or if an individual's electronic personal dosimeter reads greater than 2 millisieverts (200 milliroentgens), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personal monitoring device must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with Subpart E.

E. If an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged must be included in the records maintained in accordance with Subpart E.

F. Reports received from the individual monitoring device processor must be retained in accordance with Subpart E.

G. Each alarm ratemeter must:

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each work shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr) or lower; with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee or registrant shall maintain records of alarm ratemeter calibrations in accordance with Subpart E.

19. Radiation surveys.

The licensee shall:

A. Not conduct a radiographic operation unless calibrated and operable radiation survey instrumentation as described in E.8 is available and used at each site where radiographic exposures are made.

B. Use a survey instrument that meet the requirements of E.8.A.-C. of this Part, to conduct a physical survey of the entire circumference of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

C. Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in E.3) to ensure that the sealed source is in its shielded position.

D. Post potential radiation areas where industrial radiographic operations are to be performed in accordance with E.22, based on estimated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that E.22 requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in Part D.

E. Meet the requirements of paragraph D of this section, each time re-establishment of the restricted area is required. The requirements of E.19.E 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. Perform a lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed.

G. Perform surveys on storage containers to ensure that the source is shielded and the radiation levels do not exceed the limits specified in Part D. 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.

H. Perform a survey meeting the requirements of E.19.B, on the radiographic exposure device and the source changer after every sealed source exchange.

I. Maintain records of the surveys required by E.19 in accordance with Subpart E.

20. Requirements for underwater, offshore platform, and lay-barge radiography

A. Underwater, offshore platform, and/or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the Agency in accordance with E.4 of this Part.

B. In addition to the other requirements of this section, the following requirements apply to the performance of offshore platform or lay-barge radiography.

(1) Cobalt-60 sources with activities in excess of 20 curies (740 GBq)(nominal) and iridium-192 sources with activities in excess of 100 curies (3.7 TBq)(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 offshore platforms or lay-barges.

21. Surveillance.

A. During each radiographic operation the radiographic personnel, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part A.2.A, except at permanent radiographic installations where all entryways are locked and the requirements of E.12 are met.

B. Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal or tampering.

22. Posting.

A. All areas in which industrial radiography is being performed must be conspicuously posted as required by D.28. Exceptions listed in D.29 do not apply to industrial radiographic operations.

B. Whenever practicable, ropes and/or barriers shall be used in addition to appropriate signs to designate areas in accordance with Part D.28 and to help prevent unauthorized entry.

C. During pipeline industrial radiographic operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the area in accordance with Part D.28.

D. In lieu of the requirements of E.22.A, a restricted area may be established in accordance with Part D and be posted in accordance with E.22.A, for example, both signs may be posted at the same location at the boundary of the restricted area.

23. Reciprocity.

A. All reciprocal recognition of licenses or certificates of registration by the Agency will be granted in accordance with Parts C & E of this rule.

B. Reciprocal recognition by the Agency of an individual radiographer certification will be granted provided that:

(1) The individual holds a valid certification in the appropriate category and class issued by a certifying entity, as defined in this Part;

(2) The requirements and procedures of the certifying entity issuing the certification afford the same or comparable certification standards as those afforded by this Part; and

(3) The individual submits a legible copy of the certification to the Agency prior to entry into Maine.

C. Enforcement actions with the Agency, another agreement state, or the NRC or sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

D. Certified radiographers who are granted reciprocity by the Agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of this Part.

24. Radiation safety requirements for the use of radiation machines.

A. Locking of radiation machines. The control panel of each radiation machine shall be equipped with a locking device that 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.

B. Permanent storage precautions for the use of radiation machines. Radiation machines shall be secured, while in storage to prevent tampering or removal by unauthorized individuals.

C. Requirements for radiation machines used in industrial radiographic operations.

(1) Equipment used in industrial radiographic operations involving radiation machines manufactured after October 1, 1987, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537-1976, except accelerators used in industrial radiography.

(2) The registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, legible, clearly visible label(s) on both sides of all vehicles used to transport radiation machines for temporary job site use.

D. Operating and internal audit requirements for the use of radiation machines.

(1) Each registrant shall conduct an internal audit program to ensure that the requirements of this Part, the conditions of the certificate of registration, and the registrant's operating and emergency procedures are followed by radiographic personnel.

(2) Each radiographer's and radiographer assistant's performance during an actual radiographic operation shall be audited and documented at intervals not to exceed six months.

(3) If a radiographer or a radiographer assistant has not participated in a radiographic operation during the six months since the last audit, the radiographer or the radiographer assistant shall demonstrate knowledge of the training requirements of this Part by an oral or written and practical examination administered by the registrant before the individual can next participate in a radiographic operation.

(4) The Agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.

(5) In those operations where a single individual serves as both radiographer and RSO and performs all radiography operations, an audit program is not required.

(6) No individual, other than a radiographer or a radiographer assistant, who is under the personal supervision of a radiographer, shall manipulate controls or operate radiation machines used in industrial radiographic operations. Only one radiographer is required to operate radiation machines during industrial radiography.

(7) Radiographic operations shall not be conducted at storage sites unless specifically authorized by the certificate of registration.

(8) Records of audits specified in this subsection shall be made and maintained in accordance with Subpart E.

(9) Records of the annual refresher training required by E.16 shall be made and maintained in accordance with Subpart E.

E. Radiation surveys for the use of radiation machines.

(1) No industrial radiographic operation shall be conducted unless at least one calibrated and operable radiation survey instrument, as described in E.8, is used for each radiation machine energized.

(2) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is off.

(3) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with E.22, based on estimated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that E.22

requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in Part D.

(4) Records of the surveys required by E.24 shall be made and maintained in accordance with Subpart E.

F. Requirements for radiation machines in enclosed radiography.

(1) Systems for enclosed radiography, including shielded-room radiography and cabinet x-ray systems not otherwise exempted, shall comply with all applicable requirements of this section.

(2) Systems for enclosed radiography designed to allow admittance of individuals and systems not otherwise exempted shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of this Part and Part H as applicable.

(3) Certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals, are exempt from the requirements of this section except that:

(a) No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit.

(b) Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed 12 months.

(c) The registrant shall perform an evaluation to determine compliance with Parts E and H (as applicable) and 21 CFR 1020.40 at intervals not to exceed one year.

(4) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 and no modification shall be made to the system unless prior Agency approval has been granted.

(5) Records required by this subsection shall be made and maintained in accordance with Subpart E.

G. Registration requirements for industrial radiographic operations.

(1) Radiation machines used in industrial radiographic operations shall be registered in accordance with Parts F and/or H, as applicable.

(2) In addition to the registration requirements in Parts F and/or H, an application for a certificate of registration shall include the following information:

(a) A schedule or description of the program for training radiographic personnel that specifies:

(i) Initial training;

(ii) Annual refresher training;

(iii) On-the-job training;

(iv) Procedures for administering the oral and written examination to determine the knowledge, understanding, and ability of radiographic personnel to comply with the requirements of this Part, the conditions of the certificate of registration, and the registrant's operating and emergency procedures; and

(v) Procedures for administering the practical examination to demonstrate competence in the use of sources of radiation, and radiation survey instruments that may be employed in industrial radiographic assignments.

(b) Written operating and emergency procedures, including all items listed in E.17;

(c) A description of the internal audit program to ensure that radiographic personnel follow the requirements of this Part, the conditions of the certificate of registration, and the registrant's operating and emergency procedures at intervals not to exceed six months;

(d) A list of permanent radiographic installations, descriptions of permanent storage use sites, and the location(s) where all records required by this Part will be maintained. Radiographic equipment shall not be stored or used at a permanent site unless such site is specifically authorized by the certificate of registration. A storage site is permanent if radiation machines are stored at that location and if one or more of the following applies:

(i) The registrant establishes telephone service that is used for contracting or providing industrial radiographic services for the registrant;

(ii) Industrial radiographic services are advertised for or from the site;

(iii) Radiation machines stored at that location are used for industrial radiographic operations conducted at other sites; or

(iv) Any registrant conducting radiographic operations or storing radiation machines at any location not listed on the certificate of registration for a period in excess of 90 days in a calendar year shall notify the Agency prior to exceeding the 90 days.

(v) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program; and

(vi) Procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(3) A certificate of registration will be issued if the requirements of this subsection and all applicable sections of Parts F and/or H are met

25. Reserved

SUBPART E - RECORD KEEPING REQUIREMENTS

26. Records of the specific license for industrial radiography. Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license.

27. Records of receipt, transfer, and disposal of sealed sources

A. Each licensee and registrant shall maintain records showing the receipts, transfers, and disposal of sources of radiation and devices using DU for shielding and retain each record for three years after it is made.

B. The records must include the date of receipt, transfer, or disposal, 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.

28. Records of radiation survey instruments. Each licensee and registrant shall maintain records of the calibrations of its radiation survey instruments that are required under E.8 and retain each record for three years after the calibration date.

29. Records of leak testing of sealed sources and devices containing depleted uranium. Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU the results must be stated in units of becquerels (microcuries). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

30. Records of quarterly inventory.

A. Each licensee and registrant shall maintain records of the quarterly inventory of sources of radiation and devices containing depleted uranium required by E.10 and retain each record for three years after the date of the inventory.

B. The record must include the date of the inventory, name of the individual making the inventory record, radionuclide, number of becquerels (curies) or mass (for DU) in each in device, location of source of radiation, and manufacturer, model and serial number of each source of radiation, as appropriate.

31. Utilization logs.

A. Each licensee and registrant shall maintain logs showing for each sealed source the following information:

(1) A description, including the make, model and serial number, of the radiographic exposure device, radiation machine, or transport and storage container in which the sealed source is located.

(2) The identity and signature of the radiographer to whom assigned; and

(3) The location(s) where used and date(s) of use, including the date(s) removed and returned to storage.

B. Utilization logs shall be kept on clear, legible records containing all the information required by paragraph A above.

C. Records of utilization logs shall be made and maintained for three years after the utilization log is made.

32. Records of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

A. Each licensee and registrant shall maintain records specified in E.11 of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, survey instruments, and radiation machines; 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 or maintenance, if any, was done.

33. Records of alarm system and entrance control tests at permanent radiographic installations. Each licensee and registrant shall maintain records of alarm system and entrance control device tests required under E.12 and retain each record for three years after it is made.

34. Records of training and certification. Each licensee and registrant shall maintain the following records (training and certification) for three years after the record is made:

A. Records of training of each radiographer, and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, as required in E.16.D and names of individuals conducting and receiving the oral and practical examinations. A copy of the radiographer assistant status card will satisfy the documentation requirements of E.16.A and a certification ID card will satisfy the documentation requirements of E.16.B; and

B. Records of annual refresher safety training and semiannual inspections audits 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 audits of job performance, the records must also include a list showing the items checked and any non-compliances observed by the RSO.

35. Copies of operating procedures, emergency procedures, and internal audit requirements.

A. Each licensee and registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license or certificate of registration. Superseded material must be retained for three years after the change is made.

B. Records of the internal audit requirements for the use of radiation machines and the use of sealed sources shall be retained for three years from the date of the audit.

36. Records of personnel monitoring procedures. Each licensee and registrant shall maintain the following exposure records specified in E.19:

A. Direct reading dosimeter or electronic personal dosimeter readings and yearly operability checks for three years after the record is made.

B. Records of alarm ratemeter calibrations for three years after the record is made.

C. Reports received from the individual monitoring device processor until the Agency terminates the license or certificate of registration.

D. Records of estimates of exposure as a result of off-scale personal direct reading dosimeters, or lost or damaged individual monitoring devices, until the Agency terminates the license or certificate of registration.

37. Records of radiation surveys. Each licensee and registrant shall maintain a record of surveys required in E.19 and E.25.E for three years after it is made.

38. Form of records. Each record required by this Part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microfilm provided that the copy or microfilm is authenticated by the authorized personnel and that the microfilm is capable of reproducing a clear copy throughout the required 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.

39. Location of documents and records.

A. Each licensee and registrant shall maintain copies of records required by this Part and other applicable Parts of this rule.

B. Each licensee and registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station;

(1) The license or certificate of registration authorizing the use of sources of radiation;

(2) A copy of Parts D, E, and J of the Agency regulations;

(3) Utilization records for each radiographic exposure device or radiation machine dispatched from that location.

(4) Records of equipment problems identified in daily checks of equipment,

(5) Records of alarm system and entrance control checks, if applicable;

(6) Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeter readings, if applicable;

(7) Operating and emergency procedures;

(8) Evidence of the latest calibration of the radiation survey instruments in use at the site;

(9) Evidence of the latest calibrations of alarm rate meters and operability checks of pocket dosimeters and/or electronic personal dosimeters;

(10) Latest radiation survey records;

(11) The shipping papers for the transportation of radioactive materials; and

(12) When operating under reciprocity; a copy of the NRC or Agreement State License or certificate of registration authorizing the use of sources of radiation.

SUBPART F – NOTIFICATIONS

40. Notifications.

A. In addition to the reporting requirements specified under other sections of this Part and other applicable Parts of this rule, each licensee shall provide a written report to the Agency; Radiation Control Program, Maine Center for Disease Control and Prevention, Department of Health and Human Services, 11 State House Station, Augusta, Maine 04333-0011, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable;

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position;

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function;

(4) An indicator on a radiation machine fails to show that radiation is being produced;

(5) An exposure switch on a radiation machine fails to terminate production of radiation when turned to the off position; or

(6) A safety interlock fails to terminate x-ray production.

B. The licensee or registrant shall include the following information in each report submitted under paragraph E.40.A:

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Manufacturer and model and serial number of equipment involved in the incident;

(4) Place, 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.

C. Reports of overexposures submitted under Part D that involve failure of safety components of radiography equipment must also include the information specified in E.40.B.

41. Records required at temporary job sites. Each licensee or registrant conducting industrial radiography at a temporary site shall have the following records available at that site for inspection by the Agency:

A. Appropriate license or certificate of registration authorizing the use of sources of radiation;

B. Operating and emergency procedures;

C. Applicable regulations;

D. Survey records required pursuant to E.19, E.20, and/or E.24.E for the period of operation at the site;

E. Daily pocket dosimeter records for the period of operation at the site;

F. The utilization records for each radiographic exposure device and/or radiation machine dispatched from that location in accordance with this Part; and

G. The latest instrument calibration and leak test record for specific devices in use at the site. Acceptable records include tags or labels that are affixed to the device or survey meter.

42. Specific requirements for radiographic personnel performing industrial radiography.

A. At a job site, the following shall be supplied by the licensee or registrant:

(1) At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

(2) An individual monitoring device for each individual;

(3) An operable, calibrated pocket dosimeter or electronic personal dosimeter with a range of zero to 200 milliroentgens (2 mSv) for each worker;

(4) An operable, calibrated alarm ratemeter for each worker as specified in E.18; and

(5) The appropriate barrier ropes and signs.

B. Each radiographer at a job site shall carry a valid certification ID card issued by the Agency or another certifying entity whose certification offers the same or comparable certification standards.

C. Each radiographer assistant at a job site shall carry a radiographer assistant status card issued by the Agency or equivalent documentation in accordance with E.16.A.

D. Radiographic personnel shall not perform radiographic operations if any of the items in E.42.A-C are not available at the job site or are inoperable. Radiographic personnel shall ensure that the items listed in E.42.A, radiographic exposure devices, and radiation machines are used in accordance with the requirements of this Part.

E. Each licensee or registrant shall provide as a minimum two-person crews when sources of radiation are used at temporary job sites.

F. No individual other than a radiographer or a radiographer assistant who is under the personal supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

G. During an inspection by the Agency, the Agency inspector may terminate an operation if any of the items in E.42.A-C are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.

43. Special requirements and exemptions for radiation machines in enclosed radiography.

A. Systems for enclosed radiography, including shielded-room radiography and cabinet x-ray systems not otherwise exempted, designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this Part and D.1201 of this rule. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this Part, Part H and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in E.24. Records of these evaluations shall

be maintained for inspection by the Agency for a period of two years after the evaluation.

B. Certified and uncertified cabinet x-ray systems designed to exclude individuals are exempt from the requirements of this Part except that:

(1) Operating personnel must be provided with an individual monitoring device and reports of the results must be maintained for inspection by the Agency.

(2) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records, which demonstrate compliance with this section shall be maintained for inspection by the Agency until disposition is authorized by the Agency.

(3) Tests for proper operation of high radiation area control devices, interlocks, or alarm systems, where applicable, must be conducted and recorded in accordance with E.25.

(4) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with D.1201 of this rule. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Agency for a period of two years after the evaluation.

C. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Agency pursuant to A.3(a) of this rule.

44. Prohibitions.

A. Industrial radiography performed with a sealed source that is not fastened to or contained in a radiographic exposure device (fish pole 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.

45. Periodic survey.

A. Industrial radiography operations using radioactive materials shall be inspected at least annually.

B. Industrial radiography operations using x-ray shall be inspected prior to January 1, 1987, and once every two years thereafter.

C. Upon notification or discovery of a violation to the rules stated in this section, the Department may, in its notice of violation to the licensee, require a re-inspection, by a Qualified Expert or Qualified Individual pursuant to the requirements in Part H. This increase in frequency of inspection will depend upon the severity of the violation.

46. Radiographer examination and certification.

A. Application and fee for radiographer certification examinations.

(1) Application.

(a) An application for taking the examination shall be on forms prescribed and furnished by the Agency.

(b) The non-refundable application fee for examination shall be determined by the Agency.

(c) The appropriate fee shall be submitted with the application for examination when filing with the Agency.

(d) The application and any non-refundable fee, shall be submitted to the Agency on or before the dates specified by the Agency.

(2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

(a) The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the Agency. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of this rule, Parts A, B, C, D, E, F, H, J, L.

(b) The examination will be administered by the Agency or persons authorized by the Agency.

(c) A candidate failing an examination may apply for re-examination in accordance with E.46.A. and will be re-examined. A candidate shall not retake the same version of the Agency-administered examination.

(d) The examination shall be offered at various times throughout the year. Times, dates, and locations of the examination will be furnished by the Agency.

(e) The examination will be in the English language.

(f) To take the examination, an individual shall present a photo identification card, such as a driver's license, at the time of the examination.

(g) Calculators will be permitted during the examination. However, calculators or computers with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.

(h) The examination will be a closed-book examination.

(i) Any individual observed by an Agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and all scratch paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual must wait 90 days before taking a new examination and must resubmit a new application and a non-refundable examination fee, as determined by the Agency.

(j) Examination material shall be returned to the Agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited.

(k) The names and scores of individuals taking the examination shall be a public record.

B. Radiographer certification.

(1) An application for radiographer certification shall be on a form provided by the Agency.

(2) A certification ID card shall be issued to each individual who successfully completes the requirements of this Part.

(a) Each individual's certification ID card shall contain the individual's photograph. The Agency will take the photograph at the time the examination is administered.

(b) The certification ID card remains the property of the Agency and may be revoked or suspended under the provisions of paragraph (4) of this subsection.

(c) Any individual who needs to replace a certification ID card shall submit to the Agency a written request for a replacement certification ID card, stating the reason a replacement certification ID card is needed. A non-refundable fee determined by the Agency shall be paid to the Agency for each replacement of a certification ID card. The prescribed fee shall be submitted with the written request for a replacement certification ID card. The individual shall carry a copy of the request while performing industrial radiographic operations until a replacement certification ID card is received from the Agency.

(d) Each certification ID card is valid for a period of five years and is the property of the State, unless revoked or suspended in accordance with paragraph (4) of this section. Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card.

(3) Renewal of a radiographer certification.

(a) Applications for examination to renew a radiographer certification shall be filed in accordance with (1) of this section.

(b) The examination for renewal of a radiographer certification shall be administered in accordance with (2) of this section.

(c) A renewal certification ID card shall be issued in accordance with (2) of this section.

(4) Suspension or revocation of a radiographer certification.

(a) Any radiographer who violates the requirements of this Part, or provides any material false statement in the application or any statement of fact required in accordance with this Part, may be required to show cause at a formal hearing why the radiographer certification should not be suspended or revoked in accordance with Part B.

(b) When an Agency order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the Agency suspends or revokes the individual's radiographer certification, the radiographer shall surrender the certification ID card to the Agency until the order is changed or the suspension expires.

(c) An individual whose radiographer certification has been suspended or revoked by the Agency or another certifying entity shall obtain written approval from the Agency to apply to take the examination.

APPENDIX A.

SUBJECTS TO BE COVERED DURING THE INSTRUCTION OF RADIOGRAPHER ASSISTANTS

I. Fundamentals of radiation safety

A. Characteristics of radiation

B. Units of radiation dose in rems (sieverts) and quantity of radioactivity in curies (becquerels).

C. Significance of radiation dose

1. Radiation protection standards;

2. Biological effects of radiation;

3. Hazards of exposure to radiation; and

4. Case histories of radiography accidents.

D. Levels of radiation from sources of radiation; and

E. Methods of controlling radiation dose:

1. Working time;

2. Working distances; and

3. Shielding.

II. Radiation detection instrumentation to include the following:

A. Use of radiation survey instruments:

1. Operation;

2. Calibration

3. Limitations

B. Survey techniques; and

C. Use of individual monitoring devices to include as a minimum:

1. Film badges

2. Thermoluminescent dosimeters;

3. Optically stimulated luminescence monitors, OSL's;

4. Pocket dosimeters;

5. Alarming rate meters; and

6. Electronic personal dosimeters.

III. Radiographic equipment to be used

A. Remote handling equipment;

B. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (also known as pigtails);

C. Storage and transport containers, source changers;

D. Operation and control of x-ray equipment;

E. Collimators;

F. Storage, control, and disposal of radioactive materials; and

G. Inspection and maintenance of equipment.

IV. The requirements of pertinent federal and State regulations

V. The licensee's or registrant's written operating and emergency procedures

APPENDIX B.

Items to be Covered the Inspection of Radiographic Equipment

I. Radiographic exposure devices shall be inspected for:

A. Abnormal surface radiation levels anywhere on camera, collimator, or guide tube;

B. Condition of safety plugs;

C. Proper operation of locking mechanism;

D. Condition of the pigtail connector;

E. Condition of the carrying device (straps, handle, etc.); and

F. Proper handling and legible labeling.

II. Guide tubes shall be inspected for:

A. Rust, dirt, or sludge buildup inside the guide tube;

B. Condition of the guide tube connector;

C. Condition of the source stop;

D. Kinks or damage that could prevent proper operation; and

E. Presence of radioactive contamination.

III. Control cables and control drive mechanisms shall be inspected for:

A. Proper control drive mechanism with camera, as appropriate;

B. Changes in general operating characteristics;

C. Condition of connector on drive cable;

D. Drive cable flexibility, wear, and rust;

E. Excessive wear or damage to control drive mechanism parts;

F. Damage to drive cable conduit that could prevent the cable from moving freely;

G. Proper connector mating between the drive cable and the pigtail;

H. Proper operation of source position indicator, if applicable; and

I. Presence of radioactive contamination.

IV. Pipeliners shall be inspected for:

A. Abnormal surface radiation;

B. Changes in the general operating characteristics of the unit;

C. Proper operation of shutter mechanism;

D. Chafing or binding of shutter mechanism;

E. Damage to the device that might impair its operation;

F. Proper operation of locking mechanism;

G. Proper drive mechanism with camera, as appropriate;

H. Condition of carrying device (strap, handle, etc.); and

I. Proper and legible labeling.

V. X-ray equipment shall be inspected for:

A. Change in the general operating characteristics of the unit;

B. Wear of electrical cables and connectors;

C. Proper and legible labeling of console;

D. Proper console with machine, as appropriate;

E. Proper operation of locking mechanism;

F. Proper operation of timer run-down cutoff; and

G. Damage to tube head housing that might result in excessive radiation levels.

APPENDIX C.

Items to be Included in Operating and Emergency Procedures:

A. Handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in Part D;

B. Methods and occasions for conducting radiation surveys, including lock-out survey requirements;

C. Methods for controlling access to industrial radiography areas;

D. Methods and occasions for locking and securing sources of radiation;

E. Personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off scale (see E.18);

F. Methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation (including applicable DOT requirements);

G. Methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;

H. Procedures for notifying proper personnel in the event of an accident;

I. Specific posting requirements;

J. Maintenance of records (see Subpart E);

K. Inspection, maintenance, and operational checks of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines;

L. Method of testing and training in accordance with sections E.16 and E.33;

M. Source recovery procedures if the licensee is authorized to perform source recovery; and

N. The procedure(s) for identifying and reporting defects and noncompliance, as required by E.27 and 10 CFR Part 21, if applicable.

PART F.

X-RAYS IN THE HEALING ARTS

1. **Scope.** This Part provides for the registration of radiation machine facilities, and establishes requirements for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of this rule.

2. **Definitions.** As used in this part, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Added filtration means any filtration that is in addition to the inherent filtration.

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

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

Attenuation block means a block or stack having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

Automatic exposure control means a device that 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 photo timers and ion chambers).

Barrier (See Protective barrier.)

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Beam monitoring system means a system designed to detect and measure the radiation present in the useful beam.

C-arm x-ray system means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

This definition does not refer to a conventional fluoroscopic system or to a dental cephalametric x-ray machine.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components mean components of x-ray systems, which components are subject to the X-ray Equipment Performance Standards promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

Certified system means any x-ray system that has one or more certified component(s).

Changeable filters means any filter, exclusive of inherent filtration, which filter 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:

$$C = \frac{\sigma}{\varpi} = \frac{1}{\varpi}\left[\sum_{l=1}^{n} \frac{(\omega_l - \varpi)^2}{\eta - 1}\right]^{1/2}$$

where
σ = Estimated standard deviation of the population.
ϖ = Mean value of observations in sample.
ω_l = with observation in sample.
η = 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 5 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.

Cooling curve means the graphical relationship between heat units stored and cooling time.

CT (see Computed tomography.)

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.

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray imaging system means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage, and visual display of the resultant x-ray image.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

Direct scattered radiation means that scattered radiation, which has been deviated in direction only by materials, irradiated by the useful beam (See Scattered radiation.)

Direct supervision means that during use of the radiation producing sources and devices, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is using the radiation producing sources and devices.

Entrance exposure rate means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

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 imaging assembly means a subsystem in which x-ray photons produce a fluoroscopic image. 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.

Focal spot (actual) means the area projected on the anode of the x-ray tube bombarded 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.

Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form, which can be made into a visible image by further transformations.

Image receptor support means, for mammographic systems, that part of the system designed to support the image receptor during a mammography.

Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Irradiation means the exposure of matter to ionizing radiation.

Kilovolts peak (See .Peak tube potential.)

kV means kilovolts. kVp (See Peak tube potential.)

kWs means kilowatt second.

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

(a) The useful beam, and

(b) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the diagnostic or therapeutic assembly which are used in measuring leakage radiation.

They are defined as follows:

(a) 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 being10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(b) 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.

(c) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

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 (Vn-V1)/V1 where:
Vn = No-load line potential and
V1 = Load line potential.

mA means milliampere.

mAs means milliampere second.

Mammographic facility means a facility that has an x-ray machine that is used, exclusively or not, for taking breast radiographs. Some facilities, such as hospitals, may have mammographic x-ray machines. These x-ray machines shall comply with the requirements, which apply to mammographic facilities.

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.)

Mobile van means an x-ray facility housed within a vehicle, which facility is moved, or capable of being moved to different locations for the purpose of performing x-ray examinations.

PBL (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.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Phototimer means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit, which controls the duration of time the tube is activated (See "Automatic exposure control").

PID (See position indicating device.)

Portable C-arm x-ray system means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship.

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 (skew) distance. It may or may not incorporate or serve as a beam-limiting device.

Primary dose monitoring system means a system that will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier (See Protective barrier.)

Protective apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(a) Primary protective barrier means the material, excluding filters, placed in the useful beam.

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

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Quality assurance program (QA) means a program, including quality control, which program extends to administrative, educational, and preventive maintenance methods. For purposes of these rules, a QA program is directed at radiographic facilities and includes a continuing evaluation of the adequacy and effectiveness of the overall imaging program.

Quality control (QC) means a series of distinct technical procedures with the aim to provide high quality images while emitting as low a dose as necessary. QC includes, but is not limited to, the frequent evaluations of film processing, cassettes and intensifying screens, the film and the x-ray equipment.

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.

Radiographic imaging system means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a permanent form of an image resulting from x-ray photons.

Response time means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See direct scattered radiation).

Secondary dose monitoring system means a system that 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 intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID (See "Source-image receptor distance").

Source means the focal spot of the x-ray tube.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Spot check means a procedure that is performed to assure that a previous calibration, continues to be valid.

Spot film means a radiograph that is made during a fluoroscopic examination to permanently record conditions, which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD means the distance between the source and the skin entrance plane of the patient.

Stationary x-ray equipment (See "x-ray equipment.)

Stray radiation means the sum of leakage and scattered radiation.

Technique factors means the conditions of operation. They are specified as follows:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and

(c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, on 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.

Traceable to a national standard means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Variable-aperture beam-limiting device means a beam-limiting device, which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Wedge filter means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray 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 equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device that 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 tube means any electron tube that is designed to be used primarily for the production of x-rays.

3. 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 F.3.A.(1) are met in the operation of the x-ray system(s).

(a) Any x-ray system (whether certified or non-certified) which does not meet the provisions of this rule shall not be operated for diagnostic or therapeutic purposes unless a written exception is received from the Agency. See Section F.3.D.

(b) Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. The licensing requirements pursuant to 32 MRSA Chapters 103 § 9851 et seq and 331 § 1100 I et seq as well as the associated rules established by the Radiologic Technology Board of Examiners and the Board of Dental Examiners shall be followed.

(c) Except for intraoral and extraoral dental radiography, a chart shall be provided in the vicinity of the diagnostic x-ray system's control panel. If the posting in the vicinity of the control panel is not practical, it shall be conspicuously available to users of the equipment. The following information shall be specified on the chart:

(i) patient's anatomical size versus technique factors to be utilized,

(ii) type and size of the film or film-screen combination to be used,

(iii) type and focal distance of the grid to be used, if any,

(iv) source to image receptor distance to be used; and

(d) Written safety procedures and rules shall be posted in the vicinity of each x-ray control panel, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures. Copies of certificates of those individuals duly authorized to perform such x-rays shall be conspicuously posted.

(e) Except for human patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(i) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material.

(ii) 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.

(iii) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(f) Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(g) Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(i) Exposure of an individual for training, demonstration or other non-healing-arts purposes; and

(ii) Exposure of an individual for the purpose of healing arts screening except as authorized by F.3.A.(1)(k).

(h) When a patient or film must be provided with auxiliary support during a radiation exposure:

(i) Mechanical holding devices shall be used when the technique permits;

(ii) Written safety procedures, as required by F.3.A.(1)(d), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(iii) The human holder shall be instructed in personal radiation safety and be protected as required by paragraph F.3.A.(1)(e).

(iv) No individual shall be used routinely to hold film or patients; and

(v) In those cases where the patient must hold the film, except during intraoral or extraoral dental 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

(vi) 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.

(i) The screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Cassettes without intensifying screens shall not be used for any diagnostic radiological imaging, with the exception of standard film packets for intra-oral use in dental radiography.

(ii) Portable or mobile equipment shall only be used in cases where it is impractical to transfer the patient(s) to a stationary x-ray unit. Portable equipment is not to be used as a substitute for a stationary unit.

(iii) Film processing is to be conducted in accordance with the manufacturer's instructions.

(j) All individuals who are associated with the operation of an x-ray system are subject to the requirements of D.6, D.10 and D.18 of this rule. In addition:

(i) When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(ii) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

(iii) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by D.46 of this rule. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

(iv) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(k) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

(2) Information and maintenance record and associated information. The registrant shall maintain the following information for each x-ray system or, as appropriate, facility, for inspection by the Agency:

(a) Model and serial numbers of all certifiable components, if readily available;

(b) Aluminum equivalent filtration of the useful beam, including any routine variation;

(c) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of this rule with the names of persons who performed such services;

(d) For all facilities constructed or modified after January 1, 1986, a scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room, an estimation of the extent of occupancy by an individual in such areas, and the location of the x-ray machine. In addition, the drawing shall include:

(i) 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

(ii) The type and thickness of materials, or lead equivalency, of each protective barrier; and

(e) A copy of all correspondence with this Agency regarding that x-ray system.

(f) A copy of the facility's x-ray quality assurance program. (See Section F.5.I.)

(3) X-ray patient record. Each facility shall have available for inspection a record (either paper or electronic) or other such document identifying the patient by number or name, the type of examination, the date, the room where the examination was performed, and who performed the x-ray.

B. Shielding requirements and plan review.

(1) Prior to initial operation, 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 Agency. The required information is denoted in Appendices A and B of this part.

(2) The applicant shall utilize the services of a Radiological Physicist to determine the shielding requirements prior to plan review and approval by the Department. In determining the shielding requirements for dental x-ray facilities, the Department may authorize other professionals, providing their qualifications justify such an authorization.

(3) The submittal 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 D.6, D.12 and D.14 of this rule.

C. Initial and Periodic Survey.

(1) Pursuant to 22 MRS §682, duly authorized employees of the Department may enter into establishments during working hours to determine whether there is compliance with provisions of the Radiation Protection Act.

(2) Departmental Certification of Technicians, as authorized by 22 MRS § 682(3), designated as qualified experts, and authorized by the Department shall be utilized to perform inspection and calibration services, and to certify x-ray and/or teletherapy units (see section G.4.D and G.4.E).

(3) Existing facilities: Except as stated in section F.3.C.45, the licensee of all existing x-ray facilities shall have each x-ray machine and tube inspected at the following minimum frequency:

(a) Hospitals - prior to January 1, 1987 and once every year thereafter;

(b) Mammographic Facilities - prior to January 1, 1991, and every year thereafter;

(c) Dental Facilities - prior to January 1, 1988 and once every three years thereafter;

(d) Podiatric - prior to January 1, 1987 and once every three years thereafter;

(e) Veterinary - prior to January 1, 1987 and once every five years thereafter;

(f) All Others - prior to January 1, 1987 and once every two years thereafter.

(4) The periodic quality control survey, conducted at the above stated frequencies, is not covered by the annual registration fee but is in addition to that fee. When the inspections are carried out by third-party, non-state technicians, the fee is determined by the inspector and the facility.

(5) Except for intra-oral, panorex, mammographic and podiatric x-ray machines, all new facilities and existing facilities adding new machines shall have a survey made by a qualified expert within 30 days. The intra-oral, panorex and podiatric machines shall be inspected within 12 months. Mammographic facilities shall be inspected by a qualified expert prior to operation. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. See F.4.

(6) The registrant shall obtain a written report of the survey from the Qualified Expert and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.

(7) Upon notification or discovery of a violation to the Rules stated in this section, the Department may, in its notice of violation to the licensee, require a re-inspection by a qualified expert. This increase in frequency of inspection will depend upon the severity of the violation.

D. Exemptions.

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

(2) Radiation machines while in transit or storage incident thereto are exempt from the requirements of Part F.

(3) Domestic television receivers are exempt from the requirements of this part.

(4) Exemptions to the requirements of Part F may be granted, provided written justification is submitted by a qualified expert.

E. Applications for registration of radiation machine facilities.

(1) Each person having a radiation machine facility shall apply for registration of such facility with the Agency following the effective date of this rule or thereafter prior to the operation of a radiation machine facility. Application for registration shall be completed on form HHE 805 X-Ray Registration Form furnished by the Agency and shall contain all the information required by the form and accompanying instructions. At a minimum, the form shall include the following information.

(a) Name, address, and telephone number of the following:

(i) The radiation machine facility.

(ii) The owner of the radiation machine facility.

(iii) The individual responsible for the use of the facility.

(iv) The individual responsible for radiation protection at the facility.

(b) The manufacturer, model number, and type of each radiation machine located within the facility.

(c) The signature of the individual designated as the qualified expert.

(d) Name of the radiation machine supplier, installer, and service agent.

(e) The date of application and signature of the individual responsible for the use of the facility.

(2) Registration Fee.

(a) A registration fee for each x-ray tube shall be paid annually. Appendix F to this Part provides the schedule of fees.

(b) Submit a check payable to the Treasurer State of Maine, along with the application for annual registration for the appropriate amount specified.

(3) The licensee of all x-ray facilities shall have each x-ray machine and tube inspected in accordance with the requirements of Section F.3.C.

F. Application for Registration of Servicing and Services

(1) Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration of such services with the Agency within 30 days following the effective date of this regulation or thereafter prior to furnishing or offering to furnish any such services.

(2) Application for registration shall be completed on form HHE 825 Registration of Servicing and/or Services Employee Exposure Form furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions. No fee is required.

(3) Certification and registration of qualified experts for the conducting of the periodic survey is covered in Part F.4.

(4) The service representative shall notify the agency in writing of any address, telephone or personnel changes.

G. Issuance of notice of registration.

(1) Upon a determination that the requirements of Part F.3.E have been met, the Agency shall issue a notice of registration.

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

H. Expiration of notice of registration. Except as provided by F.3.I each notice of registration shall expire at the end of the specified day in the month and year stated therein, or upon notice issued to the registrant by the Agency.

I. Renewal of notice of registration.

(1) Application for renewal of registration shall be filed annually and in accordance with Part F.3.E.(2). Application for renewal of registration and notification of current expiration date will be provided to each licensee by the Agency at least 60 days prior to the expiration date.

(2) In any case in which a registrant not fewer than 30 days prior to the expiration of his or her 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.

J. Report of changes. The registrant shall notify the Agency in writing before making any changes which would render the information contained in the application for registration and/or the notice of registration no longer accurate.

K. Approval not implied. No person, in any advertisement, shall refer to the fact that his or her facility is registered with the Agency pursuant to these provisions, and no person shall state or imply that any activity under such registration has been approved by the Agency.

L. Assembler and/or transfer obligation.

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

(a) The name and address of persons who have received these machines;

(b) The manufacturer, model, and serial number of each radiation machine transferred; and

(c) The date of transfer of each radiation machine.

(d) In the case of diagnostic x-ray systems 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 report by the assembler.

(2) 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, meet the requirements of this rule.

M. Out-of-state radiation machines.

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

(a) The type of radiation machine;

(b) The nature, duration, and scope of use;

(c) The exact location(s) where the radiation machine is to be used; and

(d) The states in which this machine is registered.

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

(3) The person referred to in F.3.M.(1) shall:

(a) Comply with all applicable regulations of the Agency, to include the necessary inspection and registration fees;

(b) Supply the Agency with such other information as the Agency may reasonably request; and

(c) Not operate within the State on a temporary basis in excess of 90 calendar days per year.

4. Certification of qualified experts. The Department shall certify qualified experts for the purpose of inspecting, and certifying x-ray equipment to establish compliance with this rule. The Department may grant, modify or refuse to issue a certification in accordance with the Maine Administrative Procedure Act, Title 5, Chapter 375, Subchapter V.

A. Radiological physicist certification

(1) The radiological physicist, except as provided for in section F.3.C.(4), shall be responsible for the preparation and issuance of all inspection reports, and shall be accountable for all information, findings and recommendations contained therein.

(2) Certification shall be in the diagnostic x-ray and/or the therapy area. To be eligible to apply for certification as a radiological physicist an individual shall, in addition to satisfying the training and experience requirements of Part A of this rule:

(a) Not be currently employed by any company offering sales or service of x-ray equipment; and

(b) Be certified by the American Board of Radiology in diagnostic radiologic physics; or

(c) Be certified by the American Board of Health Physics and have one year of experience in the area of diagnostic x-ray as outlined in Appendix D; or

(d) Possess a master’s degree in a physical science and have three years’ experience in the area of diagnostic x-ray as outlined in Appendix D.

(3) Individuals meeting the above qualifications may apply to the Department for certification using Agency form HHE 820 Certified technician registration form. The application shall include the following information at a minimum:

(a) Name and address

(b) Telephone number

(c) Detailed description of education

(d) Detailed description of experience

(e) List of measuring and calibration equipment used

(f) Types of services to be provided

(4) Upon receipt and review of an application, the Department may require additional submissions and/or personal interviews with the applicant if deemed necessary to issue a certification.

B. X-ray survey technician certification

(1) The x-ray survey technician shall be responsible for the collection of data used in the preparation of inspection reports and shall collect such data only under the supervision of a radiologic physicist.

(2) To be considered eligible to apply for certification as an x-ray survey technician an individual shall in addition to satisfying the training and experience requirements of Part A of this rule, also not be currently employed by any company offering sales or service of x-ray equipment.

C. Application for Certification.

(1) Individuals meeting the above qualifications may apply to the Department for Certification using Agency form HHE 820 Certified Technician Registration Form. The application shall include the following information at a minimum:

(a) Name and address;

(b) Telephone number;

(c) Detailed description of education, include transcripts;

(d) Detailed description of experience, include resume;

(e) Name of Certified radiologic physicist for whom the technician will be working, if applicable; and

(f) A statement from the Radiologic physicist outlining the types of surveys the applicant is qualified to perform, if applicable.

(2) Upon receipt and review of an application the Department may require additional submission and/or personal interviews with the applicant if deemed necessary to issue a certification.

(3) All certificates issued by the Department shall be valid for a period of five years from the date of issue. Six months prior to expiration, the Department shall review the record of each individual whose certification is due to expire, and upon request of that individual issue a new certificate.

D. Radiation instrument calibrations. Pursuant to Part D.1501, of this rule, all radiation measuring instruments shall be “calibrated” at intervals not to exceed 12 months. Additionally, Mammography Quality Standards Act (MQSA) requirements shall continue to be recognized where applicable.

5. General requirements for all diagnostic x-ray systems. In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

A. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors 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 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 mC/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 2 milliroentgens (0.516 mC/kg) in one hour at 5 centimeters from any accessible surface of the component when it operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

E. Beam Quality.

(1) Half-value layer.

(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 1. If it is necessary to determine such half-value layer at an x-ray tube potential, which is not listed in Table 1, linear interpolation or extrapolation may be made.

TABLE 1

Design operating range (Kilovolts peak)	Minimum HVL (mm of AL) Measured potential (kVp)	Specified dental systems*	All other diagnostic X-ray systems
Below 50---------	30	1.5	0.3
	40	1.5	0.4
	49	1.5	0.5
50 to 70---------	50	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70---------	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

* for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980;

(b) The requirements of F.5.E.1(a) will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 2.

TABLE 2

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5
50 - 70	1.5
Above 70	2.5

(c) The required minimal half value layer of the useful beam shall include the filtration contributed by all materials, which are permanently between the source and the patient.

(2) Filtration controls. For x-ray systems constructed after 1974, 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 necessary to produce the HVL required by F.5.E.(1) is in the useful beam for the given kVp, which has been selected.

F. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes, which have been selected, shall be clearly indicated prior to initiation of the exposure. This indication shall be on the x-ray control panel.

G. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

H. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of F.5.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. Quality assurance program

(1) Each hospital, out-patient clinic, chiropractic, and private medical facility, to include approved screening programs that are performing diagnostic x-rays on humans shall establish an active quality assurance program. The quality assurance program shall incorporate the standards and records indicated in Appendix G, Quality Assurance Requirements for Facilities Performing Diagnostic X-Ray.

(2) The QA program for mammographic facilities shall be inspected by the Department annually. All other, non-dental, radiographic facilities, shall have their QA program inspected by the department prior to the end of the periodic survey time frame.

(3) All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

6. Fluoroscopic x-ray systems.

All fluoroscopic x-ray systems shall be image intensified and meet the following requirements:

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.

(2) Fluoroscopic beam limitation.

(a) Certified fluoroscopic systems, with or without spot film device neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(i) 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 a means for stepless adjustment of the x-ray field;

(ii) 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;

(iii) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or fewer.

(iv) 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

(v) For rectangular x-ray fields used with circular image reception, 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.

(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 fewer than 20 centimeters table top to the film plane distance.

(c) For uncertified fluoroscopic systems without a spot film device, the requirements of F.6.A(2)(a) apply.

(c) Other requirements for fluoroscopic beam limitation:

(e) Spot-film devices, which are certified components, shall meet the following additional requirements:

(i) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film, 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;

(ii) 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;

(iii) The center of the x-ray field in the plane of film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

(iv) 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.

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.

C. Exposure rate limits.

(1) Entrance exposure rate allowable limits

(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 an exposure rate in excess of 2.58 mC/kg (10 Roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(b) During recording of fluoroscopic images, or

(c) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.29 mC/kg (5 Roentgens) per minute (for fluoroscopic equipment manufactured before May 1995) or 5.16 mC/kg (20 Roentgens) per minute (for fluoroscopic equipment manufactured on or after May 1995) at the point where the center of the useful beam enters the patient. 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.

(d) Compliance with the requirements of F.6.C shall be determined as follows:

(i) If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(ii) If the source is above the x-ray table, the exposure rate 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.

(iii) For a C-arm type of fluoroscope, the exposure rate 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.

(iv) For a lateral type fluoroscope, the exposure 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) Periodic measurement of entrance exposure rate shall be performed as follows:

(i) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

(ii) 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 F.3.A(2)(c). The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

(iii) Conditions of periodic measurement of entrance exposure rate are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of F.6.C.1(d);

(b) The kVp and MA shall be typical of clinical use of the x-ray system;

(c) The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system; and

(d) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system.[2]

D. Barrier transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 mC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

(a) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier 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, if practicable, 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 10 centimeters from the point of measurement of entrance exposure rate 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 or mAs shall be continuously indicated.

F. Source-skin distance. The SSD shall not be less than:

(1) 38 centimeters on stationary fluoroscopes installed after the effective date of this rule,

[2] Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

(2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to the effective date of this rule,

(3) 30 centimeters on all mobile fluoroscopes, and

(4) 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

G. Fluoroscopic timer.

(1) 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.

(2) 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.

(3) Fluoroscopic on time shall be recorded.

H. Mobile fluoroscopes. In addition to the other requirements of F.6.F, mobile fluoroscopes shall provide intensified imaging.

I. Control of scattered radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(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 F.3.A.(1)(e)

(3) The Agency may grant exceptions to F.6.I(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 exception.

J. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of F.6.A, F.6.C, F.6.D, and F.6.H 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 F.5.H, 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 times be reset between examinations.

7. Radiographic systems other than fluoroscopic, dental intraoral or veterinarian systems.

A. Beam limitation. The useful beam shall be limited to the area of clinical interest.

(1) General purpose stationary and mobile x-Ray systems.

(a) There shall be provided a means for stepless adjustment of the size of the x-ray field.

(b) For those units so designed, a method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(c) The Agency may grant an exemption on non-certified x-ray systems to F.7.A.(1)(a) and (b) provided the registrant makes a written application for such exemption and in that application:

(i) Demonstrates it is impractical to comply with F.7.A.(1)(a) and (b); and

(ii) The purpose of F.7.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 F.7.A.(1), all stationary general purpose x-ray systems 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 2 percent of the SID, and to indicate the SID to within 2 percent;

(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 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-Ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Mammography equipment standards. Only x-ray systems meeting the following standards shall be used:

(a) System design: The x-ray system shall be specifically designed for mammography.

(b) Image receptor: The image receptor systems and their individual components shall be specifically designed for or appropriate for mammography.

(c) Radiographic systems designed for mammography shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system, which performs as prescribed in F.7.A.(5).

(5) Special purpose x-ray systems.

(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 percent 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 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(c) F.7.A(5)(a) and (b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.7.A(1) or, when alignment means are also provided, may be met with either:

(i) 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

(ii) 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 devices.

(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 time is set to a zero or off position if either position is provided.

(2) Manual Exposure 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:

(i) Exposure of one-half second or less, or

(ii) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(b) Each x-ray control shall be located in such a way as to meet the following requirements:

(i) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(ii) Mobile and portable x-ray systems which are:

(a) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.7.B.(2)(b)(i)

(b) Used for greater than one hour and less than one week at the same location, i.e., one room or suite, shall meet the requirement of F.7.B.(2)(b)(ii)(a) or be provided with a 6.5 feet (1.98m) high protective barrier which is placed

at least 6 (1.83m) feet from the tube housing assembly and at least 6 (1.83m) feet from the patient; or

(c) Used to make an exposure(s) of a patient at the use location shall meet the requirement of F.7.B.(2)(b)(ii)(a) or(b) or be provided with a method or x-ray control which will permit the operator to be at least six feet (3.66m) from the tube housing assembly during an exposure.

(iii) 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, if available with the unit, shall indicate that the exposure has terminated.

(3) Automatic exposure controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) 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;

(c) The minimum exposure time for all equipment other than that specified in F.7.B.(3)(b) shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

(d) 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 in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by F.7.B(3)(d), and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (Tmax) minus the minimum exposure (Tmin) when four timer tests are performed; i.e., $T > 5$ (Tmax -Tmin).

C. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters.

D. Exposure reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have

been met if, when four exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin), i.e., E > 5 (Emax - Emin).

E. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 mC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

F. Additional requirements applicable to certified systems only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum,

$$X1-X2 < 0.10\ (X1 + X2),$$

where X1 and X2 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. In the absence of the manufacturer's specifications the deviation shall not exceed 10% of the indicated value.

(4) Beam limitation for stationary and mobile general purpose x-ray systems.

(a) There shall be provided a means of stepless adjustment of the size of the x-ray field.

(b) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on or after May 27, 1980, are exempt from this requirement.

(c) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I1/I2 when I1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(5) Beam limitation for portable x-ray systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of F.7.A.(1). and F.7.F.(4).

(6) 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):

(a) Positive beam limitation (PBL) when present shall function whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are each less than 50 centimeters;

(iii) The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(vi) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;

(v) Neither tomographic nor stereoscopic radiography is being performed; and

(vi) The PBL system has not been intentionally overridden. This override provision is subject to F.7.F(6)(c).

(b) Positive beam limitation (PBL) shall prevent the production of x-rays when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by F.7.F(6)(e) from the corresponding image receptor dimensions by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in F.7.F(6)(b)(i) without regard to sign exceeds 4 percent of the SID.

(c) If a means of overriding the positive beam limitation system exists, that means:

(i) Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

(ii) If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator,

(a) Shall require that a key be utilized to defeat the PBL;

(b) Shall require that the key remain in place during the entire time the PBL system is overridden; and

(c) Shall require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

(d) Compliance with F.7.F.6(b) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of F.7.F(6)(a) are met. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

(e) The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size.

(f) The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in F.7.F.(6)(b), then any change of image receptor size or SID must cause the automatic return.

(7) Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.

(8) Transmission limit for image receptor supporting devices used for mammography. For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited

such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rate peak tube potential for the system and at the maximum rated product of the 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.

8. **Intraoral dental radiographic systems and podiatric systems.** In addition to the provisions of F.3, F.4, and F.5, the requirements of F.8 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in F.7.

A. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, i.e., SSD, to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if operable at 50 kVp.

B. Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(1) If the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters .

C. Radiation exposure control for certified and non-certified systems.

(1) Exposure Initiation

(a) 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; and

(b) 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) Exposure termination

(a) 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.

(b) An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half second or less.

(c) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to zero

(3) 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.

(4) Exposure duration (timer) reproducibility. With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (Tmax) and the minimum exposure time (Tmin) shall be less than or equal to 10 percent of the average exposure time (T), when four timing tests are performed:

$$(T_{max} - T_{min}) < 0.10T$$

D. X-Ray control.

(1) Each x-ray control shall be located in such a way as to meet the following requirements:

(a) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area, and the operator is required to remain in that protected area, or six feet away and out of the useful beam during the entire exposure; and

(b) Mobile and portable x-ray systems which are:

(i) Used for greater than one week in the same location, i.e. a room or suite, shall meet the requirements of F.8.D(1)(a);

(ii) Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of F.8.D(1)(b)(i) or be provided with a 6.5 (1.98m) foot high protective barrier which is placed at least 6 feet (1.98m) from the tube housing assembly and at least 6 feet (1.98m) from the patient; or

(iii) Used to make an exposure(s) of a patient at the use location shall meet the requirement of F.8.D(2)(b)(i) or (ii) or be provided with a method of x-ray control which will permit the operator to be at least 6 feet (3.66m) from the tube housing assembly and out of the useful beam during an exposure.

(2) 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, if available to the unit, shall indicate that the exposure has terminated.

E. Exposure reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (Emax), minus the minimum exposure (Emin): i.e., E > 5(Emax- Emin).

F. Administrative controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand-held during an exposure.

(3) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of F.8.B.(1).

(4) Dental fluoroscopy without image intensification shall not be used.

G. 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 requirements(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum,

$$\text{i.e., } X1-X2 < 0.10\ (X1 + X2),$$

where X1 and X2 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. In the absence of the manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value.

(4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.

(5) Beam quality. All certified dental x-ray systems manufactured on or after December 1, 1980, shall have a minimum half-value layer not less than 1.5

millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.5.E.(1).

9. Veterinary medicine radiographic installations.

A. Equipment.

(1) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(2) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent.

(3) A device shall be provided to terminate the exposure after a preset time or exposure.

B. Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with D.6, D.12 and D.14 of this rule.

C. Operating procedures.

(1) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

(2) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he/she shall be so positioned that no part of his/her body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

10. Mobile service.

A. In addition to the requirements of machine registration, inspection, and QA, any mobile service provider before beginning such service shall submit to the Maine Center for Disease Control and Prevention, Radiation Control Program the following:

(1) An established main location where the machines, records, etc, will be maintained for inspection. This must be a street address, not a P.O. Box.

(2) A current copy of an inspection report performed by an approved Qualified expert.

(3) Copies of the applicant's operating, safety, and emergency procedures for the protection of patients, operators, facility employees, and the public.

(4) A list of mobile service employees.

(5) A list of facilities where mobile service will be provided.

(6) A list of licensed practitioners who interpret the radiographs.

11. Mobile vans.

A. In addition to meeting all the requirements of machine registration, inspections, and QA, any mobile van with on board processing shall drain the processor tanks in an approved location between each temporary site.

B. Mobile mammographic vans shall perform phantom images after each relocation.

12. Bone densitometry.

In addition to other requirements of this part, all x-ray bone densitometry systems shall meet the following requirements:

A. The requirement for having a shielding design performed by a qualified expert for bone densitometry units has been waived.

B. An inspection of the unit and an environmental survey of the area shall be performed, within 30 days after installation to ensure that radiation levels to members of the general public outside the exam room are within regulatory limits. A copy of this report must be sent to the Maine Center for Disease Control and Prevention, Radiation Control Program.

C. The console shall be positioned such that the operator is at least 1 meter from the scan field.

D. Access to the exam room during a scan shall be controlled by the operator to prevent exposure to other personnel and the general public.

APPENDIX A.

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice and official approval on shielding requirements for a radiation installation, the following information must be submitted.

A. The plans should show, at a minimum, the following:

(1) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

(2) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor and ceiling of the room(s) concerned.

(3) The dimensions of the room(s) concerned.

(4) 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.

(5) The make and model of the x-ray equipment and the maximum technique factors.

(6) The type of examination(s) or treatment(s) which will be performed with the equipment.

B. Information on the anticipated workload of the x-ray system(s).

C. Except as provided for in section F.3.B, a report including all basic assumptions used, shall be submitted with the plans. Any assumptions differing from NCRP 35, Dental X-Ray Protection and/or NCRP 49, Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to 10 MeV, shall be specifically documented and/or explained.

APPENDIX B.

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

A. Space requirements:

(1) The operator shall be allotted not less than 7.5 square feet (0.697m2) of unobstructed floor space in the booth.

(2) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61m).

(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 on the examination table or at the wall cassette cannot reach the operator's station in the booth.

B. Structural requirements:

(1) The booth walls shall be permanently fixed barriers at least 7 feet (2.13m) 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 meet the requirements of Part D of this rule.

C. X-ray control placement:

(1) The x-ray control for the system shall be fixed within the booth and:

(a) Shall be at least 40 inches (1.02m) from any open edge of the booth wall which is nearest to the examining table.

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

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 shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then 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 1 square foot (0.0929 m2).

(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 (0.457 m) from the edge of the booth.

(c) The material constituting the window shall have the same lead equivalence as that required in the booth's wall 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 Appendix B, D.1.

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

(a) The camera shall be so located as to accomplish the general requirements of Appendix B, D.1; and

(b) There shall be an alternate viewing system as a back up for the primary system.

APPENDIX C.

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:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this State.

2. Diseases or conditions for which the x-ray examinations are to be used.

3. Description in detail of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of this rule.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of 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.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

APPENDIX D.

CHARACTERISTICS FOR QUALIFYING DIAGNOSTIC X-RAY EXPERIENCE FOR RADIOLOGICAL PHYSICISTS

1. Knowledge of physical or natural science, mathematics, or engineering sufficient to understand radiation protection standards, theories, and practices.

2. Knowledge of applicable Maine regulations for radiation protection, federal performance standards and appropriate national guides (e.g. NCRP, AAPM, etc.) and ability to understand and effectively apply them.

3. Knowledge and ability sufficient to select and operate instrumentation used in diagnostic x-ray radiation protection and to interpret the results.

4. Knowledge and ability sufficient to evaluate the need for shielding and to determine and recommend the types and amounts of shielding required.

5. Knowledge of personnel monitoring devices and the ability to recommend appropriate devices for a specific application.

6. Knowledge and ability sufficient to recognize and anticipate existing and potential radiation safety problems.

7. Knowledge and ability sufficient to evaluate and recommend effective use of protective devices for patients, machine operators and others in the immediate environs of the x-ray source.

8. Knowledge and ability sufficient to calculate external radiation doses, evaluate over-exposures and recommend procedures to reduce any reoccurrence.

9. Knowledge and ability sufficient to evaluate and recommend selection, maintenance and effective use of ancillary equipment (e.g. QA devices).

10. Knowledge and ability sufficient to evaluate and recommend quality assurance procedures to improve diagnostic image quality, reduce unnecessary radiation exposure and reduce facility operating costs.

11. Certification requirements for radiological physicists are found in section F.4.A.

APPENDIX E

CHARACTERISTICS FOR QUALIFYING DIAGNOSTIC X-RAY EXPERIENCE FOR X-RAY TECHNICIANS

1. Knowledge of physical or natural science, mathematics, or engineering sufficient to understand radiation protection standards, theories, and practices.

2. Knowledge of applicable Maine regulations for radiation protection, federal performance standards and appropriate national guides (e.g. NCRP, AAPM, etc.) and ability to understand and effectively apply them.

3. Knowledge and ability sufficient to operate instrumentation used in diagnostic x-ray radiation protection and to interpret the results.

4. Knowledge of personnel monitoring devices and the appropriate devices for specific applications.

5. Knowledge and ability sufficient to recognize and anticipate existing and potential radiation safety problems.

6. Knowledge and ability sufficient to evaluate and recommend effective use of protective devices for patients, machines operators and others in the immediate environs of the x-ray source.

7. Knowledge and ability sufficient to evaluate and recommend selection, maintenance and effective use of ancillary equipment (e.g. QA devices).

8. Certification requirements for x-ray technicians are found in section F.4.B.

APPENDIX F

X-RAY REGISTRATION FEES

A. Annual registration fee

(1) Beginning January 1, 2000, all x-ray facilities shall pay a yearly registration fee as specified below.

(a) All facilities$60.00 per tube. See note below.

(b) Existing facilities that are replacing one registered x-ray machine for another (unregistered) x-ray machine will be charged $30.00 for the new registration of the new x-ray machine. New facilities will be charged the full registration fee.

(2) Submit a check payable to the Treasurer State of Maine, along with the form indicated if the facility is:

Existing: Registration Renewal Form *;

New: Registration of Radiation Machine Facilities Form;

Additional machines: Supplemental Sheet Form.

Note: The registration fee for the mammographic facilities includes the annual registration fee, and the annual inspection of the quality assurance program. The cost of the periodic survey is not included with this fee. The periodic survey (section F.3.C(2)) fee is not governed by these rules.

* A registration renewal form is not necessary if a device is in storage, thus waiving the applicable fees. To be considered in storage means that the device will not be utilized in any way. The device must be registered with the Agency before being utilized for any reason.

APPENDIX G

QUALITY ASSURANCE FOR FACILITIES PERFORMING DIAGNOSTIC X-RAY

I. Introduction

A. Purpose

1. This rule describes a basic radiation safety/quality assurance program and represents only a portion of the Quality Assurance tests your facility may choose to perform as part of an individualized program. The Department of Health and Human Services has implemented this program to reduce radiation exposure and optimize diagnostic x-ray image quality. The goal to assist facilities to be more actively involved and responsible for quality assurance.

2. All hospitals, outpatient clinics, chiropractic, and private medical facilities, to include State-approved screening programs, that are performing diagnostic x-rays on humans, shall establish an active quality assurance program. The QA program will be reviewed throughout the year and inspected by the Department at the same frequency stated in section F.3.C.

B. General Concepts

1. Quality control and quality assurance are not well defined and are often incorrectly used. Quality control is a series of distinct technical procedures, which ensure the production of a satisfactory product. Its aim is to provide quality that is not only satisfactory and diagnostic, but also dependable and economic.

2. Quality assurance is an all-encompassing program, including quality control that extends to administrative, educational and preventive maintenance methods. It includes a continuing evaluation of the adequacy and effectiveness of the overall imaging program, with a view to initiating corrective measures when necessary.

C. ALARA principle (As Low As Reasonably Achievable)

This QA requirement has been established on the ALARA principle to assure that the benefits of using ionizing radiation exceeds the risks to the individual and the public.

D. Authority.

This program is authorized by 22 MRS §674.

II. Radiation safety/quality assurance programs

A. Radiation safety/quality assurance committee

1. Each diagnostic facility should establish a committee of individuals to be responsible for radiation safety and quality assurance. The committee should be composed of a minimum of one trained licensed professional, the chief

technologist, and/or the QC technologist. Other individuals, such as hospital administrators and representatives of contracted service companies may also be valuable.

2. This oversight committee shall convene on a frequency adequate to meet their responsibilities, with a minimum of one meeting annually. More frequent meetings will probably be important in the initial stages of this program. The minutes of these meetings shall be kept for a minimum of three years.

3. It is the responsibility of this committee to provide direction to the program, assure that proper documentation and testing is maintained, review the program's effectiveness and determine any changes which should be made.

4. The committee shall establish a quality assurance manual with assigned responsibilities recorded in the manual. The responsible individuals must be properly instructed.

III. Quality assurance manual

A. Records facilities should include are:

1. List of the individuals or companies responsible for testing, supervising and repairing/or servicing the equipment;
2. List of the tests to be performed and the frequency of performance;
3. Acceptability limits for each test;
4. Description of the procedures to be used for each test;
5. List of the equipment to be tested;
6. Protocol for correction;
7. Reference materials and their location;
8. List of the equipment to be used for testing;
9. Sample forms to be used for each test;
10. Committee organization and duties in writing;
11. Equipment records shall be maintained for each x-ray room and mobile x-ray unit to include exposure ranges;
12. Processor and sensitometer logs to regulate proper processor function to include preventive maintenance;
13. Radiation safety policies and procedures;
14. Repeat/reject analysis yearly;
15. Internal audit to self-assess the quality of mammographic interpretations.

IV. General monitoring requirements for all equipment

A. Each facility shall conduct the following tests, at the frequency specified, and maintain records of the data. The type of tests and the frequency of the tests may be modified if the facility can show that alternate tests or schedules will assure good diagnostic image quality.

Daily

Processor - Speed, contrast, base + fog, solution temperatures

Monthly

Replenishments rates, phantom image quality check-mammography only

Semi-annually

Safelights
Interlocks
Viewboxes
Aprons, gloves and drapes

Annually

SID indicators
Film/screen contact
Exposure switches

Fluoroscopic image receptor/x-ray field alignment
Fluoroscopic image resolution
Fluoroscopic timers
Fluoroscopic tabletop rates

Pixel size - CT only
Noise - CT only
Linearity and contrast scale - CT only
Water value - CT only
Spatial uniformity -CT only
Scan width - CT only
Tabletop travel - CT only
Laser alignment - CT only
Dose measurements - CT only

Light field/x-ray field alignment
Positive beam limitation sizing
X-ray field/image receptor alignment
Tomographic equipment
* Radiographic Timers including AEC
* kVp - for all tubes
* mA linearity - for all tubes
* HVL - for all tubes
* Average glandular dose – mammography

* This test is to be conducted yearly for hospital and non-hospital mammographic facilities. For all other radiographic facilities the test frequency shall be the same as the mandatory inspection in accordance with Part F.3.C.3.

V. Additional test for mammography equipment

A. Mammographic equipment. Each mammographic facility shall evaluate the following:

1. Image quality phantom to identify masses and calcifications on a monthly basis. Mobile mammographic units shall perform these tests after each relocation.

2. Average glandular dose calculation yearly.

3. Focal spot size measurement annually.

PART G.

MEDICAL USE OF RADIOACTIVE MATERIAL

SUBPART A – GENERAL INFORMATION

1. **Purpose and scope.** This Part contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this Part are in addition to, and not in substitution for, others in this rule. The requirements and provisions of this rule apply to applicants and licensees subject to this Part unless specifically exempted.

2. **Definitions.** As used in this part, the following definitions apply:

Authorized medical physicist means an individual who –

(1) Meets the requirements in G.51.A and G.59; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on:

(a) A specific medical use license or equivalent permit issued by the Agency, the Nuclear Regulatory Commission or an Agreement State;

(b) A medical use permit issued by a Nuclear Regulatory Commission master material licensee;

(c) A permit issued by an Agency, Nuclear Regulatory Commission or an Agreement State broad scope medical use licensee; or

(d) A permit issued by a Nuclear Regulatory Commission master medical license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who:

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

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

(a) A specific license or equivalent permit issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, that authorizes medical use or the practice of nuclear pharmacy;

(b) A permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(c) A permit issued by an Agency, Nuclear Regulatory Commission or an Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(d) A permit issued by a Nuclear Regulatory Commission master medical 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 Part C.11.I(2)(d).

Authorized user means a physician, dentist, or podiatrist who:

(1) Meets the requirements in G.59 and G.190, G.290, G.390, G.392.A., G.394.A, G.490, G.590, G.690 or G.790; or

(2) Is identified as an authorized user on:

(a) An Agency, Nuclear Regulatory Commission or an Agreement State license that authorizes the medical use of radioactive material;

(b) A permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the use of radioactive material;

(c) A permit issued by an Agency, Nuclear Regulatory Commission, or an Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(d) A permit issued by a Nuclear Regulatory Commission master material licensee broad scope permittee that is authorized to permit the medical use of radioactive material.

Black box means the radiopharmaceutical production purification system used in a cyclotron/ PET facility.

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

Brachytherapy Source means a radioactive source or a manufacturer-assembled source train or combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address means the area of use or a temporary job site for the purpose of providing mobile nuclear medicine services in accordance with G.31.

High dose-rate remote afterloader 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 means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

Manual brachytherapy means a type of therapy in which brachytherapy sources (e.g., seeds, ribbons) are manually applied or inserted.

Medical event means an event that meets the criteria in G.3001.

Medical institution means an organization in which more than one medical discipline is practiced.

Medical use means the intentional internal or external administration of radioactive material, or the radiation there from, to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader means a brachytherapy device that remotely delivers a dose rate of greater than 2gray (200 rads), but less than 12gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile nuclear medicine service means the transportation of radioactive material to and its medical use at the client's address.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a 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 or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

Prescribed dosage means the specified activity or range of activity of unsealed radioactive material as documented:

(1) In a written directive as specified in G.40; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to G.100, G.200, and G.300.

Prescribed dose means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader, as used in this part, means a special type of remote afterloading brachytherapy 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 for medical use means an individual who:

(1) Meets the requirements in G.50.A and G.59; or

(2) Is identified as a radiation safety officer on:

(a) A specific medical use license issued by the Agency, the Nuclear Regulatory Commission, or an Agreement State; or

(b) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Radioactive drug means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in diagnosis, treatment, or prevention of disease or other abnormal condition.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Teletherapy means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

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 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 under G.100, G.200, G.300, G.400, G.500, G.600, or G.1000.

Unit dosage means a dosage that:

(1) Is obtained and prepared in accordance with the regulations for uses described in G.100, G.200, G.300, G.400, G.500, G.600, and G.1000; and

(2) Is for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in G.15.

5. Maintenance of records.

Each record required by this Part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if 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.

6. Provisions for the protection of human research subjects.

A. A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

B. If the research is conducted, funded, supported, or regulated by a federal agency that has implemented the federal Policy for the Protection of Human Subjects (federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the federal policy; and

(2) Obtain informed consent, as defined and described in the federal Policy, from the human research subject.

C. If the research will not be conducted, funded, supported, or regulated by a federal agency that has implemented the federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the federal policy; and

(2) Obtain informed consent, as defined and described in the federal policy, from the human research subject.

D. Nothing in this section relieves licensees from complying with the other requirements in this Part.

7. [reserved.]

8. [reserved.]

9. [reserved.]

10. Implementation.

A. A licensee shall implement the provisions in this Part on the effective date of these rules.

B. When a requirement in Part G differs from the requirement in an existing license condition, the requirement in this Part shall govern.

C. Any existing license condition that is not affected by a requirement in Part G remains in effect until there is a license amendment or renewal.

D. If a license condition exempted a licensee from a provision in Part G on June 1, 2003, it will continue to exempt a licensee from the corresponding provision in Part G.

E. If a license condition cites provisions in Part G that will be deleted on the effective date of these rules, then the license condition remains in effect until other is a license amendment or license renewal that modifies or removes the condition.

F. A licensee shall continue to comply with any license condition that requires it to implement procedures required by G.610, G.642, G.643, and G.645 until there is a license amendment or renewal that modifies the license condition.

11. License required.

A. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued pursuant to this rule.

B. A specific license is not needed for an individual who:

(1) Receives, possesses, uses, or transfer radioactive material in accordance with the regulations in this Part under the supervision of an authorized user as provided in G.27, unless prohibited by license condition; or

(2) Prepares unsealed radioactive material for medical use in accordance with this rule under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.27, unless prohibited by license condition.

12. Application for license, amendment, 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 G.100, G.200, G.300, G.400, G.500, G.600, and G.1000 must be made by:

(1) Filing the appropriate HHE Form 850, Application for Radioactive Material License that includes the facility diagram, equipment, and training and

experience qualifications of the radiation safety officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by G.610, G.642, G.643 and G.645, as applicable.

C. A request for a license amendment, or renewal must be made by:

(1) Submitting either the appropriate HHE Form 850, Application for a Radioactive Material License, or a letter requesting the amendment; and

(2) Submitting procedures required by G.610, G.642, G.643, and G.645, as applicable.

D. In addition to the requirements in G.12.A, G.12.B and G.12.C, an application for a license or amendment for medical use of radioactive material as described in G.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of Part G.

(1) The applicant shall also provide specific information on:

(a) Radiation safety precautions and instructions;

(b) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

E. An applicant that satisfies the requirements specified in Part C.10.B may apply for a Type A specific license of broad scope.

13. 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 this part, but is not authorized on the licensee's current license under this part;

B. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except:

(1) For an authorized user, an individual who meets the requirements in G.190.A, G.290.A, G.390.A, G.392.A, G.394.A, G.490.A, G.590.A, G.690.A, G.690.B, and G.59;

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in G.55.A and G.59;

(3) For an authorized medical physicist, an individual who meets the requirements in G.51.A and G.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist:

(a) On an Agency, Nuclear Regulatory Commission, or an Agreement State license or other equivalent permit or license recognized by the Agency that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(b) On a permit issued by an Agency, Nuclear Regulatory Commission, or an Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(c) On a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(d) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

C. Before it changes Radiation Safety Officers, except as provided in G.24.C;

D. Before it receives radioactive material in excess of the amount, or in a different form, or receives a different radionuclide than is authorized on the license;

E. Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either G.100 or G.200;

F. Before it changes the address(es) of use identified in the application or on the license; and

G. Before it changes statements, representations, and procedures which are incorporated into the license; and

H. Before it releases licensed facilities for unrestricted use.

14. Notifications.

A. A licensee shall provide the Agency a copy of the board certification and the Agency, Nuclear Regulatory Commission, or an Agreement State license for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under G.7.B.(1) through G.7.B.(4).

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, or an authorized medical physicist, permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license; or

(4) The licensee has added to or changed the areas of use as identified in the application or on the license where radioactive material is used in accordance with either G.100 or G.200.

C. The licensee shall mail the documents required in this section to: Radiation Control Program, Maine Center for Disease Control and Prevention, Department of Health and Human Services, 11 State House Station, Augusta, ME, 04333-0011.

15. 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 G.12.C regarding the need to file an amendment to the license for medical use of radioactive material, as described in G.1000;

B. The provisions of G.13.B;

C. The provisions of G.13.E regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

D. The provisions of G.14.A;

E. The provisions of G.14.B.1 for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

F. The provisions of G.14.B.4 regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with G.100 or G.200; and

G. The provisions of G.49.A.

16. [reserved.]

17. [reserved.]

18. License issuance.

A. The Agency shall issue a license for the medical use of radioactive material if:

(1) The applicant has filed HHE Form 850, Application for a Radioactive Material License, in accordance with the instructions in G.12;

(2) The applicant has paid any applicable fee as provided in Part C;

(3) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in this rule for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part C.

B. The Agency shall issue a license for mobile nuclear medicine service if the applicant:

(1) Meets the requirements in G.18.A; and

(2) Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with G.75.

19. Specific Exemptions. The Agency may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this Part that 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.

SUBPART B -- GENERAL ADMINISTRATIVE REQUIREMENTS

24. Authority and responsibilities for the radiation protection program

A. In addition to the radiation protection program requirements of Part D, a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment 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 G.26.

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.

C. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer, under G.50 and G.59, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in G.24.G, if the licensee takes the actions required in G.24.B, G.24.E, G.24.G and G.24.H and notifies the Agency in accordance with G.14.B.

D. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with G.24.C, if needed to ensure that the licensee has a temporary radiation

safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

E. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

F. Licensees that are authorized for two or more different types of uses of radioactive material under Subparts E, F, and H of Part G, or two or more types of units under Subpart H of Part G, shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

(1) 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. The Committee may include other members the licensee considers appropriate.

(2) A licensee's radiation safety committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 12 months. The licensee shall maintain minutes of each meeting in accordance with G.2024.

G. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

H. A licensee shall retain a record of actions taken under G.24.A, G.24.B, and G.24.E in accordance with G.2024.

26. Radiation protection program changes.

A. A licensee may revise its radiation protection program without Agency approval if:

(1) The revision does not require a license amendment under G.13;

(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 the 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 G.2026.

27. 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 G.11.B.(1) shall:

(1) In addition to the requirements in Part J, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this Chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this Chapter, and license conditions with respect to the medical use of radioactive material.

B. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by G.11.B.(2), shall:

(1) In addition to the requirements in Part J, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, this rule, and license conditions.

C. Unless physical presence as described in other sections of Part G is required, a licensee who permits supervised activities under G.21 A. and G.27 B. shall require an authorized user to be immediately available to communicate with the supervised individual, and able to be physically present within three hours of notification; and

D. A licensee that permits supervised activities under G.27.A and G.27.B is responsible for the acts and omissions of the supervised individual.

28. Duties of authorized user and authorized medical physicist

A. A licensee shall assure that only authorized users for the type of radioactive material used:

(1) Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

(2) Direct, as specified in G.27 and G.40, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;

(3) Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with G.11.B. and G11.C. and G.27;

(4) Perform the final interpretation of the results of tests, studies, or treatments

B. A licensee shall assure that only authorized medical physicists perform, as applicable:

(1) Full calibration measurements as described in G.632, G.633, and G.635s;

(2) Periodic spot checks as described in G.642, G643, and G.645; and G.28.B(3)

(3) Radiation surveys as described in G.652.

29-39. [reserved.]

40. Written directives.

A. A written directive must be dated and signed by an authorized user before the administration of sodium iodide I-131 greater than 1.11 Megabecquerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

B. The written directive must contain the patient or human research subject’s name and the following information:

(1) For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(a) Before implantation: treatment site, the radionuclide, and dose; and

(b) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

C. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable.

(2) The oral revision must be documented as soon as possible in the patient's record.

(3) A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

D. The licensee shall retain a copy of the written directive in accordance with G.2040.

41. Procedures for administrations requiring a written directive.

A. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) 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. At a minimum, the procedures required by G.41.A must address the following items that are applicable to the licensee’s use of radioactive material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.600.

C. A licensee shall retain a copy of the procedures required under G.41.A in accordance with G.2041.

49. Suppliers for radioactive material, sealed sources or devices for medical use. For medical use, a licensee may only use:

A. Radioactive material, sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to this rule or the equivalent regulations of the NRC or an Agreement State.

B. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration.

C. Sealed sources or devices non-commercially transferred from a Part G licensee; or

D. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to this rule, or the equivalent regulations of the NRC or an Agreement State.

50. Training for radiation safety officer. Except as provided in G.57, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in G.24 to be an individual who:

A. Is certified by a specialty board whose certification process includes all of the requirements in G.18.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State, and who meets the requirements in paragraphs D and E of this section. (Specialty Boards whose certification processes have been recognized by the Agency, the NRC or an Agreement State will be posted on the NRC's web page.) To be 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 required experience) including 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:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, the NRC, or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the definition of an authorized user in Part A.2 or who meet the requirements for authorized users in G.57, G.290, or G.390; and

(c) Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

B. Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiation biology;

(e) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an Agency, Nuclear Regulatory Commission, Agreement State license, or a permit issued by a NRC master materials licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

(a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(c) Securing and controlling radioactive material;

(d) Using administrative controls to avoid mistakes in the administration of radioactive material;

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(f) Using emergency procedures to control radioactive material; and

(g) Disposing of radioactive material.

C. (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, the NRC, or an Agreement State under G.51.A. and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking approval of

the individual as radiation safety officer, and who meets the requirements in paragraphs G.50.D and G.50.E; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and

D. Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in paragraph G.50.E and in paragraphs G.50.A(1)(a) and A(1)(b) or 50.A.(2)(a) and A.(2)(b) or G.50.B(1) or G.50.C(1) or G.50.C(2) and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

E. Has training in the radiation safety, regulatory issues, and emergency procedures for the type of use for which a licensee seeks approval. This training requirement may be satisfied by completed training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

51. Training for an authorized medical physicist. Except as provided in G.21, the licensee shall require the authorized medical physicist to be an individual who –

A. Is certified by a specialty board whose certification process includes all of the training and experience requirements in G.19.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in paragraphs G.51.B.(2) and G.51.C. (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State, will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) 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 practicable training and/or supervised experience in medical physics:

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, the NRC, 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 definition of an authorized user in Part A.2 or who meet the requirements for authorized users in G.57, G.490 or G.690; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation

safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

B. (1) Hold a master's or doctor's degree in physics, medical physics, or other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. The 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 calibrations 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) Have obtained written certification that the individual has satisfactorily completed the requirements in G.51.C and G.51.A(1) and G.51.A(2) or G.51.B(1) and G.51.C and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in G.51 , G.57 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; and

C. In addition to meeting requirements in G.51.B, have 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 of by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

55. Training for an authorized nuclear pharmacist. Except as provided in G.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

A. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in G.20.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in paragraph B.(2) of this section. (The names of board certifications

which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.) To be 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 substitutes for no more than 2000 hours of the required training and experience;

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

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 –

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Supervised practical experience in a nuclear pharmacy involving --

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid medical events in the administration of radioactive material; and

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs G.55.A(1), G.55.A(2) and G.55.A(3) or G.55.B(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

57. Training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

A. (1) An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on an Agency, Nuclear Regulatory Commission, or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002 need not comply with the training requirements of G.50, G.51, or G.55, respectively.

(2) A radiation safety officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or federally-recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Agency, need not comply with the training requirements of G.50, G.51 or G.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates.

(3) A radiation safety officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Agency, need not comply with the training requirements of G.50, G.51 or G.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates for purposes of this Chapter.

B. (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency, the Nuclear Regulatory Commission, or an Agreement State, a permit issued by a Nuclear

Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before December 1, 2003, who perform only those medical uses for which they were authorized on that date, need not comply with the training requirements of Subparts D through H of Part G.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency, the NRC, or Agreement State, a permit issued by a NRC master material licensee, a permit issued by an Agency, NRC, or Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope licensee, or a permit issued by a NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of Part G.

(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 subparts D through H of this Part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of Part G.

C. Individuals who need not comply with the training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on an Agency, an Agreement State or NRC licenses for the same uses for which these individuals are authorized.

59. **Recentness of training.** The training and experience specified in Subparts B, D, E, F, G, and H, of Part G 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.

SUBPART C -- GENERAL TECHNICAL REQUIREMENTS

60. Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material.

A. For direct measurements performed in accordance with G.60, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B. A licensee shall calibrate the instrumentation required in G.60.A in accordance with nationally recognized standards or the manufacturer's instructions.

C. The tests shall at a minimum include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

D. A licensee shall retain a record of each instrument calibration required by this section in accordance with G.2060.

61. Calibration of survey instruments.

A. A licensee shall calibrate the survey instruments used to show compliance with this Part and Part D before first use, annually, and following a repair that affects the calibration. A licensee shall:

(1) Calibrate all required scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Have each radiation survey instrument calibrated:

(a) At energies appropriate for use and intervals not to exceed 12 months or after instrument servicing, except battery changes;

(b) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and

(c) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

B. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calibrated exposure rate is more than 20 percent.

C. A licensee shall check each survey instrument for consistent response with a dedicated check source before each use.

D. A licensee shall retain a record of each survey instrument calibration in accordance with G.2061

62. 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.

63. Determination of dosages of unsealed radioactive material for medical use.

A. A licensee shall determine and record the activity of each dosage within 30 minutes before medical use.

B. For a unit dosage, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by:

(a) A manufacturer or preparer licensed under Part C or equivalent Nuclear Regulatory Commission, or Agreement State requirements;

(b) An Agency, Nuclear Regulatory Commission, or an 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 the FDA; or

(c) A PET radioactive drug producer licensed under Part C of this rule or equivalent provisions of the NRC, or an Agreement State.

C. For other than unit dosages, this determination must be made by –

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under Part C or equivalent Nuclear Regulatory Commission, or Agreement State requirements, or a PET radioactive drug producer licensed under Part C or equivalent provisions of the NRC or an Agreement State.

D. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

E. A licensee shall retain a record of the dosage determination required by this section in accordance with G.2063.

65. Authorization for calibration, transmission, and reference sources. Any person authorized by G.11 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

A. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by persons licensed pursuant to Part C of this rule or equivalent Nuclear Regulatory Commission, or Agreement State regulations.

B. Sealed sources, not exceeding 1.11 GBq (30mCi) each, redistributed by a person licensed under Part C.11.K, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

C. Any radioactive material with a half- life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

D. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Appendix C of Part D of this rule.

E. Technetium-99m in amounts as needed.

67. Requirements for possession of sealed sources and brachytherapy sources.

A. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

B. A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Agency, the Nuclear Regulatory Commission, or an Agreement State in the Sealed Source and Device Registry.

C. To satisfy the leak test requirements of G.67.B, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

D. A licensee shall retain leak test records in accordance with G.2067.A.

E. If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store, dispose of, or cause it to be repaired in accordance with the requirements of this rule; and

(2) File a report with the Agency within five days of the leak test in accordance with G.3067.

F. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of fewer than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within six months before the date of use or transfer.

G. A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with G.2067.B.

69. Labeling of Vials and Syringes. Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded. Furthermore, a licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

70. Surveys for ambient radiation dose rate.

A. In addition to the surveys required by Part D, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material was prepared for use or administered.

B. A licensee does not need to perform the surveys required by G.70.A in an area(s) where patients or human research subjects are confined when they cannot be released under G.75.

C. A licensee shall conduct the surveys required by G.70.A and B so as to able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

D. A licensee shall establish dose rate action levels for the surveys required by G.70.A and G.70.B and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

E. A licensee shall survey for removable contamination each week of use all areas where radioactive materials are prepared for use, used, administered or stored.

F. A licensee shall conduct the surveys required by G.70.E so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm) for restricted areas and 3.33 becquerels (200 pdm) for unrestricted areas.

G. A licensee shall establish removable contamination action levels for the surveys required by G.70.E and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

I. A licensee shall retain a record of each survey in accordance with G.2070.

75. Release of individuals containing unsealed radioactive material or implants containing radioactive material

A. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

B. The licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem) . If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow guidance.

C. Release of the individual must be approved by a person listed as an authorized user on the Agency license, and who is approved for the type of radioactive material use for which the patient being released has received.

D. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2075.A.

E. The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with G.2075.B.

F. The licensee shall immediately notify the Agency in accordance with G.3075. A if a patient departs prior to an authorized release.

G. The licensee shall notify the Agency in accordance with G.3075.B

(1) When it is aware that a patient containing radioactive material dies; and

(2) If it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

[1] U.S. Nuclear Regulatory Commission Regulatory Guide NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

80. Provision of mobile nuclear medicine service

A. A licensee providing mobile nuclear medicine service shall --

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) 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 this paragraph 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 Part D of this rule.

B. A mobile nuclear medicine service shall have all radioactive material delivered directly from the manufacturer or the distributor to the mobile nuclear medicine facility. At no time may the client take receipt of any radioactive material intended for the mobile nuclear medicine service's use.

C. A licensee providing mobile medical services shall retain the letter required in G.80.A.(1) and the record of each survey required in G.80.A.(4) in accordance with G.2080.A and G.2080.B, respectively.

92. Decay-in-storage.

A. A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

(1) Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding; and

(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.

B. A licensee shall retain a record for each disposal permitted under G.92.A in accordance with G.2092.

SUBPART D – UNSEALED RADIOACTIVE MATERIAL

WRITTEN DIRECTIVE NOT REQUIRED

100. Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive Is not required. Except for quantities that require a written directive under G.40, a licensee may use any unsealed radioactive material, prepared for medical use for uptake, dilution, or excretion studies that is:

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission or Agreement State requirements; or from a PET radioactive drug producer licensed under Part C of this rule or equivalent provisions of the NRC Agreement State,

B. Excluding production of PET radionuclides prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in G.290 or G.390, and G.290.C.(1)(b)(vii); or

(2) An individual under the supervision, as specified in Part G.27, of the authorized nuclear pharmacist in G.100.B(1) or the physician who is an authorized user in G.100.B(2); and

C. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or an 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 the Food and Drug Administration; or

D. Prepared by the licensee for use in research in accordance with a [radioactive drug research committee]approved application or an [investigational new drug] (IND) protocol accepted by the Food and Drug Administration.

110. 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 of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

111-189. [reserved.]

190. Training for uptake, dilution, and excretion studies. Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.100 to be a physician who:

A. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in G.190.C(2). The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the

NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs G.190.C(1)(a) and G.190.C(1)(b) and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

B. Is an authorized user under G.290 or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements; or

(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 --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in G.57, G.190, G.290, or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements, involving --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.57, G.190, G.290, or G.390 or equivalent Nuclear Regulatory Commission, or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.190.A.(1) or G.190.C.(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100.

200. Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required. Except for quantities that require a written directive under G.40, a licensee may use for any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission or Agreement State requirements, or a PET radioactive drug producer licensed under Part C of this rule or equivalent provisions of the NRC, Agreement State, or

B. Excluding production of PET radionuclides prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in G.290 or G.390 and G.290.C(1)(b)(vii); or

(3) An individual under the supervision, as specified in G.27, of the authorized nuclear pharmacist in G.200.B(1) or the physician who is an authorized user in G.200.B(2);

C. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with a [radioactive drug research committee] approved protocol or an [investigational new drug] (IND) protocol accepted by the Food and Drug Administration; or

D. Prepared by the licensee for use in research in accordance with a [radioactive drug research committee] approved application or an [investigational new drug] (IND) protocol accepted by the Food and Drug Administration.

204. Permissible molybdenum-99 concentration.

A. A licensee may not administer to humans a radioactive drug containing:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m);

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (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 1 mCi of Rb-82).

B. To demonstrate compliance with G.204, the licensee preparing radioactive drugs from radionuclide generators shall:

(1) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator; or, as applicable.

(2) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

C. A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with G.2204.

D. A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in G.204.

220. Possession of survey instrument. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

290. Training for Imaging and Localization Studies. Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.200 to be a physician who:

A. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the NRC, or an Agreement State, and who meets the requirements in G.290.C(2). (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State, will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs G.290.C(1)(a) through G.290.C(1)(b)(vii); 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;

B. Is an authorized user under G.390 and meets the requirements in G.290.C(1)(b)(vii) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

C. (1) Has completed 700 hours of training and experience, including a minimum of 80 hours 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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the definition of an authorized user in Part A.2 for the same uses, or who meets the requirements in G.57, G.290 or G.390 and G290.C(1)(b)(vii) or equivalent Nuclear Regulatory Commission, or Agreement State requirements involving:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(vi) Administering dosages of radioactive drugs to patients or human research subjects; and

(vii) 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 signed by a preceptor authorized user, who meets the definition of an authorized user in Part A.2 for the same uses or who meets

the requirements in G.57, G.290 or G.390 and G290.C(1)(b)(vii) or equivalent Nuclear Regulatory Commission, or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.290.A(1) or G.290.C(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100 and G.200.

SUBPART E – UNSEALED RADIOACTIVE MATERIAL

WRITTEN DIRECTIVE REQUIRED

300. Use of unsealed radioactive material for which a written directive is required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

A. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent Nuclear Regulatory Commission or Agreement State requirements; or from a PET radioactive drug producer licensed under Part C of this rule or equivalent provisions of the NRC, Agreement State, or

B. Excluding production of PET radionuclides prepared by;

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in G.290 or G.390; or

(3) An individual under the supervision, as specified in Part G.27, of the authorized nuclear pharmacist in G.300.B(1); or the physician who is an authorized user in G.300.B(2); or

C. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or an 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 the Food and Drug Administration; or

D. Prepared by the licensee for use in research in accordance with a [radioactive drug research committee] approved application or an [investigational new drug] (IND) protocol accepted by the Food and Drug Administration.

310. Safety instruction. In addition to the requirements of Part J.3,

A. A licensee shall provide radiation safety instruction initially and at least annually, to one personnel caring for patients or human research subjects who cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including:

(a) Routine visitation to hospitalized individuals in accordance with Part D.27.A(1), and

(b) Visitation authorized in accordance with Part D.27.C;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the radiation safety officer or his or her designee, and the authorized user if the patient or human research subject has a medical emergency or dies.

B. A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

315. Safety precautions.

A. For each patient or human research subject who cannot be released under G.75, a licensee shall:

(1) Quarter the patient or 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 therapy with unsealed radioactive material and who also cannot be released under G.75.

(2) Visibly post the patient's or human research subject's room with a Radioactive Materials sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

(4) Either monitor material and items removed from the patient's or human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste;

B. A licensee shall notify the radiation safety officer or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. The licensee shall also notify the Agency in accordance with G.3068 if it is possible that any individual could receive exposures in excess of Part D.301 of this rule as a result from exposure to the deceased body.

320. Possession of survey instrument. A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

390. Training for use of unsealed radioactive material for which a written directive is required. Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.300 to be a physician who:

A. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State, and who meets the requirements in paragraphs G390.B(1)(b)(vii) and G.390.B(2). (Specialty Boards whose certification processes have been recognized by the Agency, the NRC, an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in G.390.B(1)(a) through G.390.B(2). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and clinical use of unsealed radioactive material for which a written directive is required; or

B. (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Work experience under the supervision of an authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B or equivalent Nuclear Regulatory Commission, or Agreement State requirements. A supervising authorized user who meets the requirements in G.390.B must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(vi) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(vii) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(a) Oral administration of less than or equal to 1.22 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[2];

(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; and/or

(d) Parenteral administration of any other radionuclide for which a written directive is required; and

[2] Experience with at least three cases in Category (vii)(b) also satisfies the requirement in Category (vii)(a).

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs G.390.A.(1) and G.390.B.(1)(b)(vii) or G.390.B(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.300.

(a) The written attestation must be signed by a preceptor authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B, or equivalent Nuclear Regulatory Commission or Agreement State requirements.

(b) The preceptor authorized user, who meets the requirements in G.390B, must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

392. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 Millicuries). Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.392.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and meets the requirements in paragraph G.392.C.(3). (Specialty Boards whose certification processes have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.); or

B. Is an authorized user under G.390.A and G.390.B, for uses listed in G.390.B(1)(b)(vii)(a) or (b), G.394 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

C. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(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 definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B, G.392, G.394 or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in G.390.B, must have experience in

administering dosages as specified in G.390.B(1)(b)(vii)(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 radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392.C.(1) and G.392.C.(2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390.A, G.390.B, G.392, G.394, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirement in G.390.B, must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(a) or (b).

394. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 Millicuries). Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in G.394.C and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in G.394.C(3) (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.); or

B. Is an authorized user under G.390.A and G.390.B for uses listed in G.390 B(1)(b)(vii)(b), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

C. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(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 definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390.A, G.390.B, G.394, or equivalent Nuclear Regulatory Commission, or Agreement State requirements. A supervising authorized user, who meets the requirements in G.390.B must have experience in administering dosages as specified in G.390 (1)(b)(vii)(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 for 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 radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Administering dosages to patients or human research subjects, including at least three cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.394.C.(1) and G.394.C.(2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under G.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390.A, G.390.B, G.394, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in G.390.B must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(b).

396. Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Except as provided in G.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

A. Is an authorized user under G.390 for uses listed in G.390.B.(1)(b)(vii)(c) and G.390.B.(1)(b)(vii)(d) or equivalent NRC or Agreement State requirements; or

B. Is an authorized user under G.490, G.690, or equivalent NRC or Agreement State requirements and who meets the requirements in G.396.D; or G.396.C

C. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the NRC or an Agreement State under G.490 or G.690, and who meets the requirements in G.396.D.

D. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

(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 definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.390, G.396, or equivalent NRC Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in G.390 must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(c) and/or G.390.B(1)(b)(vii) (d). The work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed 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 involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.396.B or G.396.C., and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.390, G.396, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in G.390 must have experience in administering dosages as specified in G.390.B(1)(b)(vii)(c) and/or G.390.B(1)(b)(vii)(d).

SUBPART F – MANUAL BRACHYTHERAPY

400. Use of Sources for manual brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

A. As approved in the sealed source and device registry; or

B. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of G.49 are met.

404. Surveys after source implant and removal.

A. Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

B. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

C. A licensee shall retain a record of the surveys required by G.404.A and G.404.B in accordance with G.2404.

406. Brachytherapy sources accountability.

A. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

B. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

C. A licensee shall maintain a record of the brachytherapy source accountability in accordance with G.2406.

410. Safety instruction. In addition to the requirements of Part J:

A. The licensee shall provide radiation safety instruction initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient and human research subject control;

(4) Visitor control, including both:

(a) Routine visitation of hospitalized individuals in accordance with Part D.1301.A(1); and

(b) Visitation authorized in accordance with Part D.1301.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 has a medical emergency or dies. The licensee shall also notify the Agency in accordance with G.3068 if it is possible that any individual could receive exposures in excess of Part D.301 of this rule as a result from exposure to the deceased body.

B. A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

415. Safety precautions.

A. For each patient or human research subject who is receiving brachytherapy and cannot be release under G.75, a licensee shall:

(1) Not quarter the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient’s or human research subject’s room with a Radioactive Materials sign; and

(3) Note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

B. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Dislodged from the patient or human research subject; and

(2) Lodged within the patient or human research subject following removal of the source applicators.

C. A licensee shall notify the radiation safety officer or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. The licensee shall also notify the Agency in accordance with G.3068 if it is possible that any individual could receive exposures in excess of Part D.301 of this rule as a result from exposure to the deceased body.

420. Possession of survey instrument. A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.61.

432. Calibration measurements of brachytherapy sources.

A. Before the first medical use of a brachytherapy source on or after December 1, 2003, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of G.630.A;

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of G.432.A.(1) and G.432.A.(2).

B. 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 G.432.A.

C. A licensee shall mathematically correct the outputs or activities determined in G.432.A for physical decay at intervals consistent with 1 percent physical decay.

D. A licensee shall retain a record of each calibration in accordance with G.2432.

433. Decay of strontium-90 sources for ophthalmic treatments.

A. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under G.432.

B. A licensee shall retain a record of the activity of each strontium-90 source in accordance with G.2433.

457. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

A. The source-specific input parameters required by the dose calculation algorithm;

B. The accuracy of dose, dwell time, and treatment time calculations at representative points;

C. The accuracy of isodose plots and graphic displays; and

D. The accuracy of the software used to determine sealed source positions from radiographic images.

490. Training for Use of manual brachytherapy sources. Except as provided in G.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G.400 to be a physician who:

A. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in G.490.B.(3). (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which 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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.490 or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing brachytherapy sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent a medical event involving the use of radioactive material; and

(vi) Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.490 or equivalent Nuclear Regulatory Commission or Agreement State, 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 G.490.B.(1)(b); and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.490 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.490.A(1) or G.490.B.(1) and G.490.B.(2) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400.

491. Training for ophthalmic use of strontium-90. Except as provided in G.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

A. Is an authorized user under G.490 or equivalent Nuclear Regulatory Commission, or Agreement State requirements; or

B. (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve --

(a) Examination of each individual to be treated;

(b) Calculation of the dose to be administered;

(c) Administration of the dose; and

(d) Follow up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the definition of an authorized user in Part A.2 for the same uses or who meets the requirements in G.57, G.490, G.491, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.491.B and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

SUBPART G - SEALED SOURCES FOR DIAGNOSIS

500. Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

590. Training for use of sealed sources for diagnosis. Except as provided in G.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who:

A. Is certified by a specialty board whose certification process includes all of the requirements in G.590.B and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.); or

B. Has had eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

SUBPART H – PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

600. Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

A. As approved in the Sealed Source and Device Registry; or

B. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the Food and Drug Administration, provided the requirements of G.49 are met.

604. Surveys of patients and human research subjects treated with a remote afterloader unit.

A. Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

B. A licensee shall retain a record of these surveys in accordance with G.2404.

605. Installation, maintenance, adjustment and repair.

A. Only a person specifically licensed by the Agency, the 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) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

B. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, the Nuclear Regulatory Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

C. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, the Nuclear Regulatory Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

D. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with G.2605.

610. Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A. A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(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 G.610.A(4) must be physically located at the unit console.

C. A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by G.610.A.(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

D. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(1) The procedures identified in G.610.A.(4); and

(2) The operating procedures for the unit.

E. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

F. A licensee shall retain a record of individuals receiving instruction required by G.643.D, in accordance with G.2310.

G. A licensee shall retain a copy of the procedures required by G.610.A.(4) and G.610.D.(2) in accordance with G.2610.

615. Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

A. A licensee shall control access to the treatment room by a door at each entrance.

B. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

C. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

D. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

E. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

F. In addition to the requirements specified in G.615.A through G.615.E, a licensee shall:

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(a) An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(b) An authorized medical physicist and either an authorized user or an individual under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require:

(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(b) An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the radiation safety officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

G. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

630. Dosimetry equipment.

A. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall 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

(2) The system must have been calibrated within the previous four years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as

applicable, and sources of the same radionuclide as the source used at the licensee's facility.

B. The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with G.630.A.. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in G.630.A

C. The licensee shall maintain a record of each calibration, intercomparison, and comparison in accordance with G.2630.

632. Full calibration measurements on teletherapy units.

A. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(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 G.632.A, full calibration measurements must include determination of:

(1) The output within +/- 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

C. A licensee shall use the dosimetry system described in G.630.A to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.630.B.(1) may be made using a dosimetry system that indicates relative dose rates.

D. A licensee shall make full calibration measurements required by G.632.A in accordance with published protocols accepted by nationally recognized bodies.

E. A licensee shall mathematically correct the outputs determined in G.632.B.(1) for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides..

F. Full calibration measurements required by G.632.A and physical decay corrections required by G.632.E must be performed by the authorized medical physicist.

G. A licensee shall retain a record of each calibration in accordance with G.2632.

633. Full calibration measurements on remote afterloader units.

A. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(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 G.633.A, full calibration measurements must include, as applicable, determination of:

(1) The output within +/- 5 percent;

(2) Source positioning accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

C. A licensee shall use the dosimetry system described in G.630.A to measure the output.

D. A licensee shall make full calibration measurements required by G.633.A in accordance with published protocols accepted by nationally recognized bodies.

E. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.607.B, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

F. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with G.633.A through G.633.E.

G. A licensee shall mathematically correct the outputs determined in G.633.B.(1) for physical decay at intervals consistent with 1 percent physical decay.

H. Full calibration measurements required by G.633.A and physical decay corrections required by G.633.G must be performed by the authorized medical physicist.

I. A licensee shall retain a record of each calibration in accordance with G.2632.
635. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

635. Full calibration measurements on gamma stereotactic radiosurgery units.

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(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 G.635.A, full calibration measurements must include determination of:

(1) The output within +/- 3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

C. A licensee shall use the dosimetry system described in G.630.A to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.635.B(1) may be made using a dosimetry system that indicates relative dose rates.

D. A licensee shall make full calibration measurements required by G.635.A in accordance with published protocols accepted by nationally recognized bodies.

E. A licensee shall mathematically correct the outputs determined in G.635.B.(1) at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

F. Full calibration measurements required by G.635.A and physical decay corrections required by G.635.E must be performed by the authorized medical physicist.

G. A licensee shall retain a record of each calibration in accordance with G.2632.

642. Periodic spot checks for teletherapy units.

A. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in G.630.A; and

(6) The difference between the measurement made in G.642.B(5) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

B. A licensee shall perform measurements required by G.642.A in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

C. A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

D. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

E. If the results of the checks required in G.642.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each spot- check required by G.642.A. and G.642.D, and a copy of the procedures required by G.642.B, in accordance with G.2642.

643. Periodic spot-checks for remote afterloader units.

A. A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

B. A licensee shall perform the measurements required by G.643.A in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

C. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

D. To satisfy the requirements of G.643.A, spot-checks must, at a minimum, assure proper operation of:

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit’s computer; and

(8) Decayed source(s) activity in the unit’s computer.

E. If the results of the checks required in G.643.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each check required by G.643.D and a copy of the procedures required by G.610.B in accordance with G.2643.

645. Periodic spot-checks for gamma stereotactic radiosurgery units.

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

B. A licensee shall:

(1) Perform the measurements required by G.645.A in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

C. To satisfy the requirements G.645.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 micro-switches;

(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 G.630.A;

(b) The difference between the measurement made in G.645.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 G.645.A(2) and G.645.(3), spot-checks must assure proper operation of:

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

E. A licensee shall arrange for the repair of any system identified in G.645.C that is not operating properly as soon as possible.

F. If the results of the checks required in G.645.D indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

G. A licensee shall retain a record of each check required by G.645.C and G.645.D and a copy of the procedures required by G.645.B in accordance with G.2611.

647. Additional technical requirements for mobile remote afterloader units.

A. A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

B. In addition to the periodic spot-checks required by G.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the proper operation of:

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

C. In addition to the requirements for checks in G.647.B, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D. If the results of the checks required in G.647.B indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

E. A licensee shall retain a record of each check required by G.647.B in accordance with G.2652.

652. Radiation surveys.

A. In addition to the survey requirement in Part D.1501, a person licensed under Part G shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

B. The licensee shall make the survey required by G.652.A at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

C. A licensee shall retain a record of the radiation surveys required by G.652.A in accordance with G.2652.

655. Five year inspection for teletherapy and gamma stereotactic radiosurgery units.

A. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

B. This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, the Nuclear Regulatory Commission, or an Agreement State.

C. A licensee shall keep a record of the inspection and servicing in accordance with G.2655.

657. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

A. The source-specific input parameters required by the dose calculation algorithm;

B. The accuracy of dose, dwell time, and treatment time calculations at representative points;

C. The accuracy of isodose plots and graphic displays;

D. The accuracy of the software used to determine sealed source positions from radiographic images; and

E. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

690. Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in G.57, the licensee shall require an authorized user of a sealed source for a use authorized under G.600 to be a physician who:

A. Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in G.690.B.(3) and G.690.B(4). (The names of board certifications which have been recognized by the Agency, the NRC, or an Agreement State will be posted on the NRC's web page.) To be 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 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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690 or equivalent Nuclear Regulatory Commission, or Agreement State requirements, at a medical institution, involving:

(i) Reviewing full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment doses and times;

(iii) Using administrative controls to prevent a medical event involving the use of radioactive material;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(v) Checking and using survey meters; and

(vi) Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.690 or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or 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 G.690.B(1)(b); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.690.A(1) or G.690.B(1) and G.690.B(2) and G.690.B(4) and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in G.57, G.690 or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(4) 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.

SUBPART I - RESERVED

SUBPART J – RESERVED

SUBPART K--OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

1000. Other medical uses of radioactive material or radiation from radioactive material. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part G if:

A. The applicant or licensee has submitted the information required by G.12.B through G.12.D; and

B. The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the material.

C. There are three modalities currently authorized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State:

(1) Yttrium 90 (Y-90) Microspheres (e.g., MDS Nordion Y-90 TheraSphere®).

(2) Liquid Brachytherapy (e.g., Proxima Therapeutics' GilaSite® Radiation Therapy System).

(3) Intravascular Brachytherapy (e.g., Cordis Checkmate™ System, Novoste Beta-Cath™ System, and Guidant Galileo™ Intravascular Radiotherapy System).

SUBPART L-- RECORDS

2024. Records of authority and responsibilities for radiation protection programs.

A. A licensee shall retain a record of actions taken by the licensee's management in accordance with G.24.A for five years. The record must include a summary of the actions taken and a signature of licensee management.

B. The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by G.24.E, and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required by G.24.B, for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

2026. Records of radiation protection program changes. A licensee shall retain a record of each radiation protection program change made in accordance with G.26.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.

2031. Records of mobile nuclear medicine services.

A. A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by G.80.A(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for three years after the last provision of service.

B. A licensee shall retain the record of each survey required by G.80.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.

2040. Records of written directives. A licensee shall retain a copy of each written directive as required by G.15 for three years.

2041. Records for procedures for administrations requiring a written directive. A licensee shall retain a copy of the procedures required by G.16.A for the duration of the license.

2060. Records of calibrations of instruments used to measure the activity of unsealed radioactive material. A licensee shall maintain a record of instrument calibrations required by G.60 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.

2061. Records of radiation survey instrument calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by G.61 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.

2063. Records of dosages of unsealed radioactive material for medical use.

A. A licensee shall maintain a record of dosage determinations required by G.63 for three years.

B. The record must contain:

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

2067. Records of leaks tests and inventory of sealed sources and brachytherapy sources.

A. A licensee shall retain records of leak tests required by G.67.B for three years. The records must include the model number, and serial number if one has been assigned, of

each source tested, the identity of each source by radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test.

B. A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by G.67.G for three years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

2070. Records of surveys for ambient radiation exposure rate. A licensee shall retain a record of each survey required by G.29 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.

2075. Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

A. A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with G.75, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

B. A licensee shall retain a record that the instructions required by G.75.B were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

C. The records required by G.2075.A and G.2075.B must be signed by the authorized user and retained for three years after the date of release of the individual.

2092. Records of decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by G.32, 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.

2204. Records of molybdenum-99 concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by G.204.B for three years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

2310. Records of safety instruction. A licensee shall maintain a record of safety instructions required by G.310, G.410, and G.610 for three years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

2404. Records of surveys of patients and human research subjects after source implant and removal. A licensee shall maintain a record of the surveys required by G.404 and G.604 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.

2406. Records of brachytherapy source accountability.

A. A licensee shall maintain a record of brachytherapy source accountability required by G.406 for three years

B. For temporary implants, the record must include:

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

C. For permanent implants, the record must include:

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

2432. Records of calibration measurements of brachytherapy sources.

A. A licensee shall maintain a record of the calibrations of brachytherapy sources required by G.432 for three years after the last use of the source.

B. The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

2433. Records of decay of strontium-90 sources for ophthalmic treatments.

A. A licensee shall maintain a record of the activity of a strontium-90 source required by G.433 for the life of the source.

B. The record must include:

(1) The date and initial activity of the source as determined under G.433; and

(2) For each decay calculation, the date and the source activity as determined under G.433.

2605. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by G.605 for 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.

2610. Records of safety procedures. A licensee shall retain a copy of the procedures required by G.610.A.(4) and G.610.D.(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

2630. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with G.630 for the duration of the license.

B. For each calibration, intercomparison, or comparison, the record must include:

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G.630.A and G.630.B;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

2632. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

A. A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by G.632, G.633, and G.635 for three years.

B. The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

2642. Records of periodic spot-checks for teletherapy units.

A. A licensee shall retain a record of each periodic spot-check for teletherapy units required by G.642 for three years.

B. The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G.642.B until the licensee no longer possesses the teletherapy unit.

2643. Records of periodic spot-checks for remote afterloader units.

A. A licensee shall retain a record of each spot-check for remote afterloader units required by G.643 for three years.

B. The record must include, as applicable:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit’s computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G.643.B until the licensee no longer possesses the remote afterloader unit.

2645. Records of periodic spot-checks for gamma stereotactic radiosurgery units.

A. A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by G.645 for three years.

B. The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

C. A licensee shall retain a copy of the procedures required by G.645.B until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

2647. Records of additional technical Requirements for mobile remote afterloader units.

A. A licensee shall retain a record of each check for mobile remote afterloader units required by G.647 for three years.

B. The record must include:

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

2652. Records of surveys of therapeutic treatment units.

A. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with G.652 for the duration of use of the unit.

B. The record must include:

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

2655. Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

A. A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by G.655 for the duration of use of the unit.

B. The record must contain:

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

SUBPART M—REPORTS

3045. Report and notification of a medical event.

A. A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material 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

(a) The total dose delivered differs from the prescribed dose by 20 percent or more;

(b) The total dosage delivered differs from the prescribed dosage by 20 percent 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 percent 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 radioactive material;

(b) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(c) An administration of a dose or dosage to the wrong individual or human research subject;

(d) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(e) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

B. 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.

C. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event.

D. The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

(1) The written report must include:

(a) The licensee's name;

(b) The name of the prescribing physician;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the individual(s) who received the administration;

(f) What actions, if any, have been taken or are planned to prevent recurrence; and

(g) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

E. The licensee shall provide notification of the 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.

(1) The licensee is not required to notify the individual without first consulting the referring physician.

(2) 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.

(3) 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.

(4) To meet the requirements of G.3045.E, 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.

(5) 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.

F. Aside from the notification requirement, nothing in this section 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.

G. A licensee shall:

(1) Annotate a copy of the report provided to the Agency with the:

(a) Name of the individual who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

3047. Report and notification of a dose to an embryo/fetus or a nursing child.

A. A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

B. A licensee shall report any dose to a nursing child that was not specifically approved in advance by the authorized user or that is a result of an administration of radioactive material to a breast-feeding individual that:

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

C. 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 G.3047.A or G.3047.B.

D. 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 G.3047.A or G.3047.B.

(1) The written report must include:

(a) The licensee's name;

(b) The name of the prescribing physician;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the embryo/fetus or the nursing child;

(f) What actions, if any, have been taken or are planned to prevent recurrence; and

(g) Certification that the licensee notified the pregnant individual or mother (or the mother’s or child’s responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child’s name or any other information that could lead to identification of the individual or child.

E. The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under G.3047.A or G.3047.B, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful.

(1) 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.

(2) 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.

(3) To meet the requirements of G.3047.E, the notification may be made to the mother’s or child’s responsible relative or guardian instead of the mother.

(4) 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.

F. A licensee shall:

(1) Annotate a copy of the report provided to the U.S. Nuclear Regulatory Commission with the:

(a) Name of the pregnant individual or the nursing child who is the subject of the event; and

(b) Social Security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

3067. Report of a leaking source. A licensee shall file a report within five days if a leak test required by G.67 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The report must be filed with the Agency. 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.

3075. Reports of patient departure prior to authorized release or patient death.

A. 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 G.75.G.

(1) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure release. 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 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.

B. 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 the limits in Part D.1301 of this rule as a result of the deceased's body.

(1) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in G.3076.A. 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(s) of known individuals who might have received exposures exceeding 5 millisieverts (500 mrem).

PART H.

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL AND OTHER INDUSTRIAL RADIATION MACHINES

1. **Purpose and scope**. This Part provides special requirements for the use of analytical and other industrial radiation machines not otherwise covered by the rule. The requirements of this Part are in addition to, and not in substitution for, applicable requirements in other Parts of this rule. This includes, but is not limited to, the following sections of Part F: F.1, F.2, F.3.M, F.4, and F.7.

2. **Definitions.** As used in this Part, the following definitions apply:

Analytical radiation machine includes, but is not limited to, x-ray diffraction, fluorescence analysis, spectroscopy, or particle size analysis.

Cabinet x-ray system means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system. The cabinet x-ray system is intended to:

(a) Contain at least that portion of a material being irradiated;

(b) Provide radiation attenuation; and

(c) Exclude personnel from its interior during generation of radiation.

Certifiable cabinet x-ray system means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR Parts 1010 through 1020.

Certified cabinet x-ray system means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled on or after April 10, 1975, according to the provisions of 21 CFR 1020.40.

Fail-safe characteristics mean a design feature, which causes beam port shutters to close, or otherwise prevent emergence of the primary beam, upon the failure of a safety or warning device.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

Local components mean part of an x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

Normal operating procedures mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include, sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

Open-beam configuration means a radiation machine in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

Other industrial radiation machine includes, but is not limited to, x-ray equipment (including cabinet x-ray equipment) used for cathodoluminescence, ion implantation, gauging, or electron beam welding.

Primary beam means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.
Safety device means a device that prevents the entry of any portion of an individual's body into the primary x-ray beam path or that causes the beam to be shut off upon entry into its path.

X-ray system means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

3. Equipment requirements.

A. Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated

(2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

B. Warning devices.

(1) Open-beam configurations shall be provided with a visible 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 effective date of this rule, warning devices shall have fail-safe characteristics.

(3) The x-ray control shall provide visual indication whenever x-rays are produced.

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 radiation machines shall be labeled in a conspicuous manner to caution individuals that radiation is produced when it is energized with a 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 similar intent, on the source housing in accordance with Part D.1901 of this rule if the radiation source is a radionuclide.

E. Shutters. On open-beam configurations installed 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 effective date of this rule, warning lights shall have fail-safe characteristics.

G. Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

(1) Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(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 5 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 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem (2.5 mSv) in one hour.

4. Hand held XRF analyzers (Non medical). All persons/companies purchasing hand held analyzers that emit electronically produced x-rays (XRF) shall be held to the following requirements.

A. Safety plan, analytical procedures, training manual and registration paperwork shall be submitted and approved by the X-Ray Section of the Radiation Control Program (RCP) prior to use of the analyzer.

B. When not in use, the unit shall be stored in a secured area, so that it is not accessible to anyone without authorization to use it.

C. Personnel using the analyzer shall wear appropriate radiation dosimetry to assess exposure to both "whole body" and "extremities." Personnel exposure will be reported to the X-Ray Section of the Radiation Control Program on a quarterly basis for a minimum of one year. (Dosimetry requirement may be relaxed after this initial monitoring period, depending upon exposure values.)

D. Analyzer shall not be used with "Dead Man Trigger" deactivated prior to specific approval (for this mode of operation) by the [X-Ray Section of the State of Maine's Department of Health and Human Services Radiation Control Program.] Any procedure that uses this mode of operation shall include proper radiological postings and / or securing of the area (per guidance from the RCP personnel).

E. All manufacturer recommendations for periodic maintenance and calibration frequency shall be followed.

F. A radiological safety officer shall be designated to be responsible for proper storage, usage, training of authorized employees, distribution of dosimetry, maintenance of exposure records (including reporting of quarterly exposure records to the X-Ray Section of the Radiation Control Program), procedural compliance, and all other safety requirements regarding the unit.

G. Only personnel who have been trained and certified by the RSO or the manufacturer's training program shall be permitted to operate the unit.

H. A trained and certified user shall be present at all times while the unit is being operated.

I. The unit and radiation safety program of the registrant shall be inspected by a qualified expert or RCP inspector within 30 days of registration. (A list of Maine Certified Qualified Experts can be obtained from the X-Ray Section of the Radiation Control Program.)

J. Requests for exemptions from any of this rule shall be submitted, along with detailed justification, to the X-Ray Section of the Radiation Control Program in writing. Exemptions shall not be implemented prior to receiving written approval by the RCP.

K. All companies selling or distributing hand-held XRF analyzers (non-medical) for use in the State of Maine shall notify the state of Maine's Department of Health and Human Services Radiation Control Program of all sales and include Part H.4 in their sales agreement. The following Information shall be provided to the Radiation Control Program:

(1) Model name and number of unit;

(2) Number of units;

(3) Name of company / person purchasing unit(s);

(4) Address company / person purchasing unit(s);

(5) Phone number of company / person purchasing unit(s); and

(6) Email address of company / person purchasing unit(s).

5. Area requirements.

A. Radiation levels. The local components of an x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in Part D.1301 of this rule. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

B. Surveys.

(1) Radiation surveys, as required by Part D.1501 of this rule, of all radiation machines and x-ray systems sufficient to show compliance with H.5.A shall be performed:

(a) Upon installation of the equipment, and as specified in Part F.3.C.3(f);

(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 D.1201 of this rule.

(2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with H.5.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.

6. Operating requirements.

A. Procedures. Normal operating procedures shall be written and available to all radiation machine operators. No person shall be permitted to operate radiation machines in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

B. Bypassing. No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device 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 radiation machines. Except as specified in H.6.B, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

D. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, or an Agreement State.

E. Whenever x-ray work is performed at a location other than a permanent installation, the radiographer must notify the requesting site's radiation safety officer or the person responsible for safety matters for those site's that do not have a radiation safety officer, before taking or utilizing radiation machines on the jobsite.

7. Personnel requirements.

A. Instruction. No person shall be permitted to operate or maintain radiation machines unless such person 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 and safety procedures for the radiation machine;

(4) Recognition of symptoms of an acute localized exposure; and

(5) Proper procedures for reporting an actual or suspected exposure in excess of limits specified in Part D.

B. Personnel Monitoring.

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:

(a) Radiation machine workers using systems having an open-beam configuration and not equipped with a safety device; and

(b) Personnel maintaining radiation machines if the maintenance procedures require the presence of a primary x-ray beam when any local component in the x-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with D.1201 of this rule unless evaluated by a qualified individual per H.8.B.

8. Periodic inspection

A. Pursuant to 22 MRS§ 682, duly authorized employees of the Department of Health and Human Services may enter into establishments during working hours to determine whether there is compliance with provisions of the Radiation Protection Act, 22 M.R.S. Chapter 160.

B. Only those individuals, who meet the qualifications below and authorized by the Agency, shall be utilized to perform inspection and calibration services, and to certify x-ray units and radiation machines pursuant to this Part. To be eligible for qualification, an individual must:

(1) Apply for and be listed as a qualified expert per F.5 of ~~these regulation~~; or

(2) Apply for and be listed as a qualified individual as outlined below:

(a) Possess a high school diploma; and

(i) A BS or BA degree in health physics or radiological health degree and have one year of experience in the field of analytical or industrial x-ray machines;

(ii) Have educational training equivalent to the above criteria; as determined by the Agency; and have five years' experience in the field of analytical or industrial x-ray machines.

C. Except as stated in Part F.3.C.4, the licensee of all x-ray facilities shall have radiation machines and tubes inspected once every two years.

D. Upon notification or discovery of a violation to the rules stated in this section, the Department may, in its notice of violation to the licensee, require a re-inspection, by a qualified individual per H.8.B. This increase in frequency of inspection will depend upon the severity of the violation.

9. Annual registration fees. All annual fees are to be paid to the Agency as outlined in Part F, Appendix F, by January 1 of each year.

PART I.

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

1. Purpose and scope.

A. This part establishes procedures for the licensing and the use of all particle accelerators.

B. In addition to the requirements of this part, all licensees are subject to the requirements of Parts A, B, C, D, and J of this rule. Licensees engaged in industrial radiographic operations are subject to the requirements of Part E of this rule and licensees engaged in the healing arts are subject to the requirements of Part F and/or Part G of this rule. Licensees whose operations result in the production of radioactive material are subject to the requirements of Part C of this rule.

LICENSE PROCEDURE

2. License requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a license issued pursuant to Parts B and C of this rule.

3. General requirements for the issuance of a license for particle accelerators. In addition to the requirements of Parts B and C of this rule, a license 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 this Part and Parts D and J of this rule in such a manner as to minimize danger to public health and safety or property;

B. The applicant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

C. The issuance of the license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in I.4;

D. The applicant has appointed a 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.

4. Human use of particle accelerators. In addition to the requirements set forth in Part B of this rule a license for use of a particle accelerator in the healing arts will be issued only if:

A. The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator whenever

deemed necessary by the Agency. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

B. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

C. The individual designated on the application as the user is a physician.

RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

5. {Reserved}

6. Limitations.

A. No licensee 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 an instruction in this Part and the applicable requirements of Part C and J of this rule, pertinent license conditions and the licensee'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 protect health and minimize danger to public health and safety or property.

7. Shielding and safety design requirements.

A. A qualified expert, acceptable to the Agency shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

B. Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with Part D.2 and D.6 of this rule.

8. Particle accelerator controls and interlock systems.

A. Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

B. Each entrance into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.

C. Each safety interlock shall be on a circuit which shall allow its operation 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 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.

9. 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 such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and all radiation areas.

C. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with Part D.11 of this rule.

10. Operating procedures.

A. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

B. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

C. All safety and warning devices, including interlocks, shall be checked for proper operability 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 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.

11. Radiation monitoring requirements.

A. There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

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.

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 area 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.

12. Ventilation systems.

A. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Part D, Appendix A, Table I of this rule.

B. A licensee, as required by Part D.7 of this rule, shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceed the limits specified in Part D, Appendix A, Table II of this rule, except as authorized pursuant to D.17, or D.7.B of this rule. For purposes of I.12.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.

PART J.

NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

1. Purpose and scope. This Part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own or transfer sources of radiation licensed by or registered with the Agency pursuant to Parts B and C of this rule.

2. Posting of notices to workers.

A. Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this Part and in Part D of this rule;

(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 Part A of this rule, and any response from the licensee or registrant.

B. If posting of a document specified in J.2.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. Agency Form HHE-845 Notice to Employees shall be posted by each licensee or registrant as required by this rule.

D. Agency documents pursuant to J.2.A.4 shall be posted within two working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within two 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 J.2 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.

3. 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 100 mrem (1mSv):

(1) Shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area;

(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 this rule and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

(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, this rule, 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 J.4

B. In determining those individuals subject to the requirements of J.3.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 in the work place.

4. Notifications and reports to individuals.

A. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in J.4. The information reported shall include data and results obtained pursuant to this rule, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to Part D.2106. of this rule. 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 the State of Maine Rules Relating to Radiation Protection, Part J. You should preserve this report for further reference."

B. Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of D.2106. The licensee or registrant shall provide an annual report to each individual monitored under D.1502 of the dose received in that monitoring year if:

(1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 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 to each worker a report of the worker's exposure to radiation or radioactive material 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 D.18 of this rule. 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 by D.2202, D.2203 or D.2204 of regulation to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also provide the individual a report on his or her exposure data included in the report to the Agency. This report to the individual must be transmitted no 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, or of a worker who, while employed by another person, is terminating assignment to work involving exposure to radiation or radioactive material, during the current year, in the licensee's or registrant's facility, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, 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.

5. 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 this rule.

B. During an inspection, Agency inspectors may consult privately with workers as specified in J.6. 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 J.3.

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 worker’s representative at a time may accompany the inspectors.

F. With the approval of the licensee or registrant and the worker’s 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 worker's representative shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

G. Notwithstanding the other provisions of J.5, 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.

6. 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 this rule 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 he or she has reason to believe may have contributed to or caused any violation of the Act, this rule, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of J.7.A.

C. The provisions of J.6.B shall not be interpreted as authorization to disregard instructions pursuant to J.3.

7. Requests by workers for inspections.

A. Any worker or representative of workers who believes that a violation of the Act, this rule 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 Radiation Control

Program, Maine Center for Disease Control and Prevention, Department of Health and Human Services, 11 State House Station, Augusta ME 04333-0011. 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 Department of Health and Human Services 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 Department of Health and Human Services determines that the complaint meets the requirements set forth in J.7.A, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to J.7 need not be limited to matters referred to in the complaint.

C. No licensee, registrant, 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 this rule 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 this Part.

8. Inspections not Warranted; informal review.

A. If the Department of Health and Human Services determines, with respect to a complaint under J.7, that an inspection is not warranted because there are not reasonable grounds to believe that a violation exists or has occurred, the Department of Health and Human Services 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 Radiation Control Program who 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 of Health and Human Services who will provide the complainant with a copy of such statement by certified mail.

B. Upon the request of the complainant, the Radiation Control Program 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. After considering all written and oral views presented, the Department of Health and Human Services shall affirm, modify, or reverse the earlier determination of the Department of Health and Human Services and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

C. If the Department of Health and Human Services determines that an inspection is not warranted because the requirements of J.7.A have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of J.7.A.

PART K.

RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

1. Purpose and scope.

A. For the purpose of this rule, the requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers, and subsurface tracer studies as specified in 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging," are incorporated by reference. The requirements of this section are in addition to, and not in substitution for, the requirements of Parts A, B, C, D, and J of this rule.

B. Notwithstanding the requirements incorporated by reference, 10 CFR 39.5 (relating to interpretations), 10 CFR 39.8 (relating to information collection), 10 CFR 39.101 (relating to violations), and 10 CFR 39.103 (relating to criminal penalties) are not incorporated by reference.

2. Effect of incorporation of 10 CFR Part 39 (effective date May 17, 2000).

A. To reconcile differences between this part and the incorporated sections of 10 CFR Part 39 (relating to using sources of radiation for wireline service operations including mineral logging, radioactive markers, and subsurface tracer studies), the following words and phrases are substituted for the language in 10 CFR Part 39 as follows:

(1) A reference to NRC or Commission means Agency.

(2) A reference to NRC or Agreement State, means Agency, NRC, Agreement State or Licensing State.

(3) The definition of licensed material shall be as defined in Part A of this rule.

(4) The definition of sealed source shall be as defined in Part A of this rule.

PART L.

TRANSPORTATION OF RADIOACTIVE MATERIAL

1. Purpose

A. For the purpose of this rule, the requirements for persons transporting sources of radiation as specified in 10 CFR Part 71, "Relating to Packaging and Transportation of Radioactive Material," are incorporated by reference. The requirements of this section are in addition to, and not in substitution for, the requirements of Parts A, B, C, D, and J of this rule.

B. Notwithstanding the requirements incorporated by reference, 10 CFR 71.2 (relating to interpretations), 10 CFR 71.6 (relating to information collection), 10 CFR 71.10 (b) and (c) (low level material exemptions), 10 CFR 71.19 (previously approved packages), 10 CFR 71.14(b) (exemption for low level materials), 10 CFR 71 Subpart D (Application for Package Approval), 10 CFR 71 Subpart E (except 71.47)(Package Approval Standards), 10 CFR 71 Subpart F (Package, Special Form, and LSA-III tests), 10 CFR 71.99 (relating to violations), 10 CFR 71.100 (relating to criminal penalties), and 10 CFR 71.101(c)(2), (d), and (e) are not incorporated by reference.

2. Effect of Incorporation of 10 CFR Part 71 (effective date June 14, 2015). To reconcile differences between this part and the incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), the following words and phrases are substituted for the language in 10 CFR Part 71 as follows:

A. A reference to NRC or "Commission means Agency.

B. A reference to NRC or Agreement State means Agency, NRC, Agreement State or Licensing State.

PART N.

REGULATION AND LICENSING OF TECHNOLOGICALLY ENHANCED NATURALLY OCCURRING RADIOACTIVE MATERIALS (TENORM)

1. Purpose. This Part establishes radiation protection standards for technologically enhanced naturally occurring radioactive materials (TENORM). This includes the possession, use, processing, distribution, transfer, disposal and manufacture of products of TENORM. This Part also establishes requirements for issuance of specific and general licenses to possess and use TENORM, including license termination.

2. Scope.

A. Except as otherwise excluded in this Part, Part N applies to any person who receives, owns, possesses, uses, processes, transfers, distributes, or disposes of TENORM.

B. The regulations in this Part address the introduction of TENORM into products in which neither the TENORM, nor the radiation emitted from the TENORM, is considered to be beneficial to the products.

C. The manufacture and distribution of products containing TENORM, in which the TENORM and/or its emitted radiation is considered to be a beneficial attribute, are licensed under the provisions of Part C of this rule.

D. This Part does not apply to source material and byproduct material as both are defined in the Atomic Energy Act of 1954, as amended (42 USC §2011 et seq.) as implemented by the US Nuclear Regulatory Commission.

E. The transportation and storage incident to transportation are governed by Parts L and D respectively of this rule.

3. Definitions. As used in this Part, the following definitions apply:

Beneficial to the product means the radioactivity of the TENORM is necessary to the product.

Conditional release means the release by a licensee for a specified use, not release for unrestricted use.

Consumer means a member of the public exposed to TENORM from final end-use products available on a retail basis.

Consumer or retail product means any product, article, or component part thereof, produced, distributed or sold for use by a consumer in or around a permanent or temporary household or residence, or for the personal use, consumption, or enjoyment of a consumer, or for use in or around a school or playground.

Natural radioactivity means radioactivity of naturally occurring nuclides.

NARM means any naturally occurring or accelerator-produced radioactive material

Product means something produced, made, manufactured, refined, or beneficiated.

Reasonably maximally exposed individual means a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

Technologically enhanced naturally occurring radioactive material (TENORM) means naturally occurring radioactive material whose radionuclide concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not source material and byproduct material as both are defined in the Atomic Energy Act of 1954, as amended (42 USC §2011 et seq.) as implemented by the Nuclear Regulatory Commission.

Transfer means the physical relocation of TENORM within a business's operation or between general or specific licensees. This term does not include commercial distribution or a change in legal title to TENORM that does not involve physical movement of those materials.

4. Exemptions.

A. Persons who receive, own, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of Part N with respect to any combination of ^{226}Ra and ^{228}Ra if the materials contain, or are contaminated at, concentrations less than 185 becquerel per kilogram (5 pCi/gm) excluding natural background. This exemption does not apply to products that are regulated pursuant to N.13.C. and N.14[1].

B. Persons who receive products or materials containing TENORM distributed in accordance with a specific license issued by the Agency pursuant to N.11.A., or to an equivalent license issued by another Licensing State, are exempt from this Part with regard to those products or materials.

C. The distribution, including custom blending, possession, and use and disposal of fertilizers and zircon, zirconia, and zircon products containing TENORM, is exempt from the requirements of this Part.

D. TENORM waste regulated by the Comprehensive Environmental Response, Compensation Liability Act (CERCLA 42 USC §9601 et seq. as amended) or by the Resources Conservation and Recovery Act (RCRA 42 USC §6901 et seq. as amended) are exempt from this Part.

E. Other TENORM shall be exempt when the Agency makes a determination, upon its own initiative or upon request for such determination, that the reasonably maximally exposed individual will not receive a TEDE of more than 1 mSv (0.1 rem) in one year from all exposure pathways. The dose specified in this subsection does not include occupational dose, dose received from background radiation, or dose received as a result of administration of radioactive material to a patient.

[1] To apply this exemption to equipment such as pipe, it must be determined that the concentration of total radium is less than 85 pCi per gram, excluding the weight of the pipe or object contaminated with TENORM.

5. Standards for radiation protection for TENORM.

A. No person licensed under N.10 or N.11 shall conduct operations, use process, distribute or transfer TENORM in a manner such that a member of the general public will receive an annual TEDE in excess of 100 mrem (1 millisievert) per year from all licensed sources including TENORM.

B. Persons subject to a license under this Part shall comply with the standards for radiation protection for members of the public set out in Part D of this rule.

C. Doses from inhalation of indoor radon and its short half-life (less than one hour) progeny shall not be included in calculations of the TEDE, unless specifically directed otherwise by the Agency. The Agency will provide its basis if it directs the inclusion of radon in such calculations.

D. No person shall release TENORM for unrestricted use in such a manner that the reasonably maximally exposed individual will receive an annual TEDE from the released TENORM, excluding inhalation of radon and its short half-life (less than 1 hour) radon progeny, in excess of 10 mrem (0.1 millisievert) per year, excluding natural background.

E. Actions taken to confine TENORM on site or to remediate sites shall be based on expected longevity related controls for 1000 years.

6. Protection of workers during operations. Each person subject to a specific or general license under Part N shall conduct operations such that protection of workers is in compliance with the standards for radiation protection set out in Parts D and J of this rule.

7. Unrestricted use and conditional release. Each person subject to a specific or general license under this Part shall only:

A. Transfer or release equipment for unrestricted use or release for unrestricted use facilities contaminated with TENORM which are not greater than the levels in Appendix A of this Part. Upon application, specific approval of alternative levels may be granted by the Agency;

B. Release land for unrestricted use where the concentration of TENORM ^{226}Ra and ^{228}Ra, averaged over 100 square meters, is less than 185 becquerel per kilogram (5 pCi/gm) above the background concentration, averaged over any 15 cm layer of soil below the surface, or compliance with N.5.B. through N.5.D. is demonstrated;

C. Transfer or release for conditional use in metal recycle, equipment contaminated with TENORM producing a maximum exposure level of 50 microroentgen per hour (0.5 uGy), including background radiation, at any accessible location. Recycling shall not include the processing or use of materials in a manner that constitutes disposal without specific written approval of the Agency[2];

D. Transfer or conditionally release with written documentation by the licensee to a specified facility. Written documentation shall include the date, recipient name and

[2] States may establish screening levels based on gamma survey instrument results for use in releasing facilities and equipment, consistent with N.5.

location, description and quantity of the material, and a description of the procedures and mechanisms used to ensure that material will not be released in another manner, as an unrestricted release; or

E. Transfer equipment contaminated with TENORM in excess of levels specified in Appendix A pursuant to N.10.E.

8. Disposal and transfer of waste for disposal.

A. Each person subject to a specific or general license under this Part shall manage and dispose of wastes containing TENORM:

(1) By transfer of the wastes for disposal to a facility licensed under requirements for uranium or thorium byproduct materials in 40 CFR 192, 10 CFR 40 Appendix A, or equivalent regulations of an Agreement State that do not exclude disposal of TENORM; or

(2) By transfer of the wastes for disposal to a disposal facility licensed by the US Nuclear Regulatory Commission, or an Agreement State, pursuant to an authorization that does not exclude disposal of TENORM; or

(3) In accordance with alternate methods authorized by the permitting Agency for the disposal site upon application or upon the Agency's initiative, consistent with N.5 and where applicable the Clean Water Act, Safe Drinking Water Act and other requirements of the U.S. Environmental Protection Agency for disposal of such wastes.

B. Equipment contaminated with TENORM in excess of levels specified in N.7.A. or N.7.B., which is to be disposed of as waste, shall be disposed:

(1) In a manner that will prevent any reintroduction into commerce or unrestricted use; and

(2) Within disposal areas specifically designed to meet the criteria referred to in N.8.A.

C. Transfers of waste containing TENORM for disposal shall be made only to a person specifically authorized by the US Nuclear Regulatory Commission, or an Agreement State, to receive such waste, or other agency with appropriate permitting authority. However, TENORM waste may also be transferred to authorized solid waste disposal facilities, providing such facility is not expressly prohibited from receiving and disposing such TENORM waste and the disposal is in accordance with applicable federal and state law.

D. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Part D of this rule.

E. Purposeful dilution to render TENORM waste exempt shall not be performed without prior Agency approval.

F. A licensee may dispose of TENORM [not away from the point of generation] in an injection well approved in accordance with Maine Department of Environmental Protection permitting requirements.

9. **Prohibition.** Purposeful dilution to render TENORM exempt shall not be performed without prior Agency approval.

General License

10. **General license.**

A. Subject to the requirements of N.5 through N.10, a general license is hereby issued to possess, own, use, transfer, distribute or dispose of TENORM without regard to quantity.

B. This general license does not authorize the manufacturing of consumer or retail products containing TENORM in concentrations greater than those specified in N.4.A. nor the receipt and disposal of wastes from other persons.

C. Employees or contractors under control and supervision of a general licensee can perform routine maintenance on equipment, facilities, and land owned or controlled by the general licensee. Maintenance that provides a pathway for exposure different from that found in daily operations and that increases the potential for additional exposure is not considered routine maintenance. The decontamination of equipment, facilities, and land shall be performed only by persons specifically licensed by the Agency or another Licensing State to conduct such work.

D. Any person subject to the general license issued by section.10.A. shall notify the Agency within 60 days of the effective date of this Part or of becoming subject to the general license. Such notification shall include:

(1) Name and address of the licensee;

(2) Location and description of the facility or operation;

(3) Description of the TENORM including estimates of the amount and extent of TENORM.

E. Transfer of material, equipment or real property.

(1) The transfer of TENORM not exempt from this rule from one general licensee to another general licensee is authorized if:

(a) The equipment and facilities contaminated with TENORM are to be used by the recipient for a similar purpose, provided a dose in excess of N.5.A. is not exceeded; or

(b) The transfer of control or ownership of land contaminated with TENORM includes an annotation of the deed records and/or notice to owners of surface and mineral rights to indicate the presence of TENORM.

(2) Transfers not made in accordance with N.10.E.(1) require prior approval by the Agency.

(3) For transfers made under N.10.E.(1), the general licensee who makes the transfer shall assess the extent of TENORM contamination or material present, inform the general licensee receiving the TENORM of these assessments prior to such transfer, and maintain records required by this rule.

(4) A general licensee intending to transfer material or real property for unrestricted use shall document compliance with the requirements of N.7 of this regulation. Records of such compliance shall be kept until the registration is terminated with this Agency.

(5) For transfers not made in accordance with N.10.E.(1), prior written approval by the Agency is required. To obtain Agency approval, the transferor shall submit information that demonstrates compliance with N.7. Records of such compliance shall be maintained as specified in Part D.

F. Distribution of TENORM products between general licensees. The distribution of TENORM products not exempt from this rule from one general licensee to another general licensee is authorized provided the product is accompanied by written disclosure of the type and amount of TENORM.

G. The Agency may, by written notice, require any person authorized by a general licensee to apply for and obtain a specific license if the Agency determines that specific licensure is necessary to ensure that exposures do not exceed the criteria. The notice shall state the reason or reasons for requiring a specific license.

Specific Licenses

11. Specific licenses.

A. A specific license is required under N.13 and N.14 to manufacture and distribute any consumer or retail product containing TENORM unless:

(1) Authorized as specified by N.10.A or N.10.F.;

(2) Licensed under the provisions of part C of this rule;

(3) Exempted under the provisions of N.4; or

(4) Otherwise exempt in accordance with another Part of this rule.

B. A specific license is required to decontaminate equipment or land not exempted under the provisions of N.4 or to decontaminate facilities contaminated with TENORM in excess of the levels in N.7, except as provided in N.10.C. For purposes of this subsection, the term decontaminate shall not include routine maintenance, which incidentally results in removal of contamination;

C. A specific license is required to receive TENORM from other persons for disposal unless otherwise exempt, or authorized in writing by the Agency.

12. Filing application for specific licenses.

A. Applications for specific licenses shall be in English and filed in a manner and on a form prescribed by the Agency, and in accordance with C.7.

B. The Agency may at any time after the filing of the original application, and before the termination 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 the licensee's behalf.

D. An application for a license may include a request for a license authorizing one or more activities.

E. Each application for a specific license shall be accompanied by the fee prescribed in Part C.

13. Requirements for the issuance of specific licenses.

A. A license application will be approved if the Agency determines that:

(1) The applicant is qualified by reason of training and experience to use the TENORM in question for the purpose requested in accordance with this rule in such a manner as to protect the public health and safety or property;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect the public health and safety or property;

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

(4) The applicant satisfied all applicable special requirements in this Part; and

(5) The applicant has met the financial assurance requirements of N.26.

(6) The applicant has adequately addressed the following items in the application:

(a) Procedures and equipment for monitoring and protecting workers;

(b) An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

(c) Operating and emergency procedures, including procedures for waste reduction and a quality assurance program designed to assess the adequacy of measurements made for the purpose of releasing items for unrestricted use; and

(d) A method for managing the radioactive material removed from contaminated equipment and facilities.

(7) For each location to be listed on the license as an authorized use location, the applicant shall submit either:

(a) A statement that the applicant owns the facility where radioactive material is to be used or stored; or

(b) A statement verifying that the facility owner has been informed, in writing, of the use or storage of radioactive material at the facility, and that the use of such material is subject to the rules of the Agency.

B. An application for a specific license to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in N.4.A., N.7.B., or Appendix A of this Part, as applicable, and to dispose of the resulting waste will be approved if:

(1) The applicant satisfies the general requirements specified in N.13.A.; and

(2) The applicant has adequately addressed the following items in the application:

(a) Procedures and equipment for monitoring and protection of workers;

(b) An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

(c) Operating and emergency procedures, including procedures for waste reduction and a quality assurance program designed to assess the adequacy of measurements made for the purpose of releasing items for unrestricted use; and

(d) Method of disposing of the TENORM removed from contaminated equipment, facilities, or land.

C. An application for a specific license to transfer or manufacture or distribute consumer or retail products containing TENORM to persons exempted from this rule pursuant to N.4.B. will be approved if:

(1) The applicant satisfies the general requirements specified in N.13.A.;

(2) The TENORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and

(3) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the TENORM product to demonstrate that the product will meet the safety criteria set forth in N.13. The information shall include:

(a) A description of product and its intended use or uses;

(b) The type, quantity, and concentration of TENORM in each product;

(c) The chemical and physical form of the TENORM in the product, and changes in chemical and physical form that may occur during the useful life of the product;

(d) An analysis of the solubility in water and body fluids of the radionuclides in the product;

(e) The details of manufacture and design of the product relating to containment and shielding of the TENORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the product;

(f) The degree of access of human beings to the product during normal handling, use, and disposal;

(g) The total quantity of TENORM expected to be distributed annually in the product;

(h) The expected useful life of the product;

(i) The proposed method of labeling or marking each unit of the product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the product;

(j) The procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;

(k) The results of the prototype testing of the product, including any change in the form of the TENORM contained in it, the extent to which the TENORM may be released to the environment, any change in radiation levels, and any other changes in safety features;

(l) The estimated external radiation doses and dose commitments relevant to the safety criteria in N.14 and the basis for such estimates;

(m) A determination that the probabilities with respect to doses referred to in N.14 meet the safety criteria;

(n) The quality control procedures to be followed in the processing of production lots of the product, and the quality control standards the product will be required to meet; and

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

D. Notwithstanding the provisions of N.14.B., the Agency may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

14. Safety criteria for products. An applicant for a license under N.13.C. shall demonstrate that the product is designed and will be manufactured so that:

A. In normal use and disposal of a single exempt item, as defined in Part C, and in normal handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the TEDE in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the doses in Column I of N.15.

B. In use and disposal of a single exempt item and in handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low[3] that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in N.14 and the probability is negligible*/that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in N.15[4].

C. It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

15. Table of doses.

Part of Body	Column I* Dose	Column II* Dose	Column III* Dose
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.05 mSv (0.005 rem)	5 mSv (0.5 rem)	150 mSv (15 rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.75 mSv (0.075 rem)	75 mSv (7.5 rem)	2000 mSv (200 rem)
Other organs	0.15mSv (0.015 rem)	15 mSv (1.5 rem)	500 mSv (50 rem)
*Dose limit is the dose above background from the product.			

16. Issuance of specific licenses.

A. Upon a determination that an application meets the requirements of Part C, 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.

[3] Low – not more than one such failure per year for each 10,000 exempt units distributed. Negligible – not more than one such failure per year for each one million exempt units distributed.

[4] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The above values may be used as guidelines in estimating compliance with the criteria.

B. The Agency may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of TENORM subject to this Part as it deems appropriate or necessary in order to:

(1) Protect 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, theft, or loss of control of TENORM subject to this Part.

17. Conditions of specific licenses issued under N.13.

A. General Terms and Conditions

(1) Each specific license issued pursuant to this Part shall be subject to all the provisions of Title 22 MRS, Maine Radiation Protection Statutes, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(2) No specific license issued or granted under this Part and no right to possess or utilize TENORM granted by any license issued pursuant to this Part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Title 22 MRS, Maine Radiation Protection Statutes, and shall give its consent in writing.

(3) Each person specifically licensed by the Agency pursuant to this Part shall confine use and possession of the TENORM licensed to the locations and purposes authorized in the specific license.

(4) Each person specifically licensed by the Agency pursuant to this Part is subject to the general license provisions of N.5 through N.8.

(5) Notification of Bankruptcy:

(a) Each licensee shall notify the Agency, in writing, (Radiation Control Program, Maine Center for Disease Control and Prevention, Department of Health and Human Services, 11 State House Station, Augusta ME, 04333-0011) immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title II (Bankruptcy) of the United States Code (11 U.S.C.) by or against:

(i) A licensee;

(ii) An entity, as defined in 11 U.S.C. 101 (15), controlling a licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate, as defined in 11 U.S.C. 101 (2), of the licensee. This notification shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(6) Each licensee shall notify the Agency in writing and receive approval prior to commencing activities to reclaim the licensed facility.

(7) Notification of Site or Area Closure. When a licensee has permanently ceased use of radioactive materials at a site or portion of a facility and the licensee has not decontaminated the area, or when an area has not been used for a period of two years, the licensee shall, within 60 days, provide the following information in writing to the Agency:

(a) The location of the site or area;

(b) The plan for reclaiming or decontaminating the site or area; and

(c) An evaluation of any changes to the financial assurance submitted in accordance with N.26.

(8) Temporary Jobsites[5]

(a) When temporary jobsites are authorized on a specific license, TENORM may be used at temporary jobsites throughout the State of Maine in accordance with N.25 in areas not under exclusive federal jurisdiction.

(b) Before TENORM can be used at a temporary jobsite at any federal facility within the State of Maine, the jurisdictional status of the jobsite shall be determined as it pertains to the TENORM. Authorization for use of TENORM at jobsites under exclusive federal jurisdiction shall be obtained from the federal agency with jurisdiction for TENORM at the temporary jobsite.

B. Quality control, labeling, and reports of transfer. Each person licensed under N.13.C. shall:

(1) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Agency;

(2) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the TENORM in the product can be identified; and

[5] Authorization for use of TENORM at jobsites under exclusive federal jurisdiction must be obtained from the federal agency having jurisdiction of the property. Also, specific licenses issued by the Agency do not authorize activities in other states or in areas of exclusive federal jurisdiction in this state or in any other state. Before radioactive materials can be used at a temporary jobsite in another state or an area of exclusive federal jurisdiction, a license must be obtained from the appropriate state or federal agency.]

(3) Maintain records. By identifying, by name and address, each person to whom TENORM is transferred for use under N.4.B. or the equivalent regulations of another Licensing State, and stating the kinds, quantities, and uses of TENORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending December 31, and shall be filed within 90 days thereafter. If no transfers of TENORM have been made pursuant to N.13.C. during the reporting period, the report shall so indicate.

18. Expiration and termination of specific licenses.

A. Except as provided in N.18.B., the authority to engage in licensed activities as specified in the specific license shall expire at the end of the specified day in the month and year stated therein. Any expiration date on a specific license applies only to the authority to engage in licensed activities. Expiration of a specific license shall not relieve the licensee of responsibility for decommissioning its facility and terminating the specific license.

B. Each licensee shall notify the Agency immediately in writing and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination shall include the documents require by N.18.D(4) and shall otherwise substantiate that the licensee has met all of the requirements in N.18.D.

C. No less than 30 days before the expiration date specified in a specific license, the licensee shall either:

(1) Submit an application for license renewal pursuant to N.19; or

(2) Notify the Agency in writing, under N.18.B, if the licensee decides to not renew the license. The licensee requesting termination of a license shall comply with the requirements of N.18.D.

D. Termination of licenses:

(1) If a licensee does not submit a complete application for license renewal pursuant to N.19, the licensee shall, on or before the expiration date specified in the license;

(a) Terminate use of the TENORM specified in the license;

(b) Remove radioactive contamination to the level outlined in N.7, to the extent practicable;

(c) Properly dispose of the TENORM specified in the license;

(d) Submit a completed Agency Form HHE-892 Certificate–Disposition of Radioactive Materials; and

(e) Submit a radiation monitoring report to confirm the absence of TENORM specified in the license or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence

of residual radioactive contamination in some other manner. The radiation monitoring report shall specify the instrumentation used and certify that each instrument was properly calibrated and tested. The licensee shall, as applicable, report levels or quantities of:

(i) Beta and gamma radiation at 1 centimeter from surfaces in units, multiples, or subunits of sieverts or rem per hour or microroentgens per hour;

(ii) Gamma radiation at 1 meter from surfaces in units, multiples, or subunits of sieverts or rem per hour or microroentgens per hour;

(iii) Removable radioactivity on surfaces in units, multiples, or subunits of becquerels or curies per 100 square centimeters of surface area or in disintegrations (transformations) per minute per 100 square centimeters of surface area;

(iv) Fixed radioactivity on surfaces in units, multiples, or subunits of becquerels or curies per 100 square centimeters of surface areas or in disintegrations (transformations) per minute per 100 square centimeters of surface area;

(v) Radioactivity in contaminated liquids such as water, oils or solvents in units, multiples, or subunits of becquerels or curies per milliliter of volume or per gram of liquid; and

(vi) Radioactivity in contaminated solids such as soils or concrete in units, multiples, or subunits of becquerels or curies per gram of solid.

(2) If levels of residual radioactive contamination attributable to activities conducted under the license are less than those established in N.7, the licenses shall so certify. If the Agency determines that this certification and the information submitted pursuant to N.18.D(1)(e)(v) is adequate and monitoring confirms the findings, then the Agency will notify the licensee, in writing, of the termination of the license;

(3) If residual radioactive contamination attributable to activities conducted under the license are not in conformance with criteria established in N.7:

(a) The license continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM material present as contamination until the Agency notifies the license in writing that the license is terminated. During this time the licensee is subject to the provisions of N.18.E.

(b) In addition to the information submitted pursuant to N.18.D.(1)(d) and N.18.D.(1)(e), the licensee shall submit a plan for decontamination and disposal, if required, as regards residual TENORM contamination remaining at the time the license expires.

E. Each licensee who possesses TENORM material pursuant to N.18.D(6), following the expiration date specified in the license, shall:

(1) Limit actions involving TENORM as specified in the license to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use or conditional release and the Agency notifies the licensee in writing that the license is terminated.

19. Renewal of specific licenses.

A. Applications for renewal of specific licenses shall be filed in accordance with N.12.

B. In any case in which a licensee, not less than 30 days prior to expiration of an 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.

20. Amendment of specific licenses at request of licensee. Applications for amendment of a license shall be filed in accordance with N.12 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

21. Agency action on applications to renew and amend specific licenses. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in N.13.

22. Modification and revocation of specific 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 Title 22 MRSA, Maine Radiation Protection Statutes, or by reason of rules, regulations, and orders issued by the Agency.

B. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of 22 MRS Ch. 160, Radiation Protection Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of 22 MRS Ch. 160, Radiation Protection Act, or of the license, or of any rule, regulation, or order of the Agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless prior to the institution of proceedings unless 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.

23. Agency action to remove an authorized user or a radiation safety officer.

A. The Agency may act to remove authorized users or the appointed radiation safety officer from a license for any one or more of the following causes:

(1) Willfully evading the statute or regulations pertaining to the radiation safety program, or willfully aiding another person in evading such statute or regulations;

(2) Having been convicted of a felony under the laws of this State, another state, or the United States, unless the convicted individual demonstrates to the Agency that he has been sufficiently rehabilitated to warrant the public trust;

(3) Exhibiting significant or repeated incompetence in the handling of radioactive material, or in the performance of radiation safety officer duties;

(4) Performing authorized user duties or radiation safety officer duties in such a manner that requirements of the Agency are violated resulting in a threat to health and safety of an individual, other workers or the public; and

B. If, based upon any of the above grounds, the Agency determines that action to remove an authorized user or the appointed radiation safety officer from a radioactive material license is warranted, the Agency shall notify the individual and shall provide an opportunity for a hearing in accordance with Part B of this rule. An opportunity for a hearing shall be provided before the Agency takes action to remove an authorized user or a radiation safety officer from a license unless the Agency finds that an immediate removal is required to protect against immediate danger to health or safety, Title 22 MRSA, in which case the Agency shall remove the individual pending a hearing.

C. If the Agency finds that removal of an authorized user or a radiation safety officer is warranted, the usual action shall be a suspension of duties for up to one year. The term of suspension may be reduced by the Commissioner of the Department of Health and Human Services or his or her designee, upon the recommendation of the hearing officer, if the hearing officer finds, based upon evidence presented during a hearing, that the conditions leading to the 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 or deficiencies that cannot be cured within one year, the Agency shall remove the individual from the radioactive material license.

D. An individual who has been removed from a radioactive material license may seek reinstatement of duties by filing with the Agency a petition for reinstatement. Such petition may be filed one year or more after the beginning of the removal period. The individual shall be afforded a hearing in accordance with 5 MRS Ch. 375, and shall bear the burden of proof of establishing that the individual should be reinstated due to rehabilitation or other just cause.]

24. **Record keeping requirements for site reclamation.** Each licensee shall keep records of information important to the safe and effective reclamation of a facility in an identified location until the license is terminated by the Agency. If records of relevant information are maintained for other purposes, reference to these records and their locations may be used. For purposes of N.24, reclaiming[6] shall mean returning property to a condition or state such that the property no longer presents a health or safety hazard or threat to the environment. Information the Agency considers important to reclaiming includes:

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 radionuclides, quantities, forms and concentrations.

B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination, such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

C. If required by N.26, records of this reclaiming cost estimate prepared for the amount approved by the Agency for reclaiming.

25. **Reciprocal recognition of specific licenses.** Subject to this rule, any person who holds a specific license from an Agreement State or a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State pursuant to C.24 of this rule, 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 working 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 N.25.A.;

[6] For purposes of N.24, the term “reclaiming” includes but is not limited to those activities necessary to decommission the licensed facility, i.e., to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

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 TENORM possessed or used under the general license provided in N.25.A. except by transfer to a person:

(1) Specifically licensed by the Agency or by another Licensing State to receive such TENORM; or

(2) Exempt from the requirements for a license for such TENORM under N.4.

26. **Financial assurance arrangements.** Pursuant to Part D, each licensee or applicant for a license under N.12 shall post with the Agency financial assurance, or security, to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness of the licensee to meet the requirements of the Act and this rule. Financial assurance arrangements shall be one of the methods listed in C.8 and:

A. Be in an amount sufficient to meet the applicant's or licensee's obligations under the Act and this rule and shall be based upon Agency approved cost estimates;

B. Be established prior to issuance of the license or the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility;

C. Be continuous for the duration of the license and for a period coincident with the applicant or licensee's responsibility under the Act and this rule;

D. Be available in Maine subject to judicial process and execution in the event required for the purposes set forth; and

E. Be established within 90 days of the effective date of this regulation for licenses in effect on that date.

27. **Effective date.** The provisions and requirements of this Part shall take effect on the effective date of this rule and shall apply to all facilities or sites owned or controlled by a person on that date. Note: Products introduced into commerce and disposals approved prior to that date are not subject to the provisions of this Part.

APPENDIX A.

ACCEPTABLE SURFACE CONTAMINATION[1] LEVELS FOR TENORM

	AVERAGE[2, 3, 6]	MAXIMUM[2, 4, 6]	REMOVABLE[2, 3, 5, 6]
Alpha	5,000 dpm/100 cm^2	15,000 dpm /100 cm^2	1,000 dpm /100 cm^2
Beta-gamma	5,000 dpm/100 cm^2	15,000 dpm /100 cm^2	1,000 dpm /100 cm^2

[1] Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

[2] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[3] Measurements of average contamination level should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.

[4] The maximum contamination level applies to an area of not more than 100 cm^2.

[5] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of surface area A (where A is less than 100 sq. cm) is determined, the entire surface should be wiped and the contamination level multiplied by 100/A to convert to a “per 100 sq cm” basis.

[6] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr (2 μGy/hr) at 1 cm and 1.0 mR/hr (10 μGy/hr) at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

PART X.

THERAPEUTIC RADIATION MACHINES

1. **Scope**. This Part establishes requirements for use of therapeutic radiation machines. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of this rule. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts.

2. **Definitions.** As used in this Part the following definitions apply.

Absorbed dose rate means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible surface means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

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).

Authorized medical physicist means an individual as defined in G.2 and in compliance with the applicable provisions of Part G of this rule.

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.

Contact therapy system means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than 5 centimeters.

Dose monitor unit (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

External beam radiation therapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Field flattening filter means a filter used to homogenize the absorbed dose rate over the radiation field.

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to Subpart X.6.

Gantry means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

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.

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.

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.

Periodic quality assurance check means a procedure, which is performed to ensure that a previous calibration continues to be valid.

Practical range of electrons corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays.

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.

Radiation field (See Useful beam.)

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 preselected number of dose monitor units.

Secondary protective barrier (See Protective barrier.)

Shadow tray means a device attached to the radiation head to support auxiliary beam blocking material.

Simulator (radiation therapy simulation system) means any x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

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.

Target means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

Target skin distance (TSD) means the distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.

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

Therapeutic radiation machine means x-ray or electron producing equipment designed and used for external beam radiation therapy.

3. Administrative requirements

A. Administrative controls.

(1) Registrant. The registrant shall be responsible for directing the operation of the therapeutic radiation machines under his/her administrative control. The registrant or the registrant's agent shall ensure that the requirements of Part X are met in the operation of the therapeutic radiation machine(s).

(a) A therapeutic radiation machine that does not meet the provisions of this rule shall not be used for irradiation of patients.

(b) Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. The licensing requirements pursuant to 32 MRS Chapters 103 §9851 et. seq. and 331 §1100 I et. seq. as well as the associated rules established by the Radiologic Technology Board of Examiners shall be followed.

(2) Written safety procedures and rules shall be developed by an authorized 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.

(3) Individuals shall not be exposed to the useful beam except for medical therapy purposes unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate

exposure of an individual for training, demonstration or other non-healing arts purposes.

(4) 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 quality management program.

(5) 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:

(a) Report of acceptance testing;

(b) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Part X, as well as the name(s) of person(s) who performed such activities;

(c) Records of maintenance and/or modifications performed on the therapeutic radiation machine after August 1, 2001 as well as the name(s) of person(s) who performed such services;

(d) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

B. Records retention.

(1) All records required by Part X shall be retained until disposal is authorized by the Agency, unless another retention period is specifically authorized in Part X.

(2) All required records shall be retained in an active file from at least the time of generation until the next inspection.

4. General requirements

A. Protection surveys.

(1) The registrant shall utilize the services of an Agency approved radiological physicist to determine the shielding requirement prior to plan review and approval by the Agency.

(2) The registrant shall ensure that radiation protection surveys of all new facilities, and annually for existing facilities with an operable radiation measurement survey instrument calibrated in accordance with X.8. The radiation protection survey shall be performed by, or under the direction of an Agency approved Radiological 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:

(a) Radiation levels in restricted areas are not likely to because personnel exposures in excess of the limits specified in Part D of this rule.; and

(b) Radiation levels in unrestricted areas do not exceed the limits specified in Part D of this rule.

(3) In addition to the requirements of Part X.4.A(2) a radiation protection survey shall also be performed prior to any subsequent medical use:

(a) After making any change in the treatment room shielding;

(b) After making any change in the location of the therapeutic radiation machine within the treatment room;

(c) After relocating the therapeutic radiation machine.

(4) The survey record shall indicate all instances where the facility, in the opinion of a qualified expert, 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; 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;

(5) If the results of the surveys required by X.4.A(2) or X.4.A(3) indicate any radiation levels in excess of the respective limit specified in X.4.A(2) 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

(1) Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by X.4.A indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Parts D. of this rule, before beginning the treatment program the registrant shall:

(a) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Part D. of this rule

(b) Perform the survey required by X.4.A again; and

(c) Include in the report required by X.4 the results of the initial survey, a description of the modification made to comply with X.4 and the results of the second survey;

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 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt 60;

(b) For beams with energies equal to or less than 1 MV (1 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 X.4.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 X.4.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 X.4.C(1) and X.4.C(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, an Agency approved radiation therapy physicist.

D. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to X.6 or X.7 shall furnish a copy of the records required in X.4.A and X.4.B to the Agency within 30 days following completion of the action that initiated the record requirement.

5. Quality management program. The facility shall implement a quality management program. The facility may use the quality management programs found in either Appendix B or Appendix C.

6. 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) 50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in any one hour.

(2) >50 and <500 kV systems. The leakage air kerma rate measured at a distance of 1 meter from the target in any direction shall not exceed 1 cGy (1 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 5 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 X.6.A(1). and X.6.A(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 five percent 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 cannot be accidentally displaced at any possible tube orientation;

(2) For equipment installed after August 1, 2001, an interlock system prevents irradiation if the proper filter is not in place;

(3) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at 1 meter 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 cannot 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 5 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 preset time interval.

(1) A timer with a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

(2) The timer shall be a cumulative timer that activates with an indication of BEAM ON and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(3) The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(4) The timer shall permit accurate presetting and determination of exposure times as short as one second;

(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) Timer shall be accurate to within one percent 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 X.6., 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) A means for indicating x-ray tube potential and current;

(4) The means for terminating an exposure at any time;

(5) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

(6) For therapeutic radiation machines manufactured after August 1, 2001, a positive display of specific filter(s) in the beam.

J. Multiple tubes. When a control panel may energize more than one x-ray tube:

(1) It shall be possible to activate only 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 skin distance (TSD). There shall be a means of determining the central axis TSD to within 1 centimeter and of reproducing this measurement to within 2 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 X.9, 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 that 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 in a totally enclosed booth, which has a ceiling, inside the room;

(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

(4) When any door referred to in X.6.O(3) is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 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 X.6 shall be performed by, or under the direct supervision of, an Authorized 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:

(i) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

(ii) 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 X.6.P(1)(c):

(i) 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

(ii) 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 X.6.P(1)(c)(i)

(2) To satisfy the requirement of X.6.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 authorized 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 X.6, which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of X.6.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 authorized 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 X.6.P.(1). 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 X.6.P.(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the authorized 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 authorized medical physicist's quality assurance check procedures, the system shall be recalibrated as required in X.6.P.(1);

(5) The registrant shall use the dosimetry system described in X.4.C(2) to make the quality assurance check required in X.6.Q.(2.);

(6) The registrant shall have the Authorized Medical Physicist review and sign the results of each radiation output quality assurance check within one month of the date that the check was performed;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to X.6 are performed at intervals not to exceed one month;

(8) Notwithstanding the requirements of X.6.Q.(6) and X.6.Q.(7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by X.6.Q.(6) and X.6.Q.(7)

have been performed within the 30-day period immediately prior to said administration;

(9) To satisfy the requirement of X.6.Q.(7), safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance;

(b) 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 from inside and outside the treatment room;

(10) The registrant shall maintain a record of each quality assurance check required by X.6.Q.(1) and X.6.Q.(7) for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

R. Operating procedures.

(1) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of X.6.P and X.6.Q have been met;

(2) Therapeutic radiation machines shall not be left unattended unless secured pursuant to X.6.I.(5);

(3) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(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 Part D of this rule.

S. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with X.6 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 10 □Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with X.8.

7. 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 X.7 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 10 □Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with X.8.

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 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent 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 X.7.B.(1), the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent 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 August 1, 2001, 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 X.7.B(1) through X.7.B(3) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

C. Leakage radiation through beam limiting devices.

(1) Photon radiation. All adjustable or interchangeable beam limiting devices 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 two percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field;

(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 two percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line 7 centimeters outside the periphery of the useful beam; and

(b) A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line 2 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 2 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 10 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 1 square centimeter suitably protected against radiation, which has been scattered from material beyond the radiation detector. Measurements shall be made using 1 centimeter of water equivalent build up material.

D. Filters/wedges.

(1) Each wedge filter that 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 re-determined;

(2) If the absorbed dose rate information required by X.7.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 August 1, 2001, which utilizes 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.

E. Stray radiation in the useful beam. For equipment manufactured after August 1, 2001, 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 X.7 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 August 1, 2001, 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 August 1, 2001, 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 August 1, 2001, the design of the beam monitoring systems shall ensure that the:

(i) Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

(ii) 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 August 1, 2001, each display shall:

(i) Maintain a reading until intentionally reset;

(ii) Have only one scale and no electrical or mechanical scale multiplying factors;

(iii) Utilize a design such that increasing dose is displayed by increasing numbers; and

(iv) In the event of power failure, the beam monitoring information required in X.7.F(3)(e)(iii) 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 X.7 shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in X.7.G.(1) shall be able to detect field asymmetry greater than 10 percent; and

(3) The device(s) referenced in X.7.G.(1) shall be configured to terminate irradiation if the specifications in X.7.G.(2) cannot 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 August 1, 2001, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

I. Air kerma rate/absorbed dose rate. For equipment manufactured after August 1, 2001, 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 X.7.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 4 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 X.7.I.(2) and X.7.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 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(3) For equipment manufactured after August 1, 2001, 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 that activates with an indication of BEAM ON and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it 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;

(3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that 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 August 1, 2001, 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 that 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 August 1, 2001:

(a) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20 percent 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 percent from the dose monitor unit value selected;

(c) An interlock shall be provided to prevent motion of more than 5 degrees or 1 cm beyond the selected limits during moving beam radiation therapy;

(d) An interlock 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 X.7.J; and

(7) For equipment manufactured after August 1, 2001, 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.

Q. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of X.9, 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 Part X, 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 that 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 Parts D of this rule, 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) Emergency cutoff switches. At least one 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 X.7.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;

(9) 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

(10) 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. Authorized medical physicist support.

(1) The services of an authorized medical physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Authorized Medical Physicist shall be responsible for:

(a) Full calibration(s) required by X.7.T and protection surveys required by X.4.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 X.7.U(5).

(e) Consultation with the authorized user in treatment planning, as needed; and

(f) Perform calculations/assessments regarding medical events.

(2) If the authorized medical physicist is not a full time employee of the registrant, the operating procedures required by X.7.S shall also specifically address how the authorized medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Authorized 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 X.4.A, X.7.T and X.7.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 X.7 shall be performed by, or under the direct supervision of, an authorized 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" 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" and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45". 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 authorized 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 five percent 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 X.7.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 authorized 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 X.7 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40";

(2) To satisfy the requirement of X.7.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". 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 that has been inter-compared within the previous 12 months with the dosimetry system described in X.4.C(1) to make the periodic quality assurance checks required in X.7.U.(2);

(4) The registrant shall perform periodic quality assurance checks required by X.7.U.(1) in accordance with procedures established by the Authorized 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 authorized 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 Authorized 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 authorized medical physicist within three treatment days; and

(c) The authorized medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(6) Therapeutic radiation machines subject to X.7 shall have safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" performed at intervals not to exceed one week;

(7) To satisfy the requirement of X.7.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.

(8) The registrant shall promptly repair any system identified in X.7.U.(7) that is not operating properly; and

(9) The registrant shall maintain a record of each quality assurance check required by X.7.U.(1) and X.7.U.(7) for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation

output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

8. Calibration of survey instruments.

A. The registrant shall ensure that the survey instruments used to show compliance with Part X have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

B. To satisfy the requirements of X.8.A, the registrant shall:

(1) Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

C. To satisfy the requirements of X.8.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 percent; and

(2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

D. The registrant shall retain a record of each calibration required in X.8.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 that contain information required by X.8.D shall be maintained by the registrant.

9. Shielding and safety design requirements.

A. Each therapeutic radiation machine subject to X.6 or X.7 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with Part D of this rule.

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 Appendix A to Part X.

APPENDIX A.

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

1. 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.

2. 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 1 meter, total beam on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. A facility drawing indicating: scale 0.25 inch = 1 foot is typical; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth 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 Part D of this rule;

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present; and

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

(1) If commercial software is used to generate shielding requirements, 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.

3. Therapeutic radiation machines over 150 kV. In addition to the requirements listed in Section 1 above, therapeutic radiation machine facilities that 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 i.e.: 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 1 meter, total beam on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. Facility drawing including both floor plan and elevation views indicating relative orientation of the therapeutic radiation machine, scale 0.25 inch = 1 foot is typical, type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier ceiling, walls and floor, as well as details of the door(s) and maze;

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy i.e.: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed, work load, presence of integral beam stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier walls, floor and ceiling and allowed radiation exposure in both restricted and unrestricted areas; and

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze and shielding material in the facility:

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

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

4. Neutron shielding. In addition to the requirements listed in Section III above, therapeutic radiation machine facilities that are capable of operating above 10 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 i.e.: restricted and unrestricted areas, entry door(s) and maze and neutron shielding material utilized in the facility:

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

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

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

5. 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 100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

APPENDIX B.

QUALITY MANAGEMENT PROGRAM

1. In addition to the definitions in X.2, the following definitions are applicable to a quality management program:

A. **Medical Event** means the administration of an external beam radiation therapy dose:

(1) Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(3) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

B. **Prescribed dose** means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic radiation machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique;

C. **Recordable event** means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

D. **Written directive** means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

2. Scope and applicability. Each applicant or registrant subject to X.6 or X.7 shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

A. Prior to administration, a written directive is prepared for any external beam radiation therapy dose;

(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 administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

(2) 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 shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(3) 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 shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.

B. Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

C. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

D. Each administration is in accordance with the written directive; and

E. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

3. Development of quality management program.

A. Each application for registration subject to X.6 or X.7 shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by Part B of this rule. The registrant shall implement the program upon issuance of a registration certificate

B. Each existing registrant subject to X.6 or X.7 shall submit to the Agency a written certification that a quality management program has been implemented.

4. As a part of the quality management program, the registrant shall:

A. Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all medical events to verify compliance with all aspects of the quality management program;

B. Conduct these reviews at intervals not to exceed 12 months;

C. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements; and

D. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for three years.

5. The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

A. Assembling the relevant facts including the cause;

B. Identifying what, if any, corrective action is required to prevent recurrence; and

C. Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

6. The registrant shall retain:

A. Each written directive; and

B. A record of each administered radiation dose, in an auditable form, for three years after the date of administration.

7. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

8. The registrant shall evaluate each medical event and shall take the following actions in response to a medical event:

A. Notify the Agency by telephone no later than the next calendar day after discovery of the medical event;

B. Submit a written report to the Agency within 15 days after discovery of the medical event. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as the patient), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

C. Notify the referring physician and also notify the patient of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the medical event, because of any delay in notification;

D. Retain a record of each medical event for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and

E. If the patient was notified, furnish, within 15 days after discovery of the medical event, a written report to the patient by sending either a copy of the report that was submitted to

the Agency, or a brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Agency can be obtained from the registrant;

9. Aside from the notification requirement, nothing in X.5.H. affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians

APPENDIX C.

ALTERNATIVE QUALITY MANAGEMENT PROGRAM

1. In addition to the definitions in X.2, the following definitions are applicable to a quality management program:

A. **Medical event**" means the administration of an external beam radiation therapy dose:

(1) Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(3) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

B. **Recordable event** means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

C. **Written directive** means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

2. Each registrant shall establish and maintain a written program to provide assurance that radiation is administered to humans as directed by the authorized user. The program shall include the following elements:

A. Procedure for preparing written directives for the administration of radiation, however, a written directive is not required when an authorized user personally administers a dosage provided the pertinent facts are documented as otherwise required;

B. Procedure for verifying by more than one method the identity of the individual to be administered radiation;

C. Procedure for updating the therapy operating and emergency procedures manual;

D. Procedure for verifying that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

E. Procedures assuring that administration of radiation is carried out as specified in the written directive or the therapy operating and emergency procedures manual;

F. Procedures for identifying and evaluating unintended deviations from the written directive or the therapy operating and emergency procedures manual including taking appropriate action for recordable events and medical event;

3. Each registrant shall evaluate and respond to medical events as follows:

A. For a medical event:

(1) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event.

(2) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event. The written report must include the licensee's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as the patient in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(3) The licensee shall notify the referring physician and also notify the patient of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the medical event, because of any delay in notification.

(4) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the medical event, a written report to the patient by sending either:

(a) A copy of the report that was submitted to the Agency; or

(b) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Agency can be obtained from the licensee.

B. Each licensee shall retain a record of each medical event for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the medical event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

C. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

4. Each registrant shall evaluate and respond to recordable events within 30 days after discovery by assembling the relevant facts, identifying the cause of the recordable event, and taking appropriate action, if any is required, to prevent recurrence.

5. Each registrant shall conduct an annual evaluation of the human administration program including any recommendations for changes to be made as well as any modifications made since the last evaluation and, if required, revise procedures to assure that the radiation is administered as directed by the authorized user. Modifications made to the program shall not decrease the effectiveness of the program.

6. Each registrant shall retain, in auditable form, for three years:

A. Each written directive;

B. A record of each administered radiation dose where a written directive is required;

C. A record of each annual review of the program including the evaluations and findings of the review;

D. A record of each recordable event, the relevant facts, and any corrective actions taken.