RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

JUNE 1978

***AS AMENDED*:**

February 1979
June 1981
October 1984
February 1990
February 1990 (E)
January 1991 (E)
August 1991
December 1993 (E)
February 1994
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January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
September 2012
November 2013

SUMMARY OF MOST RECENT AMENDMENT ACTIONS

These amended *Rules and Regulations for the Control of Radiation* [*R23-1.3-RAD*] are promulgated pursuant to the authority conferred under §23-1.3-5(f) of the General Laws of Rhode Island, as amended, to insure conformance with established radiation control standards, rules and regulations for the protection of radiation workers and the general public.

Pursuant to the provisions of §42-35-3(a)(3) and §42-35.1-4 of the General Laws of Rhode Island, as amended, the following issues were given serious consideration in arriving at the amended regulations:

(a) Alternative approaches to the regulations; and

(b) Duplication or overlap with other state laws and regulations; and

(c) Significant economic impact on small business.

Based on the available information, no known alternative approach, duplication or overlap was identified.

Upon promulgation of these amendments, these amended regulations shall supersede all previous *Rules and Regulations for the Control of Radiation*, promulgated by the Radiation Control Agency, Rhode Island Department of Health and filed with the Secretary of State.

FOREWORD

These Regulations apply to all X-ray facilities, certain providers of services to x-ray facilities and radioactive materials licenses, and all users of radioactive material, including Naturally Occurring or Accelerator-produced Radioactive Material (NARM).

NO X-RAY FACILITY OR APPLICABLE SERVICE IS AUTHORIZED TO OPERATE IN RHODE ISLAND WITHOUT A CURRENT CERTIFICATE OF REGISTRATION ISSUED BY THIS AGENCY.

NO INDIVIDUAL OR FACILITY IS ALLOWED TO USE RADIOACTIVE MATERIALS IN RHODE ISLAND WITHOUT A CURRENT GENERAL OR SPECIFIC LICENSE ISSUED BY THIS AGENCY.

New X-ray facilities and radioactive materials licensees will receive advance notice of initial inspection in order to facilitate the conduct of the inspection. No prior notice will ordinarily be given for follow-up inspections, inspections in response to complaints, or other inspections subsequent to the initial inspection of an X-ray facility or radioactive materials license.

Normally, only one copy of the rules and regulations will be furnished to each registrant or licensee. Therefore, these rules and regulations may be duplicated in whole or in part without permission.

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[R23-1.3-RAD]

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FEBRUARY 1979

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June 1981
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PART A
DEFINITIONS, GENERAL PROVISIONS OF THE REGULATIONS; STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

A.0 DEFINITIONS

Whenever used in these rules and regulations, the following terms shall be construed as follows:

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix G to Part A or may be derived in accordance with the procedures described in Appendix G to Part A. [See Type A Quantity]

A_2 means the maximum activity of radioactive material, other than special form material, LSA and SCO material, permitted in a Type A package. This value is either listed in Appendix G to Part A or may be derived in accordance with the procedures described in Appendix G to Part A. [See Type A Quantity]

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

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

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

Accessible surface means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic X-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of Part F of these Regulations but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of Part F of these Regulations but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all X-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder

Act means Title 23, Chapter 1.3 of the General Laws of the State of Rhode Island entitled "Radiation Control".

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).

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

Adult means an individual 18 or more years of age.

Agency means Rhode Island Radiation Control Agency, Office of Facilities Regulation - Radiation Control Program, Rhode Island Department of Health.

Agreement State means any State with which the United States Nuclear Regulatory Commission has entered into an effective agreement under section 274 b. of the Atomic Energy Act of 1954, as amended (73 Stat.

689).

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

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

(1) In excess of the derived air concentrations (DACs) specified in Table I of Appendix B to Part A; 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 kerma means kerma in air (see definition of Kerma).

Air kerma rate (AKR) means the air kerma per unit time

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.

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

Analytical X-ray equipment means equipment used for X-ray diffraction or fluorescence analysis.

Analytical X-ray system means a group of local and remote components utilizing X-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

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.

Annual refresher safety training means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal 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.

ANSI means the 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.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity of one of the sections to pivot on the line segment along which the sections join.

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

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

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.

Assigned protection factor (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

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.)

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.

Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[1] or other materials having equivalent attenuation.

Authorized medical physicist (for uses authorized pursuant to Subpart C.8) means an individual who:

(1) Meets the requirements in C.8.71 and C.8.74; or

(2) Is identified as an Authorized Medical Physicist or teletherapy physicist on:

(i) A specific medical use license or equivalent permit issued by the Agency, U.S. Nuclear Regulatory Commission or another Agreement State; or

(ii) A permit issued by an Agency, U.S. Nuclear Regulatory Commission or another Agreement State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized nuclear pharmacist means a pharmacist who:

(1) Meets the requirements in C.8.76 and C.8.74; or

(2) Is identified as an Authorized Nuclear Pharmacist on:

(i) A specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency, U.S. Nuclear Regulatory Commission or another Agreement State; or

(ii) A permit issued by an Agency, U.S. Nuclear Regulatory Commission or another Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

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Authorized user means an individual who is:

(1) Identified as an Authorized User on an Agency, Agreement State or U.S. Nuclear Regulatory Commission license. The Authorized User for medical use of radioactive material means a physician, dentist or podiatrist who:

(i) Meets the requirements in C.8.74 and C.8.64(a), C.8.65(a), C.8.66(a), C.8.67(a), C.8.69(a), or C.8.70(a); or

(ii) Is identified as an Authorized User on:

(a) A license or equivalent permit issued by the Agency, U.S. Nuclear Regulatory Commission, or another Agreement State; or

(b) A permit issued by an Agency, U.S. Nuclear Regulatory Commission or another Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material.

or

(2) Qualified as an Authorized User under an Agency registration by satisfying the training requirements of H.3.3 of these Regulations.

Automatic exposure rate control (AERC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time (See also Phototimer).

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

Barrier (See Protective barrier).

Beam axis means a line from the source through the centers of X-ray fields.

Beam-limiting device means a device which provides a means to restrict the dimensions of an X-ray field.

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

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

Bone densitometry system (as used in Part F) means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

Brachytherapy (for uses authorized pursuant to Subpart C.8) means a method of radiation therapy in which plated, embedded, activated or sealed sources are utilized to deliver radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application. [See Subpart H.2 for definition of electronic brachytherapy.]

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters

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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;

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

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

(ii) Any material that:

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

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

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

(i) The U.S Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of Radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on or after 8 August 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Cabinet radiography means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in Section A.2.11.

Cabinet X-ray system means an X-ray system with the X-ray tube installed in an enclosure (hereinafter termed "cabinet") that is independent of existing architectural structures except the floor. The cabinet X-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet X-ray system.

Calendar quarter means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes except at the beginning of a calendar year.

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

Camera see "Radiographic exposure device".

C-arm fluoroscope means a fluoroscopic X-ray system in which the image receptor and the X-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least one hundred (100) cm beyond the support.

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

Certifiable cabinet X-ray system means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

Certificate holder means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.

Certificate of Compliance (CoC) means the certificate issued by the U.S. Nuclear Regulatory Commission under 10 CFR 71, Subpart D which approves the design of a package for the transportation of radioactive material.

Certified cabinet X-ray system means an X-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

Certifying Entity means an independent certifying organization meeting the requirements in Appendix A to Part E or an Agreement State meeting the requirements in Parts II and III of Appendix A to Part E.

Class means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days , and for Class Y, Years, of greater than 100 days. For the purposes of these Regulations, lung class and inhalation class are equivalent terms.

Client's address means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with C.8.10 of these Regulations.

Closed transport vehicle means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

Coefficient of variation (C) means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where
s = Estimated standard deviation of the population.
$\bar{x}$ = Mean value of observations in sample.
x_i = ith observation in sample.
n = Number of observations in sample.

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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.

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.

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

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

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

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Computed tomography dose index (CTDI) means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{n\,T}\int_{-7T}^{+7T} D(z)\,dz$$

where:
z = Position along a line perpendicular to the tomographic plane.
D(z) = Dose at position z.
T = Nominal tomographic section thickness.
n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

Consignment means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

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

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

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

(1) Changes for temporary use of the land for public recreational purposes;

(2) Site exploration, including necessary borings to determine foundation conditions or other pre-construction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to these re4gulations;

(5) Excavation;

(6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(9)Taking any other action that has no reasonable nexus to radiological health and safety.

Contrast scale means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

$\overline{CTN}_x$ = CTN of the material of interest.

$\overline{CTN}_w$ = CTN of water.

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

Control cable means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

Control drive mechanism means a device that enables the source assembly to be moved into and out of the exposure device.

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.

Control tube means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

Conveyance means:

(1) For transport by public highway or rail any transport vehicle or large freight container;

(2) For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(3) For transport by any aircraft.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an X-ray table; or

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

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

Criticality Safety Index (CSI) means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in 10 CFR 71.22, 71.23 and 71.59.

CS (See Contrast scale).

CT conditions of operation means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in these Regulations.

CT dosimetry phantom means the phantom used for determination of the dose delivered by a CT X-ray system. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

CT gantry means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames and covers which hold and/or enclose these components.

CT number means the number used to represent the X-ray attenuation associated with each elemental area of the CT image:

$$\overline{\text{CTN}} = \frac{k\,(\mu_x - \mu_w)}{\mu_w}$$

where:
k = A constant[2]
u_x = Linear attenuation coefficient of the material of interest.
u_w = Linear attenuation coefficient of water.

Cumulative air kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Curie means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps).

[2] The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.

A.0

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

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

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

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.

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

Dental use of radioactive material means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Dentist means an individual with a license to practice dentistry in this State under Rhode Island general laws.

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, 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).

Diagnostic imaging system means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.

Deuterium means, for the purposes of 10 CFR 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

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.

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 (SCBA).

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

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Direct scattered radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See Scattered radiation).

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

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

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

Dose monitor unit means a unit from which the absorbed dose can be calculated.

Dose monitoring system means a system of devices for the detection, measurement, and display of quantities of radiation.

Dose profile means the dose as a function of position along a line.

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.

Drive cable [See "Control cable"].

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 ($H_E = \Sigma w_T H_T$).

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

Enclosed radiography means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.

Energy compensation source (ECS) means a small sealed source, with an activity not exceeding 3.7 MBq [100 microcuries], used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

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.

Equipment (See X-ray equipment).

Exclusive use means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier shall ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor shall issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the X-ray tube produces X-ray radiation.

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Exposure rate means the exposure per unit time.

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.)

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

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

Fail-safe characteristics means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

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.

Field size means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

Field station means a facility where sources of radiation may be stored or used and from which equipment is dispatched.

Filter means material placed in the useful beam to absorb preferentially selected radiations.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Fissile material means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

Fissile material package means a fissile material packaging together with its fissile material contents.

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.

Fluoroscopic air kerma display device means a device, subsystems or component that provides the display of AKR and cumulative air kerma, respectively, required by Subpart F.4 of these Regulations. It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

Fluoroscopic imaging assembly means a subsystem in which X-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling X-ray tube activation in any fluoroscopic mode of operation.

A.0

Fluoroscopy means a technique for generating X-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

Focal spot means the area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

Gantry means that part of the system supporting and allowing possible movements of the radiation head.

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.

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.

Gonadal shield means a protective barrier for the testes or ovaries.

Graphite means, for the purposes of 10 CFR 71.15 and 71.22, graphite with a boron equivalent content less than five (5) parts per million and density greater than one and one-half (1.5) grams per cubic centimeter.

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

Guide tube means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Hand-held X-ray equipment means X-ray equipment that is designed to be hand-held during operation.

Hands-on experience means experience in all of those areas considered to be directly involved in the radiography process.

Healing Arts as used in these Regulations, means any discipline which involves the diagnosis or treatment of individuals or animals by a practitioner who is licensed for that purpose by the State of Rhode Island, and which discipline, prior to the effective date, included the intentional exposure of individuals or animals to sources of radiation for diagnosis or treatment.

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.

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

High dose-rate (HDR) remote afterloader, as used in Subpart C.8, means a device that remotely delivers a

dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

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

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).

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

Image receptor means any device, such as a fluorescent screen, radiographic film, X-ray image intensifier tube, solid-state detector, or gaseous detector which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

Image receptor support device means, for mammography X-ray systems, the part of the system designed to support the image receptor during a mammography examination and to provide a primary protective barrier.

Independent certifying organization means an independent organization that meets all of the criteria of Appendix A to Part E.

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

Individual means any human being.

Individual monitoring means the assessment of:

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

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

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

Industrial radiography (radiography) means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

Inhalation class [see Class].

Injection tool means a device used for controlled subsurface injection of radioactive tracer material.

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

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

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

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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 smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged participles liberated by uncharged particles in a mass dm of material; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

Kilovolts peak (See Peak tube potential).

kVp (See Peak tube potential).

kWs means kilowatt second which is equal to the product of peak kilovolts, amperes, and seconds, e.g., 10^3 kV mA sec.

Last image hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral fluoroscope means the X-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral X-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the X-ray beam axis parallel to the plane of the table

Lay-barge radiography means industrial radiography performed on any water vessel used for laying pipe.

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

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

(1) the useful beam, and

(2) radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

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 the regulations adopted by the Agency.

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

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

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.

Limits [See "Dose limits"].

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential, as follows:

Percent line-voltage regulation = $100\ (V_n-V_1)/V_1$

where:

V_n = No-load line potential and
V_1 = Load line potential

Logging supervisor means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

Logging tool means a device used subsurface to perform well-logging.

Loose-fitting facepiece 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 material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Low dose-rate (LDR) remote afterloader, as used in Subpart C.8, 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.

Low specific activity (LSA) material means radioactive material with limited specific activity which is nonfissile or is excepted under 10 CFR 71.15, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material shall be in one of three (3) groups:

(a) LSA-I

(1) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radionuclides;

(2) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

(3) Radioactive material for which the A_2 value is unlimited; or

(4) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed thirty (30) times the value for exempt material activity concentration determined in accordance with Appendix G to Part A of these Regulations.

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(b) LSA-II

(1) Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L); or

(2) Other material in which the activity is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(c) LSA-III Solids[3], excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

(1) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent[4]; and

(2) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed 0.1 A_2; and

(3) The average specific activity of the solid does not exceed 2 x 10^{-3} A_2/g.

Low toxicity alpha emitters means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten (10) days.

Lung class [see Class].

Major Processor means a user processing, handling or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four (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 those persons' delegate or delegates.

Manual brachytherapy, as used in Subpart C.8, means a type of therapy in which brachytherapy sources are manually applied or inserted.

Medical institution means an organization in which several medical disciplines are practiced.

Medical use means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an Authorized User (as defined in these Regulations).

Medium dose-rate (MDR) remote afterloader, as used in Subpart C.8, means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

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

Mineral logging means any logging performed for the purpose of mineral exploration other than oil or gas.

Minor means an individual less than 18 years of age.

Misadministration means an event that meets the criteria in C.8.11(a) of these Regulations.

Mobile equipment (See X-ray equipment).

[3] For example, consolidated wastes, or activated m materials.

[4] For example, concrete, bitumen, or ceramic.

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Mobile nuclear medicine service means the transportation of nuclear imaging/uptake equipment and/or radioactive material for the purpose of providing nuclear medicine services at client facilities.

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, X-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Modulation transfer function means the modulus of the Fourier transform of the impulse response of the system.

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

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

Multiple tomogram system means a computed tomography X-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

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

Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H to Part A of these Regulations. 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.

Natural thorium means thorium isotopes with a naturally occurring distribution, which is essentially 100 weight percent thorium-232.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

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Noise means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \mu_x \cdot s}{\mu_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

Nominal tomographic section thickness means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

Non-image-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

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, deterministic effect is an equivalent term.

Normal form radioactive material means radioactive material which has not been demonstrated to qualify as special form radioactive material.

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.

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

Nuclear waste[5] means a quantity of source, byproduct or special nuclear material required to be in U.S. Nuclear Regulatory Commission-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under C.8.24 of these Regulations, from voluntary participation in medical research programs, or as a member of the public.

Offshore platform radiography means industrial radiography conducted from a platform over a body of water.

Open-beam configuration means an analytical X-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

Order of abatement means a legal order of the Administrator pursuant to Chapter 23-1.3-8 of the General Laws of the State of Rhode Island requiring that the person to whom the order is issued shall, prior to a time fixed by the Administrator, which time shall not be later than ten days from the date of service of the order, cease and abate causing, allowing, or permitting violation(s) and take such action as may be necessary to comply with this chapter and codes, rules or regulations promulgated thereunder.

[5] The definition of nuclear waste is used in the same way as in 49 CFR 173.403.

A.0

Output means the **EXPOSURE** rate, dose rate, or a quantity related in a known manner to these rates from a radiotherapy or brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

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

(1) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.

(2) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.

(3) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before 6 September 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

Packaging means the assembly of components necessary to ensure compliance with the packaging requirements of 10 CFR 71. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

Particle accelerator [See Accelerator].

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

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.

Peak tube potential means the maximum value of the potential difference across the X-ray tube during an exposure.

Permanent radiographic installation means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

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

Personnel monitoring equipment [See Individual monitoring devices].

Personal supervision means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Pharmacist means an individual registered to engage in the practice of pharmacy in this State pursuant to Section 5-19-19 of the General Laws of Rhode Island, as amended, entitled, "Pharmacy".

Phototimer (See Automatic **EXPOSURE** control).

Physician means a person with a license to practice allopathic or osteopathic medicine in this State under Rhode Island general laws.

Picture element means an elemental area of a tomogram.

PID (See Position indicating device).

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

Podiatrist means a person with a license to practice podiatric medicine in this State under Rhode Island general laws.

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

Position indicating device means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Positive beam limitation means 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.

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

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

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.

Preceptor means an individual who provides, directs or verifies the training and experience required for an individual to become an Authorized User, an Authorized Medical Physicist, an Authorized Nuclear Pharmacist or a Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of radioactive drug as documented:

(1) In a written directive; or

(2) In accordance with the directions of the Authorized User for procedures performed pursuant to C.8.28 and, C.8.30 of these Regulations.

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.

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

Primary beam means ionizing 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.

Primary dose monitoring system means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure (beyond the patient and cassette holder) for protection purposes.

Projection sheath (See "Guide tube").

Projector (See "Radiographic exposure device").

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

Protected area means an area which provides radiation protection to X-ray equipment operators, sufficient to assure compliance with Part A under all operating conditions.

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Public dose means the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under C.8.24 of these Regulations, or from voluntary participation in medical research programs.

Pulsed mode means operation of the X-ray system such that the X-ray tube current is pulsed by the X-ray control to produce one or more exposure intervals of duration less than one-half second.

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 Medical Physicist (for activities authorized pursuant to Part F) means an individual registered to provide Radiation Physics Services (Diagnostic X-ray Physics Services) in accordance with B.4 of these Regulations.

Qualified Medical Physicist (for activities authorized pursuant to Part H) means an individual qualified in accordance with H.3.4 of these Regulations.

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 Assurance Program means a program to ensure radiographic image quality whereby periodic monitoring of film processing and imaging equipment is performed.

Quality factor (Q) means the modifying factor, listed in Tables I and II of A.1.9, 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.

Quick change X-ray tube means an X-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of F.5 of these Regulations;

(2) The focal spot position will not cause noncompliance with the provisions of F.5 of these Regulations;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the X-ray system with the applicable field limitation and alignment requirements of F.5 of these Regulations.

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

Radiation means:

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

(2) any electromagnetic radiation which can be generated during the operation of a microwave oven.

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

Radiation detector means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation dose [See Dose].

Radiation head means the structure from which the useful beam emerges.

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

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

Radiation Safety Officer (for uses authorized pursuant to Subpart C.8) means an individual who:

(1) Meets the requirements in C.8.62(a) or (c)(1) and C.8.74; or

(2) Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Agency for similar types and uses of radioactive material.

Radiation safety officer for industrial radiography means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of E.2.21.

A.0

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.

Radioactive marker means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

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

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

Radiobioassay [See Bioassay].

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.

Radiographer means any individual who performs or who, in attendance at the site where the source(s) of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Agency's regulations and the conditions of the license and/or certificate of registration.

Radiographer certification means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

Radiographer's assistant means any individual who, under the direct supervision of a radiographer, uses sources of radiation, radiographic exposure devices, related handling tools, or radiation survey instruments in industrial radiography.

Radiographic exposure device (also called a camera, or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

Radiographic operations means all activities associated with the presence of sources of radiation during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

Radiography means a technique for generating and recording an X-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the X-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the X-ray high-voltage generator

Rating means the operating limits as specified by the manufacturer.

Recording means producing a retrievable form of an image resulting from X-ray photon interactions.

Reference Man means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, Report of the Task Group on Reference Man.

Reference plane means a plane which is displaced from and parallel to the tomographic plane.

A.0

Registrant means (1) any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these Regulations and the Act; or (2) as used in part B, any person who owns or possesses and administratively controls an X-ray system or particle accelerator, and any person who is engaged in the business of installing or offering to in install X-ray equipment or is engaged in the business of furnishing or offering to furnish X-ray equipment servicing or radiation physics services, and are required by part B to register with the Agency.

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

Regulations of the U.S. Department of Transportation means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

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

Remanufacturing means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT X-ray system manufactured by the original manufacturer on or after 29 November 1984. Any reference in F.10 of these Regulations to "manufacture," "manufacturer," or "manufacturing" includes remanufacture, remanufacturer and remanufacturing, respectively.

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

Research and development X-ray equipment means equipment generating x-radiation for research and development purposes.

Research and development X-ray system means a group of local and remote components utilizing X-rays for research and development purposes. Local components include those that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices and control panels.

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

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

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.

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

Roentgen (R) means the special unit of **EXPOSURE**. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air (see **EXPOSURE** and Section A.1.9).

A.0

RIGL means the General Laws of Rhode Island, as amended.

S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

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.

Scan means the complete process of collecting X-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan increment means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement.

Scan sequence means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan time means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See Direct scattered radiation).

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

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

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

Sensitivity profile means the relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

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

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 every location on the exterior meets the conditions specified in Section A.2.5.

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SI means the abbreviation for the International System of Units.

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

Single tomogram system means a CT system which obtains X-ray transmission data during a scan to produce a single tomogram.

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

A.0

Solid state X-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts X-ray photons and converts the photon energy into a modulated electronic signal representative of the X-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

Source means the focal spot of the X-ray tube.

Source assembly means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

Source changer means a device designed and used for replacement of sealed sources in radiographic exposure devices including those also used for transporting and storage of sealed sources.

Source holder means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

Source-image receptor distance (SID) means the distance from the source to the center of the input surface of the image receptor.

Source-skin distance (SSD) means the distance from the source to the center of the entrant X-ray field in the plane tangent to the patient skin surface.

Source material means:

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

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

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

Source stop [See "Exposure head"].

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

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

(b) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 in.); and

(c) It satisfies the test requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on June 30, 1983 (see 10 CFR Part 71, revised as of 1 January 1983), and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of 1 January 1983), and constructed prior to April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

Special nuclear material means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Agency declares by order to be special nuclear material after 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.

A.0

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:

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

Specific activity of a radionuclide means the radioactivity per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

Spot check means a procedure which is performed to assure that a previous calibration continues to be valid.

Spot film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

Stationary equipment (See X-ray equipment).

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

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, probabilistic effect is an equivalent term.

Storage area means any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

Storage container means a container in which sealed sources are secured and stored.

Stray radiation means the sum of leakage and scattered radiation.

Subsurface tracer study means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

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.

A.0

Surface contaminated object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. An SCO shall be in one of two groups with surface activity not exceeding the following limits:

(a) SCO-I: A solid object on which:

(1) The non-fixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 4 becquerel per cm^2 (10^{-4} $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm^2 (10^{-5} $\mu Ci/cm^2$) for all other alpha emitters;

(2) The fixed contamination on the accessible surface averaged over 300 cm2, or the area of the surface if less than 300 cm^2, does not exceed $4x10^4$ becquerel per cm2 (1.0 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ becquerel per cm2 (0.1 $\mu Ci/cm^2$) for all other alpha emitters; and

(3) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2, or the area of the surface if less than 300 cm2, does not exceed $4x10^4$ becquerel per cm^2 (1 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ becquerel per cm^2 (0.1 $\mu Ci/cm^2$) for all other alpha emitters.

(b) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(1) The non-fixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 400 becquerel per cm^2 (10^{-2} $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm^2 (10^{-3} $\mu Ci/cm^2$) for all other alpha emitters;

(2) The fixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed $8x10^5$ becquerel per cm^2 (20 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters or $8x10^4$ becquerel per cm^2 (2 $\mu Ci/cm^2$) for all other alpha emitters;

(3) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed $8x10^5$ becquerel per cm^2 (20 $\mu Ci/cm^2$) for beta and gamma and low toxicity alpha emitters or $8x10^4$ becquerel per cm^2 (2 $\mu Ci/cm^2$) for all other alpha emitters;

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

Target means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

(3) For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

(4) For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Teletherapy, as used in Subpart C.8, means a method of radiation therapy in which collimated gamma rays are delivered from a source at a distance from the patient or human research subject.

Temporary jobsite means a location where radiographic operations are conducted and where licensed material or registered machines may be stored other than those location(s) of use authorized on the license and/or certificate of registration.

Temporary jobsite, as used in Subpart C.8, means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Termination means the end of employment with the licensee or registrant or, in the case of individuals not employed by the registrant or licensee, the end of a work assignment in the registrant's or licensee's restricted areas in a given calendar quarter, without expectation or specific scheduling of reentry into the licensee's or registrant's restricted areas during the remainder of that calendar quarter.

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

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 radiation source to a patient or human research subject for palliative or curative treatment.

These regulations mean all parts of Rhode Island Rules and Regulations for the Control of Radiation.

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

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Tomographic plane means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

Tomographic section means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

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

Total organ dose equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in A.5.7(a)(6).

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.

Transport index means the dimensionless number, rounded up to the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level at 1 meter (3.3 feet) from the external surface of the package in millisievert (mSv) per hour multiplied by 100, which is thus equivalent to the maximum radiation level in millirem per hour at 1 meter.

Treatment field means the area of the patient's skin which is to be irradiated.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

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

Tritium neutron generator target source means a tritium source used within a neutron generator tube to produce neutrons for use in well logging/wireline applications.

Tube means an X-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Type A quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Appendix G to this part or may be determined by procedures described in Appendix G.

Type A package means a packaging that, together with its radioactive contents limited to A_1 or A_2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding required by this Subpart under normal conditions of transport as demonstrated by the tests set forth in 49 CFR 173.465 or 173.466, as appropriate.

Type B package means a Type B packaging together with its radioactive contents.[6]

Type B packaging means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

Type B quantity means a quantity of radioactive material greater than a Type A quantity.

Type of use means use of radioactive material as specified under C.8.28, C.8.30, C.8.34, C.8.38, C.8.40, C.8.46 or C.8.79 of these Regulations.

Unit dosage means a dosage that:

(1) Is obtained or prepared in accordance with the regulations for uses described in C.8.28, C.8.30 or C.8.34; and

(2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Underwater radiography means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

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[6] A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. No distinction is made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983 was designated only as Type B. Limitations on its use are specified in Section C.7.7

Uranium, natural, depleted, enriched:

(1) Natural uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235 and the remainder by weight essentially uranium-238).

(2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

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

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee or registrant.

Uranium [See natural, depleted and enriched uranium.]

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 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).

Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system 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.

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.

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

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

Visible area means that portion of the input surface of the image receptor over which incident X-ray photons produce a visible image.

Visiting Authorized User means an Authorized User who is not identified on the license of the licensee being visited.

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

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

A.0

Week means 7 consecutive days starting on Sunday.

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

ORGAN DOSE WEIGHTING FACTORS

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

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

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

Well-bore means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

Well-logging means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.

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

Wireline means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

Wireline service operation means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

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 1.3×10^5 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.

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Written directive means an Authorized User's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in C.8.6 of these Regulations.

X-ray equipment means an X-ray system, subsystem, or major component thereof. (Examples of major components are: tube housing assemblies, X-ray controls, X-ray high voltage generators, fluoroscopic imaging assemblies, tables, cradles, film changers, cassette holders and beam limiting devices). Types of X-ray equipment are as follows:

(1) Mobile X-ray equipment means X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(2) Portable X-ray equipment means X-ray equipment designed to be hand-carried.

(3) Stationary X-ray equipment means X-ray equipment which is installed in a fixed location.

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 field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the **AKR** is one-fourth of the maximum in the intersection.

X-ray subsystem means any combination of two or more components of an X-ray system for which there are requirements specified in Subparts A.0. F.3, F.4 and F.5 of these Regulations X-ray subsystem means any combination of two or more components of an X-ray system for which there are requirements specified in Subparts A.0. F.3, F.4 and F.5 of these Regulations.

0X-ray system means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

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

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

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A.1 GENERAL PROVISIONS

A.1.1 **Purpose and Scope.**

(a) This part establishes generally applicable provisions, including standards for protection against radiation hazards, notices, instructions and reports to workers, and inspections. Except as otherwise specifically provided, these Regulations apply to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of any source of radiation. The limits in this Part 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 under C.8.24 of these Regulations, or to voluntary participation in medical research programs; provided, however, that nothing in these Regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.

(b) The requirements of this part 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 this part. However, nothing in Part A shall be construed as limiting actions that may be necessary to protect health and safety.

A.1.2 **Exemptions.**

(a) **General Provision.** The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements 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 (DOE) Contractors and U.S. Nuclear Regulatory Commission Contractors.** Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these Regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

(1) Prime contractors performing work for the Department of Energy (DOE) 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 (DOE) 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 (DOE) 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 (DOE) or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine,

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

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

A.1.3

A.1.3 **Records.** Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. All records required by these Regulations shall be maintained indefinitely unless otherwise specified in these Regulations.

A.1.4 **Inspections.**

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

(b) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these Regulations.

A.1.5 **Tests.** Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) Sources of radiation;

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

(c) Radiation detection and monitoring instruments; and

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

A.1.6 **Additional Requirements.** The Agency may, by rule, regulations, or order, impose upon any licensee or registrant such requirements in addition to those established in these Regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

A.1.7 **Violations.** An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

A.1.8 **Communications.** All communications and reports concerning these Regulations, and applications filed thereunder, should be addressed to the Agency at its office located at:

Rhode Island Department of Health
Office of Facilities Regulation
Radiation Control Program
Three Capitol Hill - Room 305
Providence, RI 02908-5097

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A.1.9 **Units of Exposure and Dose.**

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

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

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

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

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

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

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

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high-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.

(d) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in A.1.9(c), 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

A.1.9

TABLE II

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 per Unit Dose Equivalent**[b] (neutrons cm^{-2} Sv^{-1})
(thermal)	2.5×10^{-8}	2	980×10^{6}	980×10^{8}
	1×10^{-7}	2	980×10^{6}	980×10^{8}
	1×10^{-6}	2	810×10^{6}	810×10^{8}
	1×10^{-5}	2	810×10^{6}	810×10^{8}
	1×10^{-4}	2	840×10^{6}	840×10^{8}
	1×10^{-3}	2	980×10^{6}	980×10^{8}
	1×10^{-2}	2.5	1010×10^{6}	1010×10^{8}
	1×10^{-1}	7.5	170×10^{6}	170×10^{8}
	5×10^{-1}	11	39×10^{6}	39×10^{8}
	1	11	27×10^{6}	27×10^{8}
	2.5	9	29×10^{6}	29×10^{8}
	5	8	23×10^{6}	23×10^{8}
	7	7	24×10^{6}	24×10^{8}
	10	6.5	24×10^{6}	24×10^{8}
	14	7.5	17×10^{6}	17×10^{8}
	20	8	16×10^{6}	16×10^{8}
	40	7	14×10^{6}	14×10^{8}
	60	5.5	16×10^{6}	16×10^{8}
	1×10^{2}	4	20×10^{6}	20×10^{8}
	2×10^{2}	3.5	19×10^{6}	19×10^{8}
	3×10^{2}	3.5	16×10^{6}	16×10^{8}
	4×10^{2}	3.5	14×10^{6}	14×10^{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.

A.1.10 **Units of Activity**. For purposes, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

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

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

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A.1.11 **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 A.1.11(a)(1) or (a)(2) may be subject to enforcement action in accordance with the procedures in A.7.

(c) For the purposes of A.1.11(a)(1), 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.

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A.2 STANDARDS FOR PROTECTION AGAINST RADIATION

A.2.1 **Implementation.**

(a) Any existing license or registration condition that is more restrictive than Part A remains in force until there is an amendment or renewal of the license or registration.

(b) If a license or registration condition exempts a licensee or registrant from a provision of Part A in effect on or before 1 January 1994, it also exempts the licensee or registrant from the corresponding provision of this part.

(c) If a license or registration condition cites provisions of this part in effect prior to 1 January 1994, which do not correspond to any provisions of this part, 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.

A.2.2 **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 this part. [See A.5.2 for recordkeeping requirements relating to these programs.]

(b) The licensee or registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of A.2.2(b), and notwithstanding the requirements in A.2.11, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 mSv (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 A.5.14 and promptly take appropriate corrective action to ensure against recurrence.

A.2.3 **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 A.2.8, to the following dose limits:

(1) An annual limit, which is the more limiting of:

(i) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(ii) 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:

(i) A lens-dose equivalent of 0.15 Sv (15 rem), and

(ii) A shallow-dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

A.2.3(b)

(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 A.2.8(e)(1) and (e)(2).]

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Agency. The assigned deep-dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous ten (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.

(1) 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; or

(2) For sources of radiation other than radioactive material, when a protective apron is worn and monitoring is conducted as specified in A.3.3(c), the effective dose equivalent for external radiation shall be determined as follows:

(i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in A.2.3(a), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(ii) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of Appendix B to this Part and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. [See A.5.7.]

(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 to this Part.]

(f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year. [See A.2.7 of these Regulations.]

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A.2.4 **Compliance with Requirements for Summation of External and Internal Doses.**

(a) If the licensee or registrant is required to monitor pursuant to both A.3.3(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 A.3.3(a) or only pursuant to A.3.3(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 pursuant to A.2.4(b), (c) and (d). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(b) **Intake by Inhalation.** If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation ALI for each radionuclide; 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, $w_{THT,50}$, per unit intake for any organ or tissue.

(c) **Intake by Oral Ingestion.** If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee 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. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to A.2.4(d).

A.2.5 **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 to this Part, 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.

A.2.6 **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 A.3.3, take suitable and timely measurements of:

(1) Concentrations of radioactive materials in air in work areas; or

A.2.6(a)(2)

(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 A.3.9, 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. [See Appendix B to this Part.]

(d) If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in Subparagraphs A.2.6(a)(2) or (a)(3), the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by A.5.13 or A.5.14. 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 to this Part 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 A.2.3 and in complying with the monitoring requirements in A.3.3(b); and

(2) The concentration of any radionuclide disregarded is less 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) When determining the committed effective dose equivalent, the following information may be considered:

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A.2.6(h)(1)

(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 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in A.2.3(a)(1)(ii) is met.

A.2.7 **Determination of Prior Occupational Dose.**

(a) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to A.3.3, the licensee or registrant shall:

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of lifetime cumulative occupational radiation dose.

(b) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(1) The internal and external doses from all previous planned special exposures; and

(2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

(3) Lifetime cumulative occupational radiation dose.

(c) In complying with the requirements of A.2.7(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 lifetime cumulative radiation dose, an up-to-date Agency Form RCA-2 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

(3) Obtain reports of the individual's dose equivalent 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.

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A.2.7(d)(1)

(d) (1) The licensee or registrant shall record the exposure history, as required by A.2.7(a), on Agency Form RCA-2, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Agency Form RCA-2 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form RCA-2 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 this Part in effect before 1 January 1994. Further, occupational exposure histories obtained and recorded on Agency Form RCA-2 or equivalent before 1 January 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 A.2.3(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 on Agency Form RCA-2 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form RCA-2 or equivalent for 3 years after the record is made.

A.2.8 **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 A.2.3 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 A.2.7(b) during the lifetime of the individual for each individual involved.

A.2.8(e)

(e) Subject to A.2.3(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 A.2.3(a) in any year; and

(2) Five times the annual dose limits in A.2.3(a) during the individual's lifetime.

(f) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with A.5.6 and submits a written report in accordance with A.5.15.

(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 A.2.3(a) but shall be included in evaluations required by A.2.8(d) and (e).

A.2.9 **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 A.2.3.

A.2.10 **Dose to an Embryo/Fetus.**

(a) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). [See A.5.7 for recordkeeping requirements.]

(b) The licensee or registrant shall make efforts to avoid substantial variation[7] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in A.2.10(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 resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 5 mSv (0.5 rem) or is within 0.5 mSv (0.05 rem) of this dose, the licensee or registrant shall be deemed to be in compliance with A.2.10(a) if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

A.2.11 **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 under C.8.24 of these Regulations, from voluntary participation in medical research projects, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with A.4.3 of these Regulations; and

[7] 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.

A.2.11(a)(2)

(2) The total effective dose equivalent to individual members of the public does not exceed the original design criteria of 5 mSv (0.5 rem) in a year at locations within registered facilities where only radiation machines were installed prior to 1 January 1994 and which continue to meet the original design criteria (e.g. workload, type and use of radiation machine, room configuration, etc.) on or after 1 January 1994; and

(3) The dose in any unrestricted area from external sources, exclusive of the dose contributions from individuals administered radioactive material and released in accordance with C.8.24 of these Regulations, 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 restricted areas, the limits for members of the public continue to apply to those individuals.

(c) A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 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 A.2.11(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.

(d) In addition to the requirements of this Part, 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.

(e) 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.

(f) Notwithstanding A.2.11(a)(1), a licensee or registrant may permit visitors to an individual who cannot be released, under C.8.24, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

(1) The radiation dose received does not exceed 5 mSv (0.5 rem); and

(2) The Authorized User, as defined for Subpart C.8 of these Regulations, has determined before the visit that it is appropriate.

A.2.12 **Compliance with Dose Limits for Individual Members of the Public.**

(a) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in A.2.11.

(b) A licensee or registrant shall show compliance with the annual dose limit in A.2.11 by:

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(2) Demonstrating that:

A.2.12(b)(2)(i)

(i) 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 to this Part; and

(ii) 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 Table II of Appendix B to this Part 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.

A.2.13 **Radiological Criteria for License Termination.**

(a) **Applicability.** The criteria in A.2.13 through A.2.18 apply to the decommissioning of facilities licensed under Parts C and E, as well as other facilities subject to the Agency's jurisdiction.

(b) After a site has been decommissioned and the license terminated in accordance with the criteria in A.2.13 through A.2.18, the Agency will require additional cleanup only if, based on new information, it determines that the criteria in A.2.13 through A.2.18 were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(c) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

A.2.14 **Radiological Criteria for Unrestricted Use.** A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.25 mSv (25 mrem) 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 shall take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

A.2.15 **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 A.2.14 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 shall take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv (25 mrem) per year;

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

A.2.15(c)(1)

(1) Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control , and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent (1%) real rate of return on investment;

(2) A statement of intent in the case of Federal, State, or local Government licensees, as described in C.5.16 (f)(4); or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance C.5.8(c), and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(i) Whether provisions for institutional controls proposed by the licensee:

(a) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv (25 mrem) TEDE per year;

(b) Will be enforceable; and

(c) Will not impose undue burdens on the local community or other affected parties.

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in A.2.15(d)(1), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(1) 1 mSv (100 mrem) per year; or

(2) 5 mSv (500 mrem) per year provided the licensee:

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 1 mSv/y (100 mrem/y) value of A.2.15(e)(1) are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

A.2.15(e)(2)(ii)

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of A.2.15(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in A.2.15 (c).

A.2.16 **Alternate Criteria for License Termination.**

(a) The Agency may terminate a license using alternate criteria greater than the dose criterion of A.2.14, A.2.15(b), and A.2.15(d)(1)(i)(a), if the licensee:

(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit, by submitting an analysis of possible sources of exposure;

(2) Has employed to the extent practical restrictions on site use according to the provisions of A.2.15 in minimizing exposures at the site; and

(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with C.5.8(c), 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 licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(b) The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of the Agency staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to A.2.17.

A.2.17 **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 A.2.15 or A.2.16, or whenever the Agency deems such notice to be in the public interest, the Agency shall:

(a) Notify and solicit comments from:

A.2.17(a)(1)

(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) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to A.2.16.

(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.

A.2.18 **Minimization of Contamination.**

(a) Applicants for licenses, other than renewals shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in A.2.3 through A.2.6, and A.2.8 through A.2.10 of these Regulations, and radiological criteria for license termination in A.2.13 through A.2.18 of these Regulations.

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A.3 PRECAUTIONARY PROCEDURES

A.3.1 **Testing for Leakage or Contamination of Sealed Sources.**

(a) The licensee in possession of any sealed source shall assure that:

(1) Each sealed source, except as specified in A.3.1(b), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee.

(2) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, after evaluation of information specified by C.5.5(l)(4) and (5), an Agreement State or the U.S. Nuclear Regulatory Commission.

(3) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three (3) months or at alternative intervals approved by the Agency, after evaluation of information specified by C.5.5(l)(4) and (5), an Agreement State or the U.S. Nuclear Regulatory Commission.

(4) For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee 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 4 days.

(b) A licensee need not perform test for leakage or contamination on the following sealed sources:

(1) Sealed sources containing only radioactive material with a half-life of less than 30 days;

(2) Sealed sources containing only radioactive material as a gas;

(3) Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material;

(4) Sealed sources containing only hydrogen-3;

(5) Seeds of iridium-192 encased in nylon ribbon; and

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A.3.1(b)(6)

(6) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

(c) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, another 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; or

(2) Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

(f) The licensee 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 A.5.19.

A.3.2 **General Survey and Monitoring Requirements.**

(a) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

(1) Are necessary for the licensee or registrant to comply with this Part; and

(2) Are reasonable under the circumstances to evaluate:

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding A.5.3, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with C.5.16(g).

(c) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed twelve (12) months for the radiation measured, unless a different calibration interval is specified in the appropriate Part(s) of these Regulations.

(d) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with A.2.3, with other applicable provisions, 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

A.3.2(d)(2)

(2)Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(e) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

A.3.3 **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 this Part. As a minimum:

(a) Each licensee or registrant shall monitor occupational exposure to radiation from licensed, registered, unlicensed and unregistered radiation sources under the control of the licensee or registrant and shall supply and require the use of individual monitoring devices by:

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in A.2.3(a); and

(2) Minors likely to receive, in 1 year, from radiation 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).

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem)[8]; and

(4) Individuals entering a high or very high radiation area; and

(b) Each licensee or registrant shall monitor, to determine compliance with A.2.6, 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 to this Part; and

(2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 1 mSv (0.1 rem); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).

(c) Individuals wearing a protective apron, when personnel monitoring is otherwise required by these Regulations, shall position their individual monitoring devices as follows:

(1) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to A.2.10(a), shall be located under the protective apron at the waist[9].

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[8] All of the occupational doses in Sec. A.2.3 continue to be applicable to the declared pregnant worker as long as the embryo/ fetus dose limit is not exceeded.

[9] It is recognized that, in the specific work environment of medical fluoroscopic equipment, the dose to the embryo/fetus is overestimated by the individual monitoring device because of the overlying tissue of the pregnant individual. A medical physicist who is registered with the Agency pursuant to B.4 as a Provider of Diagnostic X-Ray Physics Services should be consulted to determine the dose to the embryo/fetus for the rare occasion in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). Therefore, for purposes of these Regulations, the value to be used for determining the dose to an embryo/fetus pursuant to A.2.10(c)(1) for occupational exposure to radiation from medical fluoroscopic equipment may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by the above referenced medical physicist.

A.3.3(c)(2)

(2) An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

(3) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to A.2.3(c)(2), it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(d) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with A.2.3(a)(2)(ii), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

A.3.4 **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 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

(2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(b) In place of the controls required by A.3.4(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 A.3.4(a) and (c) in a way that does not prevent individuals from leaving a high radiation area.

(e) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

(1) The packages do not remain in the area longer than 3 days; and

(2) The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(f) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this Part and to operate within the ALARA provisions of the licensee's radiation protection program.

(g) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in A.3.4 if the registrant has met all the

specific requirements for access and control specified in other applicable Parts. (e.g. Part E for industrial radiography, Part F for x-rays in the healing arts, and Part D for particle accelerators.)

A.3.5 **Control of Access to Very High Radiation Areas.**

(a) In addition to the requirements in A.3.4, 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 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

(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 A.3.5(a) if the registrant has met all the specific requirements for access and control specified in other applicable Parts. (e.g. Part E for industrial radiography, Part F for x rays in the healing arts, and Part D for particle accelerators.)

A.3.6 **Control of Access to Very High Radiation Areas -- Irradiators.**

(a) Section A.3.6 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section A.3.6 does not apply to sources of radiation that are used in teletherapy/radiotherapy, 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 1 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:

(i) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(ii) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(iii) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

(2) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by A.3.6(b)(1):

(i) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(ii) 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.3.6(b)(3)(i)

(i) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(ii) 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 Subparagraphs A.3.6(b)(3) and (b)(4).

(6) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

(7) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(8) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

(9) The entry control devices required in A.3.6(b)(1) shall be tested for proper functioning. [See A.5.10 for recordkeeping requirements.]

(i) 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

(ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(iii) 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.

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A.3.6(c)

(c) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of A.3.6(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 A.3.6(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 A.3.6(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 A.3.6(b) and (c) shall be established in such a way that no individual will be prevented from leaving the area.

A.3.7 **Use of Process or Other Engineering Controls.** The licensee or registrant shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

A.3.8 **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 the 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 or registrant performs an ALARA analysis to determine whether or not respirators should be used, the licensee or registrant may consider safety factors other than radiological factors. The licensee or registrant should also consider the impact of respirator use on workers' industrial health and safety.

A.3.9 **Use of Individual Respiratory Protection Equipment.**

(a) If the licensee or assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material:

(1) 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) except as otherwise noted in this Part.

(2) If the licensee or registrant wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee or registrant shall submit an application to the Agency for authorized use of this equipment except as provided in this Part. The application shall include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This shall be demonstrated either by licensee/registrant 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.3.9(a)(3)(i)

(i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(ii) Surveys and bioassays, as necessary, to evaluate actual intakes;

(iii) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(iv) Written procedures regarding:

(a) Monitoring, including air sampling and bioassays;

(b) Supervision and training of respirator users;

(c) Fit testing;

(d) Respirator selection;

(e) Breathing air quality;

(f) Inventory and control;

(g) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(h) Recordkeeping; and

(i) Limitations on periods of respirator use and relief from respirator use;

(v) Determination by a physician that the individual user is medically fit to use respiratory protection equipment:

(a) Before the initial fitting of a face sealing respirator;

(b) Before the first field use of nonface sealing respirators, and

(c) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

(vi) Fit testing, with fit factor >10 times the APF for negative pressure devices, and a fit factor >500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing shall be performed with the facepiece operating in the negative pressure mode.

(4) [**RESERVED**]

(5) 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.

(6) The licensee or registrant shall also consider limitations appropriate to the type and mode of use When selecting respiratory devices the licensee or registrant shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee or registrant shall use equipment in such a way as not to interfere with the proper operation of the respirator.

A.3.9(a)(7)

(7) 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 shall 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 shall be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(8) Atmosphere-supplying respirators shall be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G–7.1, ''Commodity Specification for Air,'' 1997 and included in the regulations of the Occupational Safety and Health Administration [29 CFR 1910.134(i)(1)(ii)(A) through (E)]. Grade D quality air criteria include:

(i) Oxygen content (v/v) of 19.5-23.5%;

(ii) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(iii) Carbon monoxide (CO) content of 10 ppm or less;

(iv) Carbon dioxide content of 1,000 ppm or less; and

(v) Lack of noticeable odor.

(9) The licensee or registrant shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face to facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(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 respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value shall be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

(b) The Agency may impose restrictions in addition to the provisions of A.3.7, A.3.8, and Appendix A to Part A of these Regulations, in order to:

(1) Ensure that the respiratory protection program of the licensee or registrant is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

(c) The licensee or registrant shall obtain authorization from the Agency before using assigned protection factors in excess of those specified in Appendix A to Part A of these Regulations. The Agency may authorize a licensee or registrant to use higher assigned protection factors on receipt of an application that:

(1) Describes the situation for which a need exists for higher protection factors; and

(2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

A.3.10

A.3.10 **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 unrestricted areas.

A.3.11 **Control of Sources of Radiation Not in Storage.**

(a) The licensee shall control and maintain constant surveillance of licensed radioactive material that is in an unrestricted area and that is not in storage.

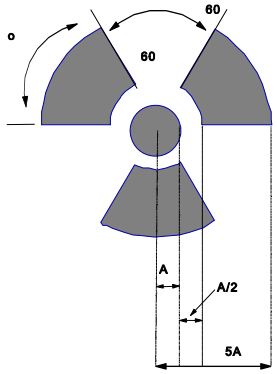
(b) The registrant shall maintain control of radiation machines that are in an unrestricted area and that are not in storage.

A.3.12 **Caution Signs.**

(a) **Standard Radiation Symbol.** Unless otherwise authorized by the Agency, the symbol prescribed by A.3.12 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 A.3.12(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 A, 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.

A.3.13 **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**".

A.3.13(c)

(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**".[10] .

(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 RADIO-ACTIVITY AREA**" or "**DANGER, AIRBORNE RADIOACTIVITY AREA**".

(e) **Posting of Areas or Rooms in which Licensed Material is Used or Stored.** The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in Appendix C to this Part with a conspicuous sign or signs bearing the radiation symbol and the words "**CAUTION, RADIOACTIVE MATERIAL(S)**" or "**DANGER, RADIOACTIVE MATERIAL(S)**".

A.3.14 **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 less than 8 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 this Part; 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 A.3.13 provided that the patient could be released from licensee control pursuant to C.8.24.

(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) 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.

(e) A licensee or registrant is not required to post caution signs in rooms in hospitals or clinics that are used for teletherapy or external beam radiation therapy, if each of the following conditions is met:

(1) Access to the room is controlled pursuant to C.8.50; 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.

A.3.15 **Labeling Containers and Radiation Machines.**

(a) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "**CAUTION, RADIOACTIVE MATERIAL**" or "**DANGER, RADIOACTIVE MATERIAL**". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

[10] Not required to use the word **GRAVE,** this may be omitted.

A.3.15(b)

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(c) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

A.3.16 **Exemptions to Labeling Requirements.** A licensee is not required to label:

(a) Containers holding licensed material in quantities less than the quantities listed in Appendix C; or

(b) Containers holding licensed material in concentrations less than those specified in Table III of Appendix B to this Part; 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 this Part; or

(d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation;[11] 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.

A.3.17 **Procedures for Receiving and Opening Packages.**

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in A.0 and Appendix G to Part C of these Regulations, 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 shall:

(1) Monitor the external surfaces of a labeled[12] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in A.0; and

(2) Monitor the external surfaces of a labeled[12] 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 A.0 and Appendix G to Part C of these Regulations; and

[11] 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.

[12] 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.

A.3.17(b)(3)

(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 shall perform the monitoring required by A.3.17(b) as soon as practicable after receipt of the package, but not later than 3 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 3 hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:

(1) Removable radioactive surface contamination exceeds the limits contained in Appendix G to this Part; or

(2) External radiation levels exceed the limits contained in Appendix G to this Part.

(e) Each licensee 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 transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of A.3.17(b), but are not exempt from the monitoring requirement in A.3.17(b) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

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A.4 WASTE DISPOSAL

A.4.1 **General Requirements.**

(a) A licensee shall dispose of licensed material only:

(1) By transfer to an authorized recipient as provided in A.4.6, Part C, or to the U.S. Department of Energy; or

(2) By decay in storage; or

(3) By release in effluents within the limits in A.2.11; or

(4) As authorized pursuant to A.4.2, A.4.3, A.4.4, A.4.5 or A.4.8.

(b) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed pursuant to 10 CFR 61 or the equivalent regulations of an Agreement State; or

(5) Storage until transferred to a storage or disposal facility authorized to receive the waste.

A.4.2 **Method for Obtaining Approval of Proposed Disposal Procedures.** A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in these Regulations, to dispose of licensed material generated in the licensee's operations. Each application shall include:

(a) A description of the waste containing licensed 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 this Part.

A.4.3 **Disposal by Release into Sanitary Sewerage.**

(a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble, or is readily dispersible biological material, in water; and

(2) The quantity of licensed radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B to this Part; and

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A.4.3(a)(3)

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(i) The licensee shall determine the fraction of the limit in Table III of Appendix B to this Part represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B to this Part; and

(ii) The sum of the fractions for each radionuclide required by A.4.3(a)(3)(i) does not exceed unity; and

(4) The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in A.4.3(a).

A.4.4 **Treatment or Disposal by Incineration.** A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in A.4.5 or as specifically approved by the Agency pursuant to A.4.2.

A.4.5 **Disposal of Specific Wastes.**

(a) A licensee may dispose of the following licensed material as if it were not radioactive:

(1) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(b) A licensee shall not dispose of tissue pursuant to A.4.5(a)(2) in a manner that would permit its use either as food for humans or as animal feed.

(c) The licensee shall maintain records in accordance with A.5.9.

A.4.6 **Transfer for Disposal and Manifests.**

(a) The requirements of A.4.6 and Appendix D to this part are designed to:

(1) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this Part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility;

(2) Establish a manifest tracking system; and

(3) Supplement existing requirements concerning transfers and record keeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on 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.

(c) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix D to this Part.

A.4.6(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 III of Appendix D to this Part.

(e) Any licensee shipping byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in A.0, intended for ultimate disposal at a land disposal facility licensed under 10 CFR 61, or the equivalent regulations of an Agreement State, shall 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 Part A.

A.4.7 **Compliance with Environmental and Health Protection Regulations.** Nothing in this Subpart relieves the licensee from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to this Subpart.

A.4.8 **Disposal of 11e(3) and 11e(4) Byproduct Material.**

(a) Licensed material, as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in A.0, may be disposed of in accordance with 10 CFR 61, or the equivalent regulations of an Agreement State, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR 61, or the equivalent regulations of an Agreement State, shall meet the requirements of A.4.6.

(b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of byproduct material set forth in A.0, 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.

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A.5 RECORDS, REPORTS AND ADDITIONAL REQUIREMENTS

A.5.1 **General Provisions.**

(a) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part.

(b) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Part (e.g., total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, committed effective dose equivalent).

A.5.2 **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 A.5.2(a)(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by A.5.2(a)(2) for 3 years after the record is made.

A.5.3 **Records of Surveys.**

(a) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by A.3.2 and A.3.17(b). The licensee or registrant shall retain these records for 3 years after the record is made.

(b) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

(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 Subparagraphs A.3.9(a)(3)(i) and (a)(3)(ii); 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 make arrangements, satisfactory to the Agency, for permanent storage of records contained on Agency Form RCA-2 or equivalent.

A.5.4 **Records of Tests for Leakage or Contamination of Sealed Sources.** Records of tests for leakage or contamination of sealed sources required by A.3.1 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for 5 years after the records are made.

A.5.5 **Records of Prior Occupational Dose.**

(a) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in A.2.7 on Agency Form RCA-2 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form RCA-2 or equivalent for 3 years after the record is made.

(b) Upon termination of the license or registration, the licensee or registrant shall make arrangements, satisfactory to the Agency, for permanent storage of records contained on Agency Form RCA-2 or equivalent.

A.5.6 **Records of Planned Special Exposures.**

(a) For each use of the provisions of A.2.8 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; and

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(3) What actions were necessary; and

(4) Why the actions were necessary; and

(5) What precautions were taken to assure that doses were maintained ALARA; and

(6) What individual and collective doses were expected to result; and

(7) The doses actually received in the planned special exposure.

(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 make arrangements, satisfactory to the Agency, for permanent storage of records contained on Agency Form RCA-2 or equivalent.

A.5.7 **Records of Individual Monitoring Results.**

(a) **Recordkeeping Requirement.** Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to A.3.3, 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 1 January 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; and

(2) The estimated intake of radionuclides [See A.2.4]; and

(3) The committed effective dose equivalent assigned to the intake of radionuclides; and

(4) The specific information used to assess the committed effective dose equivalent pursuant to A.2.6(a) and (c), and when required by A.3.3; and

(5) The total effective dose equivalent when required by A.2.4; and

A.5.7(a)(6)

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) **Recordkeeping Frequency.** The licensee or registrant shall make entries of the records specified in A.5.7(a) at intervals not to exceed 1 year.

(c) **Recordkeeping Format.** The licensee or registrant shall maintain the records specified in A.5.7(a) on Agency Form RCA-3, in accordance with the instructions for Agency Form RCA-3, or in clear and legible records containing all the information required by Agency Form RCA-3.

(d) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(e) The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.

(f) Upon termination of the license or registration, the licensee or registrant shall make arrangements, satisfactory to the Agency, for permanent storage of records contained on Agency Form RCA-2 or equivalent.

A.5.8 **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 A.2.11.]

(b) The licensee or registrant shall retain the records required by A.5.8(a) until the Agency terminates each pertinent license or registration requiring the record.

A.5.9 **Records of Waste Disposal.**

(a) Each licensee shall maintain records of the disposal of licensed materials made pursuant to A.4.2, A.4.3, A.4.4, A.4.5, and disposal by burial in soil, including burials authorized before 1 June 1981[13].

(b) The licensee shall retain the records required by A.5.9(a) until the Agency terminates each pertinent license requiring the record.

A.5.10 **Records of Testing Entry Control Devices for Very High Radiation Areas.**

(a) Each licensee or registrant shall maintain records of tests made pursuant to A.3.6(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 A.5.10(a) for 3 years after the record is made.

A.5.11 **Form of Records.** Each record required by this Part 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.

[13] A previous A.4.4 permitted burial of small quantities of licensed materials in soil before 1 June 1981, without specific Agency authorization.

A.5.12

A.5.12 **Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.**

(a) **Telephone Reports.** Each licensee or registrant shall report to the Agency by telephone as follows:

(1) Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to this Part under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

(2) Within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C to this Part; or

(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 A.5.12(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 A.5.12 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

A.5.13 **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) Immediately notify the Agency of each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(i) An individual to receive:

(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 rad) or more; or

(ii) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the 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.

(2) Immediately notify the Agency as soon as possible, but not later than 4 hours after the discovery, of an event (e.g., fire, explosion toxic gas release, etc.) that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits.

(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:

(i) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(ii) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

(iii) 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. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area; and

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified for the material in Appendix B to Part A of these Regulations; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(4) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or license/registration condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and/or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; and

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

A.5.13(b)(5)

(5) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(6) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified for the material in Appendix B to Part A of these Regulations; and

(ii) The damage affects the integrity of the licensed material or its container.

(c) The licensee or registrant shall prepare each report filed with the Agency pursuant to A.5.13 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 A.5.13(a) and (b) to the Agency by telephone, telegram, mailgram, or facsimile to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(1) The name of the person making the report and their call-back telephone number;

(2) A description of the event, including time and date;

(3) The exact location of the event;

(4) The levels of radiation and the isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

(e) The provisions of A.5.13 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 A.5.15.

A.5.14 **Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.**

(a) **Reportable Events.** In addition to the notification required by A.5.13, 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 A.5.13; or

(2) Doses in excess of any of the following:

(i) The occupational dose limits for adults in A.2.3; or

(ii) The occupational dose limits for a minor in A.2.9; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in A.2.10; or

(iv) The limits for an individual member of the public in A.2.11; or

(v) Any applicable limit in the license or registration; or

(v) The ALARA constraints for air emissions established under A.2.2(d); or

(3) Levels of radiation or concentrations of radioactive material in:

(i) A restricted area in excess of applicable limits in the license or registration; or

A.5.14(a)(3)(ii)

(ii) An unrestricted area in excess of 10 times the applicable limit set forth in Part A or in the license or registration, whether or not involving exposure of any individual in excess of the limits in A.2.11; 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 A.5.14(a) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation, concentrations of radioactive material, and the isotopes, quantities, and chemical and physical form of the licensed material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and

(iv) A description of the event including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned; and

(v) The exact location, date and time of the event; and

(vi) Corrective actions, including the results of any evaluations or assessments, 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 A.5.14(a) shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in A.2.10, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(c) All licensees or registrants who make reports pursuant to A.5.14(a) shall submit the report in writing to the Agency.

A.5.15 **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 A.2.8, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by A.5.6.

A.5.16 [**RESERVED**]

A.5.17 [**RESERVED**]

A.5.18 **Notifications and Reports to Individuals.**

(a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in A.6.4.

(b) When a licensee or registrant is required pursuant to A.5.14 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 A.6.4(a).

A.5.19

A.5.19 **Reports of Leaking or Contaminated Sealed Sources.** The licensee or registrant shall file a report within 5 working days with the Agency if the test for leakage or contamination required pursuant to A.3.1 indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

A.5.20 **Vacating Premises.** Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his 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.

A.5.21 **Reports of Transactions Involving Nationally Tracked Sources.** Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in A.5.21(a) through (e) 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 shall 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 shall 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 shall include the following information:

(1) The name, address, and license number of the reporting licensee;

A.5.21(c)(2)

(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 shall include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall 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 A.5.21(a) through (e) shall 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 shall 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

A.5.21(f)(5)

(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 (5) business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory[14] of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation shall be conducted during the month of January in each year. The reconciliation process shall include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by A.5.21(a) through (e). By January 31 of each year, each licensee shall submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

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[14] Each licensee that possessed Category 1 and/or Category 2 nationally tracked source(s) prior to 31 January 2009 was required to report its initial inventory of Category 1 and/or Category 2 nationally tracked source(s) to the National Source Tracking System by 31 January 2009.

A.6 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

A.6.1 **Purpose and Scope.** This subpart establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work 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, licenses and certificates of registration issued thereunder regarding radiological working conditions. The regulations in this subpart apply to all persons who receive, possess, use, own or transfer radiation sources licensed by or registered with the Agency pursuant to these Regulations.

A.6.2 **Posting of Notices to Workers.**

(a) Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this part;

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to work under the license or registration;

(4) Any Statement of Deficiencies involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to the Act, and any response from the licensee or registrant.

(b) If posting of a document specified in A.6.2(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 RCA-1 "Notice to Employees" shall be posted by each licensee or registrant as required by these Regulations.

(d) Documents, notices or forms posted pursuant to this section 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.

(e) Agency documents posted pursuant to A.6.2(a)(4) shall be posted within 5 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 2 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

A.6.3 **Instructions to Workers.**

(a) All individuals who in the course of employment are likely to receive an annual occupational dose in excess of 1 mSv (100 mrem) shall be:

(1) Kept informed of the storage, transfer, or use of radiation or radioactive material;

(2) Instructed in the health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these Regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

A.6.3(a)(4)

(4) Instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these Regulations, and licenses or unnecessary exposure to radiation or radioactive material;

(5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(6) Advised as to the radiation exposure reports which workers shall be furnished pursuant to A.6.4.

(b) In determining those individuals subject to the requirements of Paragraph A.6.3(a), licensees and registrants shall take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility. The extent of these instructions shall be commensurate with the potential radiological health protection problems present in the work place.

(c) **Use of Latex Gloves**. Persons, firms or corporations licensed or registered by the Agency that utilize latex gloves are subject to Rules And Regulations Pertaining To The Use Of Latex Gloves By Health Care Workers, In Licensed Health Care Facilities, And By Other Persons, Firms, Or Corporations Licensed Or Registered By The Department [R23-73-LAT], and the posting and employee notification requirements contained therein.

A.6.4 Not**ifications 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 this section. The information reported shall include data and results obtained pursuant to Agency regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to A.5.7. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions of Rhode Island Rules and Regulations for the Control of Radiation, Subpart A.6. You should preserve this report for further reference."

(b) Each licensee or registrant shall advise each worker annually of the worker's dose as shown in records maintained by the licensee or registrant pursuant to A.5.7.

(c) Each licensee or registrant shall furnish to each worker and, upon request, to each former worker engaged in activities controlled by the licensee or registrant a report of the worker's exposure to sources of radiation. The report shall include the dose record for each year the worker was required to be monitored pursuant to A.3.3. Such report shall be furnished within 30 days from the date of request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to A.5.14 to report to the Agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

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A.6.4(e)

(e) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

A.6.5 **Presence of Representatives of Licenses 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 these Regulations.

(b) During an inspection, Agency inspectors may consult privately with workers as specified in A.6.6. 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 workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in A.6.3.

(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 workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged to work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

A.6.6 **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 Agency regulations, licenses and certificates of registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these Regulations, license or certificate of registration condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered X-ray system under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of A.6.7(a).

(c) The provisions of A.6.6(b) shall not be interpreted as authorization to disregard instructions pursuant to A.6.3

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A.6.7 **Requests by Workers for Inspections.**

(a) Any worker or representative of workers believing that a violation of the Act, these Regulations or license or certificate of registration conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

(b) If, upon receipt of such notice, the Agency Administrator determines that the complaint meets the requirements set forth in A.6.7(a), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(c) No licensee, or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these Regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this part.

A.6.8 **Inspections Not Warranted; Informal Review.**

(a) If the Agency determines, with respect to a complaint under A.6.7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Director of Health 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 Director of Health who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Director of Health may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Director of Health shall affirm, modify, or reverse the determination of the Agency and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefor.

(b) If the Agency determines that an inspection is not warranted because the requirements of A.6.7(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 A.6.7(a).

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A.7 COMPLIANCE PROCEDURES

To ensure compliance with these Regulations, the Agency shall proceed in accordance with the provisions of this subpart, as appropriate.

A.7.1 **Statement of Deficiencies**[15]**.**

(a) If, upon inspection or investigation, the administrator or his authorized representative finds that a registrant, licensee or other person subject to the Agency's jurisdiction has violated any of the provisions of the Act, these Regulations, or any rules, orders or conditions imposed pursuant to the Act, he may issue a written Statement of Deficiencies to the licensee, registrant, or other person subject to the Agency's jurisdiction.

(b) Each Notice of Violation shall describe the nature of the violation(s), including a reference to the provision(s) of the law, regulation, rule, order or condition alleged to have been violated.

(c) Each Statement of Deficiencies shall require a consent agreement, whereby the registrant, licensee or other person subject to the Agency's jurisdiction shall provide a written plan of correction to the Agency within ten (10) days of the service of the Statement of Deficiencies. The plan of correction shall specify the corrective actions which the registrant, licensee or other person subject to the Agency's jurisdiction proposes to take, along with an estimate of the time required to implement such actions. If the plan of correction is acceptable to the Agency, and the consent agreement is implemented, no further action will be taken.

A.7.2 **Order of Abatement.** If, upon inspection or investigation, the administrator or his authorized representative finds that a registrant, licensee or other person subject to the Agency's jurisdiction has violated any of the provisions of the Act, these Regulations, or any rules, orders or conditions imposed pursuant to the Act, or a consent agreement, he may issue an Order of Abatement. Also, if a registrant, licensee or other person subject to the Agency's jurisdiction fails to respond within ten (10) days to a Statement of Deficiencies, the Agency may issue an Order of Abatement.

(a) Each Order of Abatement shall describe the nature of the violation(s), including a reference to the provision(s) of the law, regulation, rule, order, condition, or consent agreement alleged to have been violated.

(b) Each Order of Abatement shall fix a reasonable time for the abatement of violations, which time shall not be later than ten days from the date of service of the order.

(c) Each Order of Abatement issued under this section shall be prominently posted so as to be conspicuously visible to employees and patrons of the licensee, registrant or other person subject to the Agency's jurisdiction.

A.7.3 **Emergency Authority.**

(a) Whenever the administrator finds that an emergency exists requiring immediate action to protect the public health or welfare, he may issue an order stating that an emergency exists and requiring that such action be taken as he deems necessary to meet the emergency. Such order shall be effective immediately.

(b) Any person to whom an emergency order is directed shall comply therewith immediately.

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[15] The term *Notice of Violation* was use in these Regulations prior to the October 2013 edition. The change was made for consistency with other enforcement correspondence issued by the Office of Facilities Regulation. The terms *Notice of Violation* and *Statement of Deficiencies* shall be deemed to be equivalent for the purposes of these Regulations.

A.7.4 **Orders of Suspension, Modification, and Revocation.**

(a) An order may be issued for immediate suspension of a registration or license, or a portion thereof, as necessary to remove an immediate threat to the health or safety of a registrant's or licensee's employees or the public. Non-payment of fees beyond the due date may also result in the suspension of a registration or license.

(b) An order for the modification of a registration or license, in whole or in part, may be issued as an enforcement sanction, when it is determined that a registrant's or licensee's operations or activities must be limited or modified to protect the health, safety or interest of the registrant's or licensee's employees or the public.

(c) An order may be issued to revoke a registration or license when

(1) The registrant's or licensee's performance shows that he is not qualified to perform the activities covered by the registration or license; or

(2) The registrant or licensee refuses to correct violations; or

(3) A registrant or licensee does not comply with an Order of Abatement, or

(4) A registrant's or licensee's response to a Notice of Violation indicates inability or unwillingness to maintain compliance with regulatory requirements; or

(5) Any material false statement is made in the application or in any statement of fact required under these Regulations.

A.7.5 **Agency Hearings.** In any proceeding under these Regulations for granting, suspending, revoking, or modifying any registration or license, or for determining compliance with or granting exemptions from rules and regulations of the Agency, the Agency or any person whose interest may be affected by the proceeding may request and shall be afforded an opportunity for a hearing on the record.

A.7.6 **Formal Hearings.**

(a) Any person aggrieved by a finding or order of the Agency may request a hearing before the Director of Health or his authorized representative, at any time within fifteen days after notification. The Director of Health may affirm the finding or order of the Agency or reverse or modify it.

(b) Any person to whom an emergency order is directed shall, on application to the Director of Health, be afforded a hearing within fifteen days. On the basis of such hearing, the Director of Health shall continue such order in effect, revoke it, or modify it.

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PART A

APPENDIX A

PROTECTION FACTORS FOR RESPIRATORS[16]

Respirator Type	Operating Mode	Assigned Protection Factors
I. Air-Purifying Respirators [particulate[17] only][18]		
Filtering facepiece disposable	Negative Pressure	(19)
Facepiece, half[20]	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[21]]		
1. Air-line respirator:		
Facepiece, half	Demand	10

[16] These assigned protection factors apply only in a respiratory protection program that meets the requirements of Part A. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances shall also comply with U.S. Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to Part A of these Regulations 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.

[17] Air purifying respirators with APF <100 shall be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF = 100 shall be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs >100 shall be equipped with particulate filters that are at least 99.97 percent efficient.

[18] The licensee or registrant 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).

[19] Licensees or registrants 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 A.3.9 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee or registrant can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[20] 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 Part A are met.

[21] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

Respirator Type	Operating Mode	Assigned Protection Factors
II. Atmosphere supplying respirators [particulate, gases and vapors] (cont.)		
1. Air-line respirator: (cont.)		
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([22])
2. Self-contained breathing Apparatus (SCBA):		
Facepiece, full	Demand	[23]100
Facepiece, full	Pressure Demand	[24]10,000
Facepiece, full	Demand, Recirculating	[23]100
Facepiece, full	Positive Pressure Recirculating	[24]10,000
III. Combination Respirators		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above.	

[22] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., A.3.9).

[23] The licensee or registrant should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[24] 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.

PART A

APPENDIX B

ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

Introduction

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 μm, micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note:

The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600, and 6E+0 represents 6×10^{0} or 6.

Table I "Occupational Values"

Note that the columns in Table I of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 0.05 Sv (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in A.0. 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; Blad wall = bladder wall; and

St wall = stomach wall; Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 Sv (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, Σ (intake (in μCi) of each radionuclide/ALI_{ns}) ≤ 1.0. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than $1 - (H_d/50)$, instead of ≤ 1.0.

> Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

$$DAC = ALI(\text{in } \mu Ci)/(2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \times 2 \times 10^4 \text{ ml per minute})$$

$$= [ALI/2.4 \times 10^9] \ \mu Ci/ml,$$

where 2×10^4 ml is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. [See A.2.4.] When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table II "Effluent Concentrations"

The columns in Table II of this appendix captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of A.2.12. 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 as was the case in Appendix A to Part A of the August 1991 edition of these Regulations.

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.

Table III "Releases to Sewers"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in A.4.3. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by Reference Man, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a Reference Man during a year, would result in a committed effective dose equivalent of 5 mSv (0.5 rem).

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LIST OF ELEMENTS

Name	Symbol	Atomic No.	Name	Symbol	Atomic No.
Actinium	Ac	89	Molybdenum	Mo	42
Aluminum	Al	13	Neodymium	Nd	60
Americium	Am	95	Neptunium	Np	93
Antimony	Sb	51	Nickel	Ni	28
Argon	Ar	18	Niobium	Nb	41
Arsenic	As	33	Nitrogen	N	7
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Oxygen	O	8
Berkelium	Bk	97	Palladium	Pd	46
Beryllium	Be	4	Phosphorus	P	15
Bismuth	Bi	83	Platinum	Pt	78
Bromine	Br	35	Plutonium	Pu	94
Cadmium	Cd	48	Polonium	Po	84
Calcium	Ca	20	Potassium	K	19
Californium	Cf	98	Praseodymium	Pr	59
Carbon	C	6	Promethium	Pm	61
Cerium	Ce	58	Protactinium	Pa	91
Cesium	Cs	55	Radium	Ra	88
Chlorine	Cl	17	Radon	Rn	86
Chromium	Cr	24	Rhenium	Re	75
Cobalt	Co	27	Rhodium	Rh	45
Copper	Cu	29	Rubidium	Rb	37
Curium	Cm	96	Ruthenium	Ru	44
Dysprosium	Dy	66	Samarium	Sm	62
Einsteinium	Es	99	Scandium	Sc	21
Erbium	Er	68	Selenium	Se	34
Europium	Eu	63	Silicon	Si	14
Fermium	Fm	100	Silver	Ag	47
Fluorine	F	9	Sodium	Na	11
Francium	Fr	87	Strontium	Sr	38
Gadolinium	Gd	64	Sulfur	S	16
Gallium	Ga	31	Tantalum	Ta	73
Germanium	Ge	32	Technetium	Tc	43
Gold	Au	79	Tellurium	Te	52
Hafnium	Hf	72	Terbium	Tb	65
Holmium	Ho	67	Thallium	Tl	81
Hydrogen	H	1	Thorium	Th	90
Indium	In	49	Thulium	Tm	69
Iodine	I	53	Tin	Sn	50
Iridium	Ir	77	Titanium	Ti	22
Iron	Fe	26	Tungsten	W	74
Krypton	Kr	36	Uranium	U	92
Lanthanum	La	57	Vanadium	V	23
Lead	Pb	82	Xenon	Xe	54
Lutetium	Lu	71	Ytterbium	Yb	70
Magnesium	Mg	12	Yttrium	Y	39
Manganese	Mn	25	Zinc	Zn	30
Mendelevium	Md	101	Zirconium	Zr	40
Mercury	Hg	80			

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[1]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{7}Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
8	Oxygen-15[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
9	Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, 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	-	-

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)
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
14	Silicon-32	W, see ^{31}Si	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn2+, S3+, Mg2+, Fe3+, Bi3+, and lanthanides	-	4E+2	2E-7	5E-10	-	-
15	Phosphorus-33	D, see ^{32}P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see ^{32}P	-	3E+3	1E-6	4E-9	-	-
16	Sulfur-35	Vapor	-	1E+4	6E-6	2E-8	-	-
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
			LLI wall (8E+3)	-	-	-	1E-4	1E-3
		W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3 -	2E+3	9E-7	3E-9	-	-
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-
17	Chlorine-38[2]	D, see ^{36}Cl	2E+4	4E+4	2E-5	6E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
		W, see ^{36}Cl	-	5E+4	2E-5	6E-8	-	-
17	Chlorine-39[2]	D, see ^{36}Cl	2E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{36}Cl	-	6E+4	2E-5	8E-8	-	-
18	Argon-37	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

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)
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, $SrTi0_3$	-	6E+0	2E-9	8E-12	-	-
22	Titanium-45	D, see ^{44}Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{44}Ti	-	4E+4	1E-5	5E-8	-	-
		Y, see ^{44}Ti	-	3E+4	1E-5	4E-8	-	-
23	Vanadium-47[2]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
23	Vanadium-48	D, see ^{47}V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
23	Vanadium-48	W, see ^{47}V	-	6E+2	3E-7	9E-10	-	-
23	Vanadium-49	D, see ^{47}V	7E+4	3E+4	1E-5	-	-	-
			LLI wall (9E+4)	Bone surf (3E+4)	-	5E-8	1E-3	1E-2
		W, see ^{47}V	-	2E+4	8E-6	2E-8	-	-
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
		Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24	Chromium-49[2]	D, see ^{48}Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{48}Cr	-	1E+5	4E-5	1E-7	-	-
		Y, see ^{48}Cr	-	9E+4	4E-5	1E-7	-	-
24	Chromium-51	D, see ^{48}Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see ^{48}Cr	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{48}Cr	-	2E+4	8E-6	3E-8	-	-

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)
25	Manganese-51[2]	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	8E-8	-	-
25	Manganese-52m[2]	D, see ^{51}Mn	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{51}Mn	-	1E+5	4E-5	1E-7	-	-
25	Manganese-52	D, see ^{51}Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see ^{51}Mn n	-	9E+2	4E-7	1E-9	-	-
25	Manganese-53	D, see ^{51}Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
			-	Bone surf (2E+4)	-	3E-8	-	-
		W, see ^{51}Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see ^{51}Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see ^{51}Mn	-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see ^{51}Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{51}Mn	-	2E+4	9E-6	3E-8	-	-
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26	Iron-55	D, see ^{52}Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see ^{52}Fe	-	4E+3	2E-6	6E-9	-	-
26	Iron-59	D, see ^{52}Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see ^{52}Fe	-	5E+2	2E-7	7E-10	-	-
26	Iron-60	D, see ^{52}Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see ^{52}Fe	-	2E+1	8E-9	3E-11	-	-
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
27	Cobalt-56	W, see ^{55}Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see ^{55}Co	4E+2	2E+2	8E-8	3E-10	-	-
27	Cobalt-57	W, see ^{55}Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see ^{55}Co	4E+3	7E+2	3E-7	9E-10	-	-
27	Cobalt-58m	W, see ^{55}Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see ^{55}Co	-	6E+4	3E-5	9E-8	-	-
27	Cobalt-58	W, see ^{55}Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see ^{55}Co	1E+3	7E+2	3E-7	1E-9	-	-
27	Cobalt-60m[2]	W, see ^{55}Co	1E+6	4E+6	2E-3	6E-6	-	-
			St wall (1E+6)	-	-	-	2E-2	2E-1
		Y, see ^{55}Co	-	3E+6	1E-3	4E-6	-	-
27	Cobalt-60	W, see ^{55}Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see ^{55}Co	2E+2	3E+1	1E-8	5E-11	-	-
27	Cobalt-61[2]	W, see ^{55}Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{55}Co	2E+4	6E+4	2E-5	8E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
27	Cobalt-62m[2]	W, see ^{55}Co	4E+4	2E+5	7E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{55}Co	-	2E+5	6E-5	2E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	-	1E+3	5E-7	2E-9	-	-
		Vapor	-	1E+3	5E-7	2E-9	-	-
28	Nickel-57	D, see ^{56}Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	6E+3	3E-6	9E-9	-	-
28	Nickel-59	D, see ^{56}Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see ^{56}Ni	-	7E+3	3E-6	1E-8	-	-
		Vapor	-	2E+3	8E-7	3E-9	-	-
28	Nickel-63	D, see ^{56}Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	8E+2	3E-7	1E-9	-	-
28	Nickel-65	D, see ^{56}Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{56}Ni	-	3E+4	1E-5	4E-8	-	-
		Vapor	-	2E+4	7E-6	2E-8	-	-
28	Nickel-66	D, see ^{56}Ni	4E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see ^{56}Ni	-	6E+2	3E-7	9E-10	-	-
		Vapor	-	3E+3	1E-6	4E-9	-	-
29	Copper-60[2]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-
29	Copper-61	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	-	4E+4	2E-5	6E-8	-	-
		Y, see ^{60}Cu	-	4E+4	1E-5	5E-8	-	-
29	Copper-64	D, see 60Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{60}Cu	-	2E+4	9E-6	3E-8	-	-
29	Copper-67	D, see 60Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see ^{60}Cu	-	5E+3	2E-6	7E-9	-	-
		Y, see ^{60}Cu	-	5E+3	2E-6	6E-9	-	-
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-632	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-692	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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65[2]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31	Gallium-66	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see ^{65}Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ^{65}Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68[2]	D, see ^{65}Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{65}Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70[2]	D, see ^{65}Ga	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		W, see ^{65}Ga	-	2E+5	8E-5	3E-7	-	-
31	Gallium-72	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-73	D, see ^{65}Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{65}Ga	-	2E+4	6E-6	2E-8	-	-
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
32	Germanium-66	W, oxides, sulfides, and halides	-	2E+4	8E-6	3E-8	-	-
32	Germanium-67[2]	D, see ^{66}Ge	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, see ^{6}6Ge	-	1E+5	4E-5	1E-7	-	-
32	Germanium-68	D, see ^{66}Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see ^{66}Ge	-	1E+2	4E-8	1E-10	-	-
32	Germanium-69	D, see ^{66}Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see ^{66}Ge	-	8E+3	3E-6	1E-8	-	-
32	Germanium-71	D, see ^{66}Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see ^{66}Ge	-	4E+4	2E-5	6E-8	-	-
32	Germanium-75[2]	D, see ^{66}Ge	4E+4	8E+4	3E-5	1E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see ^{66}Ge	-	8E+4	4E-5	1E-7	-	-
32	Germanium-77	D, see ^{66}Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see ^{66}Ge	-	6E+3	2E-6	8E-9	-	-
32	Germanium-78[2]	D, see ^{66}Ge	2E+4	2E+4	9E-6	3E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see ^{66}Ge	-	2E+4	9E-6	3E-8	-	-
33	Arsenic-69[2]	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
33	Arsenic-70[2]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3

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)
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	-	-
34	Selenium-73m[2]	D, see ^{70}Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	6E-5	2E-7	-	-
34	Selenium-73	D, see ^{70}Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see ^{70}Se	-	2E+4	7E-6	2E-8	-	-
34	Selenium-75	D, see ^{70}Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see ^{70}Se	-	6E+2	3E-7	8E-10	-	-
34	Selenium-79	D, see ^{70}Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see ^{70}Se	-	6E+2	2E-7	8E-10	-	-
34	Selenium-81m[2]	D, see ^{70}Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{70}Se	2E+4	7E+4	3E-5	1E-7	-	-
34	Selenium-81[2]	D, see ^{70}Se	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		W, see ^{70}Se	-	2E+5	1E-4	3E-7	-	-
34	Selenium-83[2]	D, see ^{70}Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	5E-5	2E-7	-	-
35	Bromine-74m[2]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, bromides of 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 ^{74m}Br	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m} Br	-	8E+4	4E-5	1E-7	-	-

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)
35	Bromine-75[2]	D, see ^{74m}Br	3E+4	5E+4	2E-5	7E-8	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m}Br	-	5E+4	2E-5	7E-8	-	-
35	Bromine-76	D, see ^{74m}Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see ^{74m}Br	-	4E+3	2E-6	6E-9	-	-
35	Bromine-77	D, see ^{74m}Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see ^{74m}Br	-	2E+4	8E-6	3E-8	-	-
35	Bromine-80m	D, see ^{74m}Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see ^{74m}Br	-	1E+4	6E-6	2E-8	-	-
35	Bromine-80[2]	D, see ^{74m}Br	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{74m}Br	-	2E+5	9E-5	3E-7	-	-
35	Bromine-82	D, see ^{74}m Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{74m}Br	-	4E+3	2E-6	5E-9	-	-
35	Bromine-83	D, see ^{74m}Br	5E+4	6E+4	3E-5	9E-8	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see ^{74m}Br	-	6E+4	3E-5	9E-8	-	-
35	Bromine-84[2]	D, see ^{74m}Br	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see ^{74m}Br	-	6E+4	3E-5	9E-8	-	-
36	Krypton-74[2]	Submersion[1]	-	-	3E-6	1E-8	-	-
36	Krypton-76	Submersion[1]	-	-	9E-6	4E-8	-	-
36	Krypton-77[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
36	Krypton-79	Submersion[1]	-	-	2E-5	7E-8	-	-
36	Krypton-81	Submersion[1]	-	-	7E-4	3E-6	-	-
36	Krypton-83m[2]	Submersion[1]	-	-	1E-2	5E-5	-	-
36	Krypton-85m	Submersion[1]	-	-	2E-5	1E-7	-	-
36	Krypton-85	Submersion[1]	-	-	1E-4	7E-7	-	-
36	Krypton-87[2]	Submersion[1]	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion[1]	-	-	2E-6	9E-9	-	-
37	Rubidium-79[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
37	Rubidium-81m[2]	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5

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)
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88[2]	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
37	Rubidium-89[2]	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
38	Strontium-80[2]	D, all soluble compounds except $SrTiO_3$	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and $SrTi0_3$	-	1E+4	5E-6	2E-8	-	-
38	Strontium-81[2]	D, see ^{80}Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{80}Sr	2E+4	8E+4	3E-5	1E-7	-	-
38	Strontium-82	D, see ^{80}Sr	3E+2	4E+2	2E-7	6E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		Y, see ^{80}Sr	2E+2	9E+1	4E-8	1E-10	-	-
38	Strontium-83	D, see ^{80}Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{80}Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m[2]	D, see ^{80}Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see ^{80}Sr	-	8E+5	4E-4	1E-6	-	-
38	Strontium-85	D, see ^{80}Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see ^{80}Sr	-	2E+3	6E-7	2E-9	-	-
38	Strontium-87m	D, see ^{80}Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see 80Sr	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see ^{80}Sr	6E+2	8E+2	4E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{80}Sr	5E+2	1E+2	6E-8	2E-10	-	-
38	Strontium-90	D, see ^{80}Sr	3E+1	2E+1	8E-9	-	-	-
			Bone surf (4E+1)	Bone surf (2E+1)	-	3E-11	5E-7	5E-6
		Y, see ^{80}Sr	-	4E+0	2E-9	6E-12	-	-
38	Strontium-91	D, see ^{80}Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see ^{80}Sr	-	4E+3	1E-6	5E-9	-	-
38	Strontium-92	D, see ^{80}Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{80}Sr	-	7E+3	3E-6	9E-9	-	-
39	Yttrium-86m[2]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39	Yttrium-86	W, see ^{86m}Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-87	W, see ^{86m}Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-88	W, see ^{86m}Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see ^{86m}Y	-	2E+2	1E-7	3E-10	-	-

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)
39	Yttrium-90m	W, see ^{86m}Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see ^{86m}Y	-	1E+4	5E-6	2E-8	-	-
39	Yttrium-90	W, see ^{86m}Y	4E+2	7E+2	3E-7	9E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see ^{86m}Y	-	6E+2	3E-7	9E-10	-	-
39	Yttrium-91m[2]	W, see ^{86m}Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see ^{86m}Y	-	2E+5	7E-5	2E-7	-	-
39	Yttrium-91	W, see ^{86m}Y	5E+2	2E+2	7E-8	2E-10	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{86m}Y	-	1E+2	5E-8	2E-10	-	-
39	Yttrium-92	W, see ^{86m}Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{86m}Y	-	8E+3	3E-6	1E-8	-	-
39	Yttrium-93	W, see ^{86m}Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{86m}Y	-	2E+3	1E-6	3E-9	-	-
39	Yttrium-94[2]	W, see ^{86mY}	2E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, see ^{86m}Y	-	8E+4	3E-5	1E-7	-	-
39	Yttrium-95[2]	W, see ^{86m}Y	4E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{86m}Y	-	1E+5	6E-5	2E-7	-	-
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
		Y, carbide	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-88	D, see ^{86}Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see ^{86}Zr	-	5E+2	2E-7	7E-10	-	-
		Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-89	D, see ^{86}Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
		Y, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-93	D, see ^{86}Zr	1E+3	6E+0	3E-9	-	-	-
			Bone surf (3E+3)	Bone surf (2E+1)	-	2E-11	4E-5	4E-4
		W, see ^{86}Zr	-	2E+1	1E-8	-	-	-
			-	Bone surf (6E+1)	-	9E-11	-	-
		Y, see ^{86}Zr	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	9E-11	-	-
40	Zirconium-95	D, see ^{86}Zr	1E+3	1E+2	5E-8	-	2E-5	2E-4
			Bone surf -	(3E+2)	-	4E-10	-	-
		W, see ^{86}Zr	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-

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)
40	Zirconium-97	D, see ^{86}Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see ^{86}Zr	-	1E+3	6E-7	2E-9	-	-
		Y, see ^{86}Zr	-	1E+3	5E-7	2E-9	-	-
41	Niobium-88[2]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41	Niobium-89m[2] (66 min)	W, see ^{88}Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see ^{88}Nb	-	4E+4	2E-5	5E-8	-	-
41	Niobium-89 (122 min)	W, see ^{88}Nb	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{88}Nb	-	2E+4	6E-6	2E-8	-	-
41	Niobium-90	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-93m	W, see ^{88}Nb	9E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+4)	-	-	-	2E-4	2E-3
		Y, see ^{88}Nb	-	2E+2	7E-8	2E-10	-	-
41	Niobium-94	W, see ^{88}Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see ^{88}Nb	-	2E+1	6E-9	2E-11	-	-
41	Niobium-95m	W, see ^{88}Nb	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{88}Nb	-	2E+3	9E-7	3E-9	-	-
41	Niobium-95	W, see ^{88}Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see ^{88}Nb	-	1E+3	5E-7	2E-9	-	-
41	Niobium-96	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-97[2]	W, see ^{88}Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{88}Nb	-	7E+4	3E-5	1E-7	-	-
41	Niobium-98[2]	W, see ^{88}Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see ^{88}Nb	-	5E+4	2E-5	7E-8	-	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS_2	2E+3	5E+3	2E-6	6E-9	-	-
42	Molybdenum-93m	D, see ^{90}Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see ^{90}Mo	4E+3	1E+4	6E-6	2E-8	-	-
42	Molybdenum-93	D, see ^{90}Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see ^{90}Mo	2E+4	2E+2	8E-8	2E-10	-	-
42	Molybdenum-99	D, see ^{90}Mo	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{90}Mo	1E+3	1E+3	6E-7	2E-9	-	-

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)
42	Molybdenum-101[2]	D, see ^{90}Mo	4E+4	1E+5	6E-5	2E-7	--	
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{90}Mo	-	1E+5	6E-5	2E-7	-	-
43	Technetium-93m[2]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43	Technetium-93	D, see ^{93m}Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see ^{93m}Tc	-	1E+5	4E-5	1E-7	-	-
43	Technetium-94m[2]	D, see ^{93m}Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{93m}Tc	-	6E+4	2E-5	8E-8	-	-
43	Technetium-94	D, see ^{93m}Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	-	2E+4	1E-5	3E-8	-	-
43	Technetium-95m	D, see ^{93m}Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see ^{93m}Tc	-	2E+3	8E-7	3E-9	-	-
43	Technetium-95	D, see ^{93m}Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	-	2E+4	8E-6	3E-8	-	-
43	Technetium-96m[2]	D, see ^{93m}Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-96	D, see ^{93m}Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{93m}Tc	-	2E+3	9E-7	3E-9	-	-
43	Technetium-97m	D, see ^{93m}Tc	5E+3	7E+3	3E-6	-	6E-5	6E-4
			-	St wall (7E+3)	-	1E-8	-	-
		W, see ^{93m}Tc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see ^{93m}Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m}Tc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see ^{93m}Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m}Tc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see ^{93m}Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see ^{93m}Tc	4E+3	5E+3	2E-6	-	6E-5	6E-4
			-	St wall (6E+3)	-	8E-9	-	-
		W, see ^{93m}Tc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101[2]	D, see ^{93m}Tc	9E+4	3E+5	1E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, see ^{93m}Tc	-	4E+5	2E-4	5E-7	-	-
43	Technetium-104[2]	D, see ^{93m}Tc	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see ^{93m}Tc	-	9E+4	4E-5	1E-7	-	-
44	Ruthenium-94[2]	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	-	6E+4	3E-5	9E-8	-	-
		Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
44	Ruthenium-97	D, see ^{94}Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
		Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-103	D, see ^{94}Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see ^{94}Ru	-	1E+3	4E-7	1E-9	-	-
		Y, see ^{94}Ru	-	6E+2	3E-7	9E-10	-	-
44	Ruthenium-105	D, see ^{94}Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{94}Ru	-	1E+4	6E-6	2E-8	-	-
		Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-106	D, see ^{94}Ru	2E+2	9E+1	4E-8	1E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		W, see ^{94}Ru	-	5E+1	2E-8	8E-11	-	-
		Y, see ^{94}Ru	-	1E+1	5E-9	2E-11	-	-
45	Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	-	8E+4	3E-5	1E-7	-	-
		Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
45	Rhodium-99	D, see ^{99m}Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{94}Ru	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{99m}Rh	-	2E+3	8E-7	3E-9	-	-
45	Rhodium-100	D, see ^{99m}Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{99m}Rh	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{99m}Rh	-	4E+3	2E-6	5E-9	-	-
45	Rhodium-101m	D, see ^{99m}Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{99m}Rh	-	8E+3	4E-6	1E-8	-	-
		Y, see ^{99m}Rh	-	8E+3	3E-6	1E-8	-	-
45	Rhodium-101	D, see ^{99m}Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{99m}Rh	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{99m}Rh	-	2E+2	6E-8	2E-10	-	-
45	Rhodium-102m	D, see ^{99m}Rh	1E+3	5E+2	2E-7	7E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		W, see ^{99m}Rh	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{99m}Rh	-	1E+2	5E-8	2E-10	-	-
45	Rhodium-102	D, see ^{99m}Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see ^{99m}Rh	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{99m}Rh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m[2]	D, see ^{99m}Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
		Y, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
45	Rhodium-105	D, see ^{99m}Rh	4E+3	1E+4	5E-6	2E-8	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see ^{99m}Rh	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{99m}Rh	-	6E+3	2E-6	8E-9	-	-
45	Rhodium-106m	D, see ^{99m}Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{99m}Rh	-	4E+4	2E-5	5E-8	-	-
		Y, see ^{99m}Rh	-	4E+4	1E-5	5E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
45	Rhodium-107[2]	D, see ^{99m}Rh	7E+4	2E+5	1E-4	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{99m}Rh	-	3E+5	1E-4	4E-7	-	-
		Y, see ^{99m}Rh	-	3E+5	1E-4	3E-7	-	-
46	Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	-	1E+3	5E-7	2E-9	-	-
		Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46	Palladium-101	D, see ^{100}Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{100}Pd	-	3E+4	1E-5	5E-8	-	-
		Y, see ^{100}Pd	-	3E+4	1E-5	4E-8	-	-
46	Palladium-103	D, see ^{100}Pd	6E+3	6E+3	3E-6	9E-9	-	-
			LLI wall (7E+3)	-	-	-	1E-4	1E-3
		W, see ^{100}Pd	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{100}Pd	-	4E+3	1E-6	5E-9	-	-
46	Palladium-107	D, see ^{100}Pd	3E+4	2E+4	9E-6	-	-	-
			LLI wall (4E+4)	Kidneys (2E+4)	-	3E-8	5E-4	5E-3
		W, see ^{100}Pd	-	7E+3	3E-6	1E-8	-	-
		Y, see ^{100}Pd	-	4E+2	2E-7	6E-10	-	-
46	Palladium-109	D, see ^{100}Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		W, see ^{100}Pd	-	5E+3	2E-6	8E-9	-	-
		Y, see ^{100}Pd	-	5E+3	2E-6	6E-9	-	-
47	Silver-102[2]	D, all compounds except those given for W and Y	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, nitrates and sulfides	-	2E+5	9E-5	3E-7	-	-
		Y, oxides and hydroxides	-	2E+5	8E-5	3E-7	-	-
47	Silver-103[2]	D, see ^{102}Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104m[2]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see ^{102}Ag	-	1E+5	5E-5	2E-7	-	-
47	Silver-104[2]	D, see ^{102}Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-
		Y, see ^{102}Ag	-	1E+5	6E-5	2E-7	-	-
47	Silver-105	D, see ^{102}Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
		W, see ^{102}Ag	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{102}Ag	-	2E+3	7E-7	2E-9	-	-
47	Silver-106m	D, see ^{102}Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
		W, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-106[2]	D, see ^{102}Ag	6E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, see ^{102}Ag	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{102}Ag	-	2E+5	8E-5	3E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
47	Silver-108m	D, see ^{102}Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
		W, see ^{102}Ag	-	3E+2	1E-7	4E-10	-	-
		Y, see ^{102}Ag	-	2E+1	1E-8	3E-11	-	-
47	Silver-110m	D, see ^{102}Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
		W, see ^{102}Ag	-	2E+2	8E-8	3E-10	-	-
		Y, see ^{102}Ag	-	9E+1	4E-8	1E-10	-	-
47	Silver-111	D, see ^{102}Ag	9E+2 LLI wall (1E+3)	2E+3 Liver (2E+3)	6E-7 -	- 2E-9	- 2E-5	- 2E-4
		W, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-112	D, see ^{102}Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{102}Ag	-	1E+4	4E-6	1E-8	-	-
		Y, see ^{102}Ag	-	9E+3	4E-6	1E-8	-	-
47	Silver-115[2]	D, see ^{102}Ag	3E+4 St wall (3E+4)	9E+4 -	4E-5 -	1E-7 -	- 4E-4	- 4E-3
		W, see ^{102}Ag	-	9E+4	4E-5	1E-7	-	-
		Y, see ^{102}Ag	-	8E+4	3E-5	1E-7	-	-
48	Cadmium-104[2]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
48	Cadmium-107	D, see ^{104}Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{104}Cd	-	6E+4	2E-5	8E-8	-	-
		Y, see ^{104}Cd	-	5E+4	2E-5	7E-8	-	-
48	Cadmium-109	D, see ^{104}Cd	3E+2 Kidneys (4E+2)	4E+1 Kidneys (5E+1)	1E-8 -	- 7E-11	- 6E-6	- 6E-5
		W, see ^{104}Cd	- -	1E+2 Kidneys (1E+2)	5E-8 -	- 2E-10	- -	- -
		Y, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
48	Cadmium-113m	D, see ^{104}Cd	2E+1 Kidneys (4E+1)	2E+0 Kidneys (4E+0)	1E-9 -	- 5E-12	- 5E-7	- 5E-6
		W, see ^{104}Cd	- -	8E+0 Kidneys (1E+1)	4E-9 -	- 2E-11	- -	- -
		Y, see ^{104}Cd	-	1E+1	5E-9	2E-11	-	-
48	Cadmium-113	D, see ^{104}Cd	2E+1 Kidneys (3E+1)	2E+0 Kidneys (3E+0)	9E-10 -	- 5E-12	- 4E-7	- 4E-6
		W, see ^{104}Cd	- -	8E+0 Kidneys (1E+1)	3E-9 -	- 2E-11	- -	- -
		Y, see ^{104}Cd	-	1E+1	6E-9	2E-11	-	-
48	Cadmium-115m	D, see ^{104}Cd	3E+2	5E+1 Kidneys	2E-8	-	4E-6	4E-5
			-	(8E+1)	-	1E-10	-	-
		W, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{104}Cd	-	1E+2	6E-8	2E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
48	Cadmium-115	D, see ^{104}Cd	9E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
		W, see ^{104}Cd	-	1E+3	5E-7	2E-9	-	-
		Y, see ^{104}Cd	-	1E+3	6E-7	2E-9	-	-
48	Cadmium-117m	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-
48	Cadmium-117	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	9E-8	-	-
49	Indium-110[2] (69.1 min)	D, see ^{109}In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	-	6E+4	2E-5	8E-8	-	-
49	Indium-110 (4.9 h)	D, see ^{109}In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		W, see ^{109}In	-	2E+4	8E-6	3E-8	-	-
49	Indium-111	D, see ^{109}In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see ^{109}In	-	6E+3	3E-6	9E-9	-	-
49	Indium-112[2]	D, see ^{109}In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see ^{109}In	-	7E+5	3E-4	1E-6	-	-
49	Indium-113m[2]	D, see ^{109}In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see ^{109}In	-	2E+5	8E-5	3E-7	-	-
49	Indium-114m	D, see ^{109}In	3E+2	6E+1	3E-8	9E-11	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		W, see ^{109}In	-	1E+2	4E-8	1E-10	-	-
49	Indium-115m	D, see ^{109}In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	-	5E+4	2E-5	7E-8	-	-
49	Indium-115	D, see ^{109}In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see ^{109}In	-	5E+0	2E-9	8E-12	-	-
49	Indium-116m[2]	D, see ^{109}In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{109}In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m[2]	D, see ^{109}In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{109}In	-	4E+4	2E-5	6E-8	-	-
49	Indium-117[2]	D, see ^{109}In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see ^{109}In	-	2E+5	9E-5	3E-7	-	-
49	Indium-119m[2]	D, see ^{109}In	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, see ^{109}In	-	1E+5	6E-5	2E-7	-	-
50	Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	-	1E+4	5E-6	2E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
50	Tin-111[2]	D, see ^{110}Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
		W, see ^{110}Sn	-	3E+5	1E-4	4E-7	-	-
50	Tin-113	D, see ^{110}Sn	2E+3	1E+3	5E-7	2E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-117m	D, see ^{110}Sn	2E+3	1E+3	5E-7	-	-	-
			LLI wall (2E+3)	Bone surf (2E+3)	-	3E-9	3E-5	3E-4
		W, see ^{110}Sn	-	1E+3	6E-7	2E-9	-	-
50	Tin-119m	D, see ^{110}Sn	3E+3	2E+3	1E-6	3E-9	-	-
			LLI wall (4E+3)	-	-	-	6E-5	6E-4
		W, see ^{110}Sn	-	1E+3	4E-7	1E-9	-	-
50	Tin-121m	D, see ^{110}Sn	3E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-121	D, see ^{110}Sn	6E+3	2E+4	6E-6	2E-8	-	-
			LLI wall (6E+3)	-	-	-	8E-5	8E-4
		W, see ^{110}Sn	-	1E+4	5E-6	2E-8	-	-
50	Tin-123m[2]	D, see ^{110}Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
		W, see ^{110}Sn	-	1E+5	6E-5	2E-7	-	-
50	Tin-123	D, see ^{110}Sn	5E+2	6E+2	3E-7	9E-10	-	-
			LLI wall (6E+2)	-	-	-	9E-6	9E-5
		W, see ^{110}Sn	-	2E+2	7E-8	2E-10	-	-
50	Tin-125	D, see ^{110}Sn	4E+2	9E+2	4E-7	1E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see ^{110}Sn	-	4E+2	1E-7	5E-10	-	-
50	Tin-126	D, see ^{110}Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
		W, see ^{110}Sn	-	7E+1	3E-8	9E-11	-	-
50	Tin-127	D, see ^{110}Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see ^{110}Sn	-	2E+4	8E-6	3E-8	-	-
50	Tin-128[2]	D, see ^{110}Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{110}Sn	-	4E+4	1E-5	5E-8	-	-
51	Antimony-115[2]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51	Antimony-116m[2]	D, see ^{115}Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{115}Sb	-	1E+5	6E-5	2E-7	-	-
51	Antimony-116[2]	D, see ^{115}Sb	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{115}Sb	-	3E+5	1E-4	5E-7	-	-

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)
51	Antimony-117	D, see ^{115}Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see ^{115}Sb	-	3E+5	1E-4	4E-7	-	-
51	Antimony-118m	D, see ^{115}Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see ^{115}Sb	5E+3	2E+4	9E-6	3E-8	-	-
51	Antimony-119	D, see ^{115}Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{115}Sb	2E+4	3E+4	1E-5	4E-8	-	-
51	Antimony-120[2] (16 min)	D, see ^{115}Sb	1E+5	4E+5	2E-4	6E-7	-	-
			St wall (2E+5)	-	-	-	2E-3	2E-2
		W, see ^{115}Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120 (5.76 d)	D, see ^{115}Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see ^{115}Sb	9E+2	1E+3	5E-7	2E-9	-	-
51	Antimony-122	D, see ^{115}Sb	8E+2	2E+3	1E-6	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see ^{115}Sb	7E+2	1E+3	4E-7	2E-9	-	-
51	Antimony-124m[2]	D, see ^{115}Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see ^{115}Sb	2E+5	6E+5	2E-4	8E-7	-	-
51	Antimony-124	D, see ^{115}Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	2E+2	1E-7	3E-10	-	-
51	Antimony-125	D, see ^{115}Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see ^{115}Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m[2]	D, see ^{115}Sb	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see ^{115}Sb	-	2E+5	8E-5	3E-7	-	-
51	Antimony-126	D, see ^{115}Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	5E+2	2E-7	7E-10	-	-
51	Antimony-127	D, see ^{115}Sb	8E+2	2E+3	9E-7	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see ^{115}Sb	7E+2	9E+2	4E-7	1E-9	-	-
51	Antimony-128[2] (10.4 min)	D, see ^{115}Sb	8E+4	4E+5	2E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ^{115}Sb	-	4E+5	2E-4	6E-7	-	-
51	Antimony-128 (9.01 h)	D, see ^{115}Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see ^{115}Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see ^{115}Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see ^{115}Sb	-	9E+3	4E-6	1E-8	-	-
51	Antimony-130[2]	D, see ^{115}Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{115}Sb	-	8E+4	3E-5	1E-7	-	-
51	Antimony-131[2]	D, see ^{115}Sb	1E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (4E+4)	-	6E-8	2E-4	2E-3
		W, see ^{115}Sb	-	2E+4	1E-5		-	-
			Thyroid -	(4E+4)	-	6E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	-	-
52	Tellurium-121m	D, see ^{116}Te	5E+2 Bone surf (7E+2)	2E+2 Bone surf (4E+2)	8E-8 -	- 5E-10	- 1E-5	- 1E-4
		W, see ^{116}Te	-	4E+2	2E-7	6E-10	-	-
52	Tellurium-121	D, see ^{116}Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{116}Te	-	3E+3	1E-6	4E-9	-	-
52	Tellurium-123m	D, see ^{116}Te	6E+2 Bone surf (1E+3)	2E+2 Bone surf (5E+2)	9E-8 -	- 8E-10	- 1E-5	- 1E-4
		W, see ^{116}Te	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-123	D, see ^{116}Te	5E+2 Bone surf (1E+3)	2E+2 Bone surf (5E+2)	8E-8 -	- 7E-10	- 2E-5	- 2E-4
		W, see ^{116}Te	- -	4E+2 Bone surf (1E+3)	2E-7 -	- 2E-9	- -	- -
52	Tellurium-125m	D, see ^{116}Te	1E+3 Bone surf (1E+3)	4E+2 Bone surf (1E+3)	2E-7 -	- 1E-9	- 2E-5	- 2E-4
		W, see ^{116}Te	-	7E+2	3E-7	1E-9	-	-
52	Tellurium-127m	D, see ^{116}Te	6E+2	3E+2 Bone surf (4E+2)	1E-7 -	- 6E-10	9E-6 -	9E-5 -
		W, see ^{116}Te	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{116}Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ^{116}Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129[2]	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{116}Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see ^{116}Te	3E+2 Thyroid (6E+2)	4E+2 Thyroid (1E+3)	2E-7 -	- 2E-9	- 8E-6	- 8E-5
		W, see ^{116}Te	- -	4E+2 Thyroid (9E+2)	2E-7 -	- 1E-9	- -	- -
52	Tellurium-131[2]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- 8E-5	- 8E-4
		W, see ^{116}Te	- -	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- -	- -
52	Tellurium-132	D, see ^{116}Te	2E+2 Thyroid (7E+2)	2E+2 Thyroid (8E+2)	9E-8 -	- 1E-9	- 9E-6	- 9E-5
		W, see ^{116}Te	- -	2E+2 Thyroid (6E+2)	9E-8 -	- 9E-10	- -	- -

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
52	Tellurium-133m[2]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- 9E-5	- 9E-4
		W, see ^{116}Te	- -	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- -	- -
52	Tellurium-133[2]	D, see ^{116}Te	1E+4 Thyroid (3E+4)	2E+4 Thyroid (6E+4)	9E-6 -	- 8E-8	- 4E-4	- 4E-3
		W, see ^{116}Te	- -	2E+4 Thyroid (6E+4)	9E-6 -	- 8E-8	- -	- -
52	Tellurium-134[2]	D, see ^{116}Te	2E+4 Thyroid (2E+4)	2E+4 Thyroid (5E+4)	1E-5 -	- 7E-8	- 3E-4	- 3E-3
		W, see ^{116}Te	- -	2E+4 Thyroid (5E+4)	1E-5 -	- 7E-8	- -	- -
53	Iodine-120m[2]	D, all compounds	1E+4 Thyroid (1E+4)	2E+4 -	9E-6 -	3E-8 -	- 2E-4	- 2E-3
53	Iodine-120[2]	D, all compounds	4E+3 Thyroid (8E+3)	9E+3 Thyroid (1E+4)	4E-6 -	- 2E-8	- 1E-4	- 1E-3
53	Iodine-121	D, all compounds	1E+4 Thyroid (3E+4)	2E+4 Thyroid (5E+4)	8E-6 -	- 7E-8	- 4E-4	- 4E-3
53	Iodine-123	D, all compounds	3E+3 Thyroid (1E+4)	6E+3 Thyroid (2E+4)	3E-6 -	- 2E-8	- 1E-4	- 1E-3
53	Iodine-124	D, all compounds	5E+1 Thyroid (2E+2)	8E+1 Thyroid (3E+2)	3E-8 -	- 4E-10	- 2E-6	- 2E-5
53	Iodine-125	D, all compounds	4E+1 Thyroid (1E+2)	6E+1 Thyroid (2E+2)	3E-8 -	- 3E-10	- 2E-6	- 2E-5
53	Iodine-126	D, all compounds	2E+1 Thyroid (7E+1)	4E+1 Thyroid (1E+2)	1E-8 -	- 2E-10	- 1E-6	- 1E-5
53	Iodine-128[2]	D, all compounds	4E+4 St wall (6E+4)	1E+5 -	5E-5 -	2E-7 -	- 8E-4	- 8E-3
53	Iodine-129	D, all compounds	5E+0 Thyroid (2E+1)	9E+0 Thyroid (3E+1)	4E-9 -	- 4E-11	- 2E-7	- 2E-6
53	Iodine-130	D, all compounds	4E+2 Thyroid (1E+3)	7E+2 Thyroid (2E+3)	3E-7 -	- 3E-9	- 2E-5	- 2E-4

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)
53	Iodine-131	D, all compounds	3E+1 Thyroid (9E+1)	5E+1 Thyroid (2E+2)	2E-8 - -	- 2E-10	- 1E-6	- 1E-5
53	Iodine-132m[2]	D, all compounds	4E+3 Thyroid (1E+4)	8E+3 Thyroid (2E+4)	4E-6 - -	- 3E-8	- 1E-4	- 1E-3
53	Iodine-132	D, all compounds	4E+3 Thyroid (9E+3)	8E+3 Thyroid (1E+4)	3E-6 - -	- 2E-8	- 1E-4	- 1E-3
53	Iodine-133	D, all compounds	1E+2 Thyroid (5E+2)	3E+2 Thyroid (9E+2)	1E-7 - -	- 1E-9	- 7E-6	- 7E-5
53	Iodine-134[2]	D, all compounds	2E+4 Thyroid (3E+4)	5E+4 - -	2E-5 - -	6E-8 - -	- 4E-4	- 4E-3
53	Iodine-135	D, all compounds	8E+2 Thyroid (3E+3)	2E+3 Thyroid (4E+3)	7E-7 - -	- 6E-9	- 3E-5	- 3E-4
54	Xenon-120[2]	Submersion[1]	-	-	1E-5	4E-8	-	-
54	Xenon-121[2]	Submersion[1]	-	-	2E-6	1E-8	-	-
54	Xenon-122	Submersion[1]	-	-	7E-5	3E-7	-	-
54	Xenon-123	Submersion[1]	-	-	6E-6	3E-8	-	-
54	Xenon-125	Submersion[1]	-	-	2E-5	7E-8	-	-
54	Xenon-127	Submersion[1]	-	-	1E-5	6E-8	-	-
54	Xenon-129m	Submersion[1]	-	-	2E-4	9E-7	-	-
54	Xenon-131m	Submersion[1]	-	-	4E-4	2E-6	-	-
54	Xenon-133m	Submersion[1]	-	-	1E-4	6E-7	-	-
54	Xenon-133	Submersion[1]	-	-	1E-4	5E-7	-	-
54	Xenon-135m[2]	Submersion[1]	-	-	9E-6	4E-8	-	-
54	Xenon-135	Submersion[1]	-	-	1E-5	7E-8	-	-
54	Xenon-138[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
55	Cesium-125[2]	D, all compounds	5E+4 St wall (9E+4)	1E+5 - -	6E-5 - -	2E-7 - -	- 1E-3	- 1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130[2]	D, all compounds	6E+4 St wall (1E+5)	2E+5 - -	8E-5 - -	3E-7 - -	- 1E-3	- 1E-2
55	Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cesium-134m	D, all compounds	1E+5 St wall (1E+5)	1E+5 - -	6E-5 - -	2E-7 - -	- 2E-3	- 2E-2

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)
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cesium-135m[2]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138[2]	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
56	Barium-126[2]	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m[2]	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
			St wall (5E+5)	-	-	-	7E-3	7E-2
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139[2]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
56	Barium-141[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131[2]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57	Lanthanum-132	D, see ^{131}La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-135	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
57	Lanthanum-137	D, see ^{131}La	1E+4	6E+1	3E-8	-	2E-4	2E-3
			-	Liver (7E+1)	-	1E-10	-	-
		W, see ^{131}La	-	3E+2	1E-7	-	-	-
			-	Liver (3E+2)	-	4E-10	-	-
57	Lanthanum-138	D, see ^{131}La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see ^{131}La	-	1E+1	6E-9	2E-11	-	-
57	Lanthanum-140	D, see ^{131}La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{131}La	-	1E+3	5E-7	2E-9	-	-
57	Lanthanum-141	D, see ^{131}La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
57	Lanthanum-142[2]	D, see ^{131}La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{131}La	-	3E+4	1E-5	5E-8	-	-
57	Lanthanum-143[2]	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see ^{134}Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ^{134}Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see ^{134}Ce	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	4E+3	2E-6	5E-9	-	-
58	Cerium-137	W, see ^{134}Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ^{134}Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see ^{134}Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ^{134}Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see ^{134}Ce	2E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see ^{134}Ce	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall 1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{134}Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see ^{134}Ce	2E+2	3E+1	1E-8	4E-11	-	-
			LLI wall (3E+2)	-	-	-	3E-6	3E-5
		Y, see ^{134}Ce	-	1E+1	6E-9	2E-11	-	-
59	Praseodymium-136[2]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-
59	Praseodymium-137[2]	W, see ^{136}Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-138m	W, see ^{136}Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see ^{136}Pr	-	4E+4	2E-5	6E-8	-	-
59	Praseodymium-139	W, see ^{136}Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-142m[2]	W, see ^{136}Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-142	W, see ^{136}Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see ^{136}Pr	-	2E+3	8E-7	3E-9	-	-

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)
59	Praseodymium-143	W, see ^{136}Pr	9E+2	8E+2	3E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{136}Pr	-	7E+2	3E-7	9E-10	-	-
59	Praseodymium-144[2]	W, see ^{136}Pr	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-145	W, see ^{136}Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{136}Pr	-	8E+3	3E-6	1E-8	-	-
59	Praseodymium-147[2]	W, see ^{136}Pr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		Y, see ^{136}Pr	-	2E+5	8E-5	3E-7	-	-
60	Neodymium-136[2]	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60	Neodymium-138	W, see ^{136}Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see ^{136}Nd	-	5E+3	2E-6	7E-9	-	-
60	Neodymium-139m	W, see ^{136}Nd	5E+3	2E+4	7E-6	2E-8	7E-57E-4	
		Y, see ^{136}Nd	-	1E+4	6E-6	2E-8	-	-
60	Neodymium-139[2]	W, see ^{136}Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see ^{136}Nd	-	3E+5	1E-4	4E-7	-	-
60	Neodymium-141	W, see ^{136}Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see ^{136}Nd	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see ^{136}Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{136}Nd	-	8E+2	4E-7	1E-9	-	-
60	Neodymium-149[2]	W, see ^{136}Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see ^{136}Nd	-	2E+4	1E-5	3E-8	-	-
60	Neodymium-151[2]	W, see ^{136}Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see ^{136}Nd	-	2E+5	8E-5	3E-7	-	-
61	Promethium-141[2]	W, all compounds except those given for Y	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	7E-5	2E-7	-	-
61	Promethium-143	W, see ^{141}Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see ^{141}Pm	-	7E+2	3E-7	1E-9	-	-
61	Promethium-144	W, see ^{141}Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see ^{141}Pm	-	1E+2	5E-8	2E-10	-	-
61	Promethium-145	W, see ^{141}Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see ^{141}Pm	-	2E+2	8E-8	3E-10	-	-

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)
61	Promethium-146	W, see ^{141}Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see ^{141}Pm	-	4E+1	2E-8	6E-11	-	-
61	Promethium-147	W, see ^{141}Pm	4E+3 LLI wall 5E+3)	1E+2 Bone surf (2E+2)	5E-8 -	- 3E-10	- 7E-5	- 7E-4
		Y, see ^{141}Pm	-	1E+2	6E-8	2E-10	-	-
61	Promethium-148m	W, see ^{141}Pm	7E+2	3E+2	1E-7	4E-10	1E-51E-4	
		Y, see ^{141}Pm	-	3E+2	1E-7	5E-10	-	-
61	Promethium-148	W, see ^{141}Pm	4E+2 LLI wall (5E+2)	5E+2 -	2E-7 -	8E-10 -	- 7E-6	- 7E-5
		Y, see ^{141}Pm	-	5E+2	2E-7	7E-10	-	-
61	Promethium-149	W, see ^{141}Pm	1E+3 LLI wall (1E+3)	2E+3 -	8E-7 -	3E-9 -	- 2E-5	- 2E-4
		Y, see ^{141}Pm	-	2E+3	8E-7	2E-9	-	-
61	Promethium-150	W, see ^{141}Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{141}Pm	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see ^{141}Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{141}Pm	-	3E+3	1E-6	4E-9	-	-
62	Samarium-141m[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141[2]	W, all compounds	5E+4 St wall (6E+4)	2E+5 -	8E-5 -	2E-7 -	- 8E-4	- 8E-3
62	Samarium-142[2]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1 Bone surf (3E+1)	4E-2 Bone surf (6E-2)	1E-11 -	- 9E-14	- 3E-7	- 3E-6
62	Samarium-147	W, all compounds	2E+1 Bone surf (3E+1)	4E-2 Bone surf (7E-2)	2E-11 -	- 1E-13	- 4E-7	- 4E-6
62	Samarium-151	W, all compounds	1E+4 LLI wall (1E+4)	1E+2 Bone surf (2E+2)	4E-8 -	- 2E-10	- 2E-4	- 2E-3
62	Samarium-153	W, all compounds	2E+3 LLI wall (2E+3)	3E+3 -	1E-6 -	4E-9 -	- 3E-5	- 3E-4
62	Samarium-155[2]	W, all compounds	6E+4 St wall (8E+4)	2E+5 -	9E-5 -	3E-7 -	- 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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
			Bone surf -	(1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[2]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[2]	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64	Gadolinium-146	D, see ^{145}Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see ^{145}Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see ^{145}Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{145}Gd	-	4E+3	1E-6	5E-9	-	-
64	Gadolinium-148	D, see ^{145}Gd	1E+1	8E+3	3E-12	-	-	-
			Bone surf (2E+1)	Bone surf (2E-2)	-	2E-14	3E-7	3E-6
		W, see ^{145}Gd	-	3E-2	1E-11	-	-	-
			-	Bone surf (6E-2)	-	8E-14	-	-
64	Gadolinium-149	D, see ^{145}Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see ^{145}Gd	-	2E+3	1E-6	3E-9	-	-
64	Gadolinium-151	D, see ^{145}Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4
			-	Bone surf (6E+2)	-	9E-10	-	-
		W, see ^{145}Gd	-	1E+3	5E-7	2E-9	-	-
64	Gadolinium-152	D, see ^{145}Gd	2E+1	1E-2	4E-12	-	-	-
			Bone surf (3E+1)	Bone surf (2E-2)	-	3E-14	4E-7	4E-6
		W, see ^{145}Gd	-	4E-2	2E-11	-	-	-
			-	Bone surf (8E-2)	-	1E-13	-	-
64	Gadolinium-153	D, see ^{145}Gd	5E+3	1E+2	6E-8	-	6E-5	6E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		W, see ^{145}Gd	-	6E+2	2E-7	8E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
64	Gadolinium-159	D, see ^{145}Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{145}Gd	-	6E+3	2E-6	8E-9	-	-
65	Terbium-147[2]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65	Terbium-157	W, all compounds	5E+4	3E+2	1E-7	-	-	-
			LLI wall (5E+4)	Bone surf (6E+2)	-	8E-10	7E-4	7E-3
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3	2E+3	7E-7	2E-9	-	-
			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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (9E+2)	-	-	-	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
69	Thulium-162[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-
			LLI wall (1E+3)	-	-	-	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-
			LLI wall (1E+4)	Bone surf (6E+2)	-	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
70	Ytterbium-162[2]	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		Y, oxides, hydroxides, and fluorides	-	3E+5	1E-4	4E-7	-	-
70	Ytterbium-166	W, see ^{162}Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		Y, see ^{162}Yb	-	2E+3	8E-7	3E-9	-	-
70	Ytterbium-167[2]	W, see ^{162}Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
		Y, see ^{162}Yb	-	7E+5	3E-4	1E-6	-	-
70	Ytterbium-169	W, see ^{162}Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
		Y, see ^{162}Yb	-	7E+2	3E-7	1E-9	-	-

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)
70	Ytterbium-175	W, see ^{162}Yb	3E+3	4E+3	1E-6	5E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see ^{162}Yb	-	3E+3	1E-6	5E-9	-	-
70	Ytterbium-177[2]	W, see ^{162}Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
		Y, see ^{162}Yb	-	5E+4	2E-5	6E-8	-	-
70	Ytterbium-178[2]	W, see ^{162}Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		Y, see ^{162}Yb	-	4E+4	2E-5	5E-8	-	-
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		Y, oxides, hydroxides, and fluorides	-	4E+3	2E-6	6E-9	-	-
71	Lutetium-170	W, see ^{169}Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
		Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-171	W, see ^{169}Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
		Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-172	W, see ^{169}Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
		Y, see ^{169}Lu	-	1E+3	5E-7	2E-9	-	-
71	Lutetium-173	W, see ^{169}Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
			-	Bone surf (5E+2)	-	6E-10	-	-
		Y, see ^{169}Lu	-	3E+2	1E-7	4E-10	-	-
71	Lutetium-174m	W, see ^{169}Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall (3E+3)	Bone surf (3E+2)	-	5E-10	4E-5	4E-4
		Y, see ^{169}Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see ^{169}Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see ^{169}Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see ^{169}Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ^{169}Lu	-	2E+4	9E-6	3E-8	-	-
71	Lutetium-176	W, see ^{169}Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
			-	Bone surf (1E+1)	-	2E-11	-	-
		Y, see ^{169}Lu	-	8E+0	3E-9	1E-11	-	-
71	Lutetium-177m	W, see ^{169}Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
		Y, see ^{169}Lu	-	8E+1	3E-8	1E-10	-	-
71	Lutetium-177	W, see ^{169}Lu	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see ^{169}Lu	-	2E+3	9E-7	3E-9	-	-
71	Lutetium-178m[2]	W, see ^{169}Lu	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
		Y, see ^{169}Lu	-	2E+5	7E-5	2E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
71	Lutetium-178[2]	W, see ^{169}Lu	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see ^{169}Lu	-	1E+5	5E-5	2E-7	-	-
71	Lutetium-179	W, see ^{169}Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{169}Lu	-	2E+4	6E-6	3E-8	-	-
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72	Hafnium-172	D, see ^{170}Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
72	Hafnium-172	W, see ^{170}Hf	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
72	Hafnium-173	D, see ^{170}Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{170}Hf	-	1E+4	5E-6	2E-8	-	-
72	Hafnium-175	D, see ^{170}Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
			-	Bone surf (1E+3)	-	1E-9	-	-
		W, see ^{170}Hf	-	1E+3	5E-7	2E-9	-	-
72	Hafnium-177m[2]	D, see ^{170}Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{170}Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see ^{170}Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
			-	Bone surf (2E+0)	-	3E-12	-	-
		W, see ^{170}Hf	-	5E+0	2E-9	-	-	-
			-	Bone surf (9E+0)	-	1E-11	-	-
72	Hafnium-179m	D, see ^{170}Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
			-	Bone surf (6E+2)	-	8E-10	-	-
		W, see ^{170}Hf	-	6E+2	3E-7	8E-10	-	-
72	Hafnium-180m	D, see ^{170}Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{170}Hf	-	3E+4	1E-5	4E-8	-	-
72	Hafnium-181	D, see ^{170}Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see ^{170}Hf	-	4E+2	2E-7	6E-10	-	-
72	Hafnium-182m[2]	D, see ^{170}Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see ^{170}Hf	-	1E+5	6E-5	2E-7	-	-
72	Hafnium-182	D, see ^{170}Hf	2E+2	8E-1	3E-10	-	-	-
			Bone surf (4E+2)	Bone surf (2E+0)	-	2E-12	5E-6	5E-5
		W, see ^{170}Hf	-	3E+0	1E-9	-	-	-
			-	Bone surf (7E+0)	-	1E-11	-	-
72	Hafnium-183[2]	D, see ^{170}Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{170}Hf	-	6E+4	2E-5	8E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
72	Hafnium-184	D, see ^{170}Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{170}Hf	-	6E+3	3E-6	9E-9	-	-
73	Tantalum-172[2]	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-
73	Tantalum-173	W, see ^{172}Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-174[2]	W, see ^{172}Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	-	9E+4	4E-5	1E-7	-	-
73	Tantalum-175	W, see ^{172}Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see ^{172}Ta	-	1E+4	6E-6	2E-8	-	-
73	Tantalum-176	W, see ^{172}Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see ^{172}Ta	-	1E+4	5E-6	2E-8	-	-
73	Tantalum-177	W, see ^{172}Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-178	W, see ^{172}Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see ^{172}Ta	-	7E+4	3E-5	1E-7	-	-
73	Tantalum-179	W, see ^{172}Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ^{172}Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see ^{172}Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{172}Ta	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-180	W, see ^{172}Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ^{172}Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m[2]	W, see ^{172}Ta	2E+5	5E+5	2E-4	8E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
		Y, see ^{172}Ta	-	4E+5	2E-4	6E-7	-	-
73	Tantalum-182	W, see ^{172}Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see ^{172}Ta	-	1E+2	6E-8	2E-10	-	-
73	Tantalum-183	W, see ^{172}Ta	9E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{172}Ta	-	1E+3	4E-7	1E-9	-	-
73	Tantalum-184	W, see ^{172}Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see ^{172}Ta	-	5E+3	2E-6	7E-9	-	-
73	Tantalum-185[2]	W, see ^{172}Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	-	6E+4	3E-5	9E-8	-	-
73	Tantalum-186[2]	W, see ^{172}Ta	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, see ^{172}Ta	-	2E+5	9E-5	3E-7	-	-
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3

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)
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 ^{177}Re	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ^{177}Re	-	3E+5	1E-4	4E-7	-	-
75	Rhenium-181	D, see ^{177}Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see ^{177}Re	-	9E+3	4E-6	1E-8	-	-
75	Rhenium-182 (12.7 h)	D, see ^{177}Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
		W, see ^{177}Re	-	2E+4	6E-6	2E-8	-	-
75	Rhenium-182 (64.0 h)	D, see ^{177}Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{177}Re	-	2E+3	9E-7	3E-9	-	-
75	Rhenium-184m	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	4E+2	2E-7	6E-10	-	-
75	Rhenium-184	D, see ^{177}Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{177}Re	-	1E+3	6E-7	2E-9	-	-
75	Rhenium-186m	D, see ^{177}Re	1E+3	2E+3	7E-7	-	-	-
			St wall (2E+3)	St wall (2E+3)	-	3E-9	2E-5	2E-4
		W, see ^{177}Re	-	2E+2	6E-8	2E-10	-	-
75	Rhenium-186	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	2E+3	7E-7	2E-9	-	-
75	Rhenium-187	D, see ^{177}Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
			-	St wall (9E+5)	-	1E-6	-	-
		W, see ^{177}Re	-	1E+5	4E-5	1E-7	-	-
75	Rhenium-188m[2]	D, see ^{177}Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{177}Re	-	1E+5	6E-5	2E-7	-	-
75	Rhenium-188	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see ^{177}Re	-	3E+3	1E-6	4E-9	-	-
75	Rhenium-189	D, see ^{177}Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see ^{177}Re	-	4E+3	2E-6	6E-9	-	-

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)
76	Osmium-180[2]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	-	5E+5	2E-4	7E-7	-	-
		Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-	-
76	Osmium-181[2]	D, see ^{180}Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{180}Os	-	5E+4	2E-5	6E-8	-	-
		Y, see ^{180}Os	-	4E+4	2E-5	6E-8	-	-
76	Osmium-182	D, see ^{180}Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
76	Osmium-185	D, see ^{180}Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
76	Osmium-189m	D, see ^{180}Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see ^{180}Os	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{180}Os	-	2E+5	7E-5	2E-7	-	-
76	Osmium-191m	D, see ^{180}Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{180}Os	-	2E+4	8E-6	3E-8	-	-
		Y, see ^{180}Os	-	2E+4	7E-6	2E-8	-	-
76	Osmium-191	D, see ^{180}Os	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	3E-5	3E-4
		W, see ^{180}Os	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{180}Os	-	1E+3	6E-7	2E-9	-	-
76	Osmium-193	D, see ^{180}Os	2E+3	5E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		W, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
		Y, see 180Os	-	3E+3	1E-6	4E-9	-	-
76	Osmium-194	D, see ^{180}Os	4E+2	4E+1	2E-8	6E-11	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		W, see ^{180}Os	-	6E+1	2E-8	8E-11	-	-
		Y, see ^{180}Os	-	8E+0	3E-9	1E-11	-	-
77	Iridium-182[2]	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
77	Iridium-184	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	5E-8	-	-
		Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-185	D, see ^{182}Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{182}Ir	-	1E+4	5E-6	2E-8	-	-
		Y, see ^{182}Ir	-	1E+4	4E-6	1E-8	-	-
77	Iridium-186	D, see ^{182}Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{182}Ir r	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{182}Ir	-	6E+3	2E-6	8E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
77	Iridium-187	D, see ^{182}Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-188	D, see ^{182}Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-
		Y, see ^{182}Ir	-	3E+3	1E-6	5E-9	-	-
77	Iridium-189	D, see ^{182}Ir	5E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	7E-5	7E-4
		W, see ^{182}Ir	-	4E+3	2E-6	5E-9	-	-
		Y, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-
77	Iridium-190m^{2}	D, see ^{182}Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see ^{182}Ir	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{182}Ir	-	2E+5	8E-5	3E-7	-	-
77	Iridium-190	D, see ^{182}Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see ^{182}Ir	-	1E+3	4E-7	1E-9	-	-
		Y, see ^{182}Ir	-	9E+2	4E-7	1E-9	-	-
77	Iridium-192m	D, see ^{182}Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
		Y, see ^{182}Ir	-	2E+1	6E-9	2E-11	-	-
77	Iridium-192	D, see ^{182}Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see ^{182}Ir	-	4E+2	2E-7	6E-10	-	-
		Y, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
77	Iridium-194m	D, see ^{182}Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
		W, see ^{182}Ir	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{182}Ir	-	1E+2	4E-8	1E-10	-	-
77	Iridium-194	D, see ^{182}Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{182}Ir	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{182}Ir	-	2E+3	8E-7	3E-9	-	-
77	Iridium-195m	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see ^{182}Ir	-	2E+4	9E-6	3E-8	-	-
77	Iridium-195	D, see ^{182}Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{182}Ir	-	5E+4	2E-5	7E-8	-	-
		Y, see ^{182}Ir	-	4E+4	2E-5	6E-8	-	-
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	-	-
			LLI wall (3E+4)	-	-	-	4E-5	4E-4
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

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)
78	Platinum-197m[2]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Platinum-199[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
		Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79	Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193}Au	-	5E+3	2E-6	8E-9	-	-
		Y, see ^{193}Au	-	5E+3	2E-6	7E-9	-	-
79	Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{193}Au	-	1E+3	6E-7	2E-9	-	-
		Y, see ^{193}Au	-	4E+2	2E-7	6E-10	-	-
79	Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
		Y, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
79	Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	-	2E+3	8E-7	3E-9	-	-
		Y, see ^{193}Au	-	2E+3	7E-7	2E-9	-	-
79	Gold-199	D, see ^{193}Au	3E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see ^{193}Au	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{193}Au	-	4E+3	2E-6	5E-9	-	-
79	Gold-200m	D, see ^{193}Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{193}Au	-	2E+4	1E-6	3E-9	-	-
79	Gold-200[2]	D, see ^{193}Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{193}Au	-	8E+4	3E-5	1E-7	-	-
		Y, see ^{193}Au	-	7E+4	3E-5	1E-7	-	-
79	Gold-201[2]	D, see ^{193}Au	7E+4	2E+5	9E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{193}Au	-	2E+5	1E-4	3E-7	-	-
		Y, see ^{193}Au	-	2E+5	9E-5	3E-7	-	-
80	Mercury-193m	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-
80	Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		D, see ^{193m}Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{193m}Hg	-	4E+4	2E-5	6E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
80	Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
		Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
		D, see ^{193m}Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
		W, see ^{193m}Hg	-	1E+2	5E-8	2E-10	-	-
80	Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
		Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
		D, see ^{193m}Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
		W, see ^{193m}Hg	-	4E+3	2E-6	5E-9	-	-
80	Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		D, see ^{193m}Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{193m}Hg	-	3E+4	1E-5	5E-8	-	-
80	Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
		Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		D, see ^{193m}Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193m}Hg	-	5E+3	2E-6	7E-9	-	-
80	Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
		D, see ^{193m}Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{193m}Hg	-	9E+3	4E-6	1E-8	-	-
80	Mercury-199m[2]	Vapor	-	8E+4	3E-5	1E-7	-	-
		Organic D	6E+4	2E+5	7E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		D, see ^{193m}Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
		W, see ^{193m}Hg	-	2E+5	7E-5	2E-7	-	-
80	Mercury-203	Vapor	-	8E+2	4E-7	1E-9	-	-
		Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
		D, see ^{193m}Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		W, see ^{193m}Hg	-	1E+3	5E-7	2E-9	-	-
81	Thallium-194m[2]	D, all compounds	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
81	Thallium-194[2]	D, all compounds	3E+5	6E+5	2E-4	8E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
81	Thallium-195[2]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198m[2]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-199[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E-1 Bone surf (1E+0)	2E-1 Bone surf (4E-1)	1E-10 -	- 6E-13	- 1E-8	- 1E-7
82	Lead-211[2]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1 Bone surf (1E+2)	3E+1 -	1E-8 -	5E-11 -	- 2E-6	- 2E-5
82	Lead-214[2]	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bismuth-200[2]	D, nitrates W, all other compounds	3E+4 -	8E+4 1E+5	4E-5 4E-5	1E-7 1E-7	4E-4 -	4E-3 -
83	Bismuth-201[2]	D, see ^{200}Bi W, see ^{200}Bi	1E+4 -	3E+4 4E+4	1E-5 2E-5	4E-8 5E-8	2E-4 -	2E-3 -
83	Bismuth-202[2]	D, see ^{200}Bi W, see ^{200}Bi	1E+4 -	4E+4 8E+4	2E-5 3E-5	6E-8 1E-7	2E-4 -	2E-3 -
83	Bismuth-203	D, see ^{200}Bi W, see ^{200}Bi	2E+3 -	7E+3 6E+3	3E-6 3E-6	9E-9 9E-9	3E-5 -	3E-4 -
83	Bismuth-205	D, see ^{200}Bi W, see ^{200}Bi	1E+3 -	3E+3 1E+3	1E-6 5E-7	3E-9 2E-9	2E-5 -	2E-4 -
83	Bismuth-206	D, see ^{200}Bi W, see ^{200}Bi	6E+2 -	1E+3 9E+2	6E-7 4E-7	2E-9 1E-9	9E-6 -	9E-5 -
83	Bismuth-207	D, see ^{200}Bi W, see ^{200}Bi	1E+3 -	2E+3 4E+2	7E-7 1E-7	2E-9 5E-10	1E-5 -	1E-4 -
83	Bismuth-210m	D, see ^{200}Bi W, see ^{200}Bi	4E+1 Kidneys (6E+1) -	5E+0 Kidneys (6E+0) 7E-1	2E-9 - 3E-10	- 9E-12 9E-13	- 8E-7 -	- 8E-6 -
83	Bismuth-210	D, see ^{200}Bi W, see ^{200}Bi	8E+2 - - -	2E+2 Kidneys (4E+2) 3E+1	1E-7 - 1E-8	- 5E-10 4E-11	1E-5 - -	1E-4 - -
83	Bismuth-212[2]	D, see ^{200}Bi W, see ^{200}Bi	5E+3 -	2E+2 3E+2	1E-7 1E-7	3E-10 4E-10	7E-5 -	7E-4 -
83	Bismuth-213[2]	D, see ^{200}Bi W, see ^{200}Bi	7E+3 -	3E+2 4E+2	1E-7 1E-7	4E-10 5E-10	1E-4 -	1E-3 -

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
83	Bismuth-214[2]	D, see ^{200}Bi	2E+4	8E+2	3E-7	1E-9	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see ^{200}Bi	-	9E-2	4E-7	1E-9	-	-
84	Polonium-203[2]	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-	-
84	Polonium-205[2]	D, see ^{203}Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see ^{203}Po	-	7E+4	3E-5	1E-7	-	-
84	Polonium-207	D, see ^{203}Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{203}Po	-	3E+4	1E-5	4E-8	-	-
84	Polonium-210	D, see ^{203}Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see ^{203}Po	-	6E-1	3E-10	9E-13	-	-
85	Astatine-207[2]	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	-	2E+3	9E-7	3E-9	-	-
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	-	5E+1	2E-8	8E-11	-	-
86	Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
		With daughters present	-	2E+1 (or 12 WLM)	9E-9 (or 1.0 WL)	3E-11	-	-
86	Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
		With daughters present	-	1E+2 (or 4 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
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

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
89	Actinium-224	D, all compounds except those given for W and Y	2E+3 LLI wall (2E+3)	3E+1 Bone surf (4E+1)	1E-8 -	- 5E-11	- 3E-5	- 3E-4
		W, halides and nitrates	-	5E+1	2E-8	7E-11	-	-
		Y, oxides and hydroxides	-	5E+1	2E-8	6E-11	-	-
89	Actinium-225	D, see ^{224}Ac	5E+1 LLI wall (5E+1)	3E-1 Bone surf (5E-1)	1E-10 -	- 7E-13	- 7E-7	- 7E-6
		W, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
		Y, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
89	Actinium-226	D, see ^{224}Ac	1E+2 LLI wall (1E+2)	3E+0 Bone surf (4E+0)	1E-9 -	- 5E-12	- 2E-6	- 2E-5
		W, see ^{224}Ac	-	5E+0	2E-9	7E-12	-	-
		Y, see ^{224}Ac	-	5E+0	2E-9	6E-12	-	-
89	Actinium-227	D, see ^{224}Ac	2E-1 Bone surf (4E-1)	4E-4 Bone surf (8E-4)	2E-13 -	- 1E-15	- 5E-9	- 5E-8
89	Actinium-227	W, see ^{224}Ac	-	2E-3 Bone surf (3E-3)	7E-13 -	- 4E-15	- -	- -
		Y, see ^{224}Ac	-	4E-3	2E-12	6E-15	-	-
89	Actinium-228	D, see ^{224}Ac	2E+3 -	9E+0 Bone surf (2E+1)	4E-9 -	- 2E-11	3E-5 -	3E-4 -
		W, see ^{224}Ac	- -	4E+1 Bone surf (6E+1)	2E-8 -	- 8E-11	- -	- -
		Y, see ^{224}Ac	-	4E+1	2E-8	6E-11	-	-
90	Thorium-226[2]	W, all compounds except those given for Y	5E+3 St wall 5E+3)	2E+2 -	6E-8 -	2E-10 -	- 7E-5	- 7E-4
		Y, oxides and hydroxides	-	1E+2	6E-8	2E-10	-	-
90	Thorium-227	W, see ^{226}Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
		Y, see ^{226}Th	-	3E-1	1E-10	5E-13	-	-
90	Thorium-228	W, see ^{226}Th	6E+0 Bone surf (1E+1)	1E-2 Bone surf (2E-2)	4E-12 -	- 3E-14	- 2E-7	- 2E-6
		Y, see ^{226}Th	-	2E-2	7E-12	2E-14	-	-
90	Thorium-229	W, see ^{226}Th	6E-1 Bone surf (1E+0)	9E-4 Bone surf (2E-3)	4E-13 -	- 3E-15	- 2E-8	- 2E-7
		Y, see ^{226}Th	- Bone surf -	2E-3 (3E-3)	1E-12 -	- 4E-15	- -	- -
90	Thorium-230	W, see ^{226}Th	4E+0 Bone surf (9E+0)	6E-3 Bone surf (2E-2)	3E-12 -	- 2E-14	- 1E-7	- 1E-6
		Y, see ^{226}Th	-	2E-2 Bone surf (2E-2)	6E-12 -	- 3E-14	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
90	Thorium-231	W, see ^{226}Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see ^{226}Th	-	6E+3	3E-6	9E-9	-	-
90	Thorium-232	W, see ^{226}Th	7E-1 Bone surf (2E+0)	1E-3 Bone surf (3E-3)	5E-13 -	- 4E-15	- 3E-8	- 3E-7
		Y, see ^{226}Th	-	3E-3 Bone surf (4E-3)	1E-12 -	- 6E-15	- -	- -
90	Thorium-234	W, see ^{226}Th	3E+2 LLI wall (4E+2)	2E+2 -	8E-8 -	3E-10 -	- 5E-6	- 5E-5
		Y, see ^{226}Th	-	2E+2	6E-8	2E-10	-	-
91	Protactinium-227[2]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91	Protactinium-228	W, see ^{227}Pa	1E+3	1E+1 Bone surf (2E+1)	5E-9 -	- 3E-11	2E-5 -	2E-4 -
		Y, see ^{227}Pa	-	1E+1	5E-9	2E-11	-	-
91	Protactinium-230	W, see ^{227}Pa	6E+2 Bone surf (9E+2)	5E+0 -	2E-9 -	7E-12 -	- 1E-5	- 1E-4
		Y, see ^{227}Pa	-	4E+0	1E-9	5E-12	-	-
91	Protactinium-231	W, see ^{227}Pa	2E-1 Bone surf (5E-1)	2E-3 Bone surf (4E-3)	6E-13 -	- 6E-15	- 6E-9	- 6E-8
		Y, see ^{227}Pa	-	4E-3 Bone surf (6E-3)	2E-12 -	- 8E-15	- -	- -
91	Protactinium-232	W, see ^{227}Pa	1E+3	2E+1 Bone surf (6E+1)	9E-9 -	- 8E-11	2E-5 -	2E-4 -
		Y, see ^{227}Pa	-	6E+1 Bone surf (7E+1)	2E-8 -	- 1E-10	- -	- -
91	Protactinium-233	W, see ^{227}Pa	1E+3 LLI wall (2E+3)	7E+2 -	3E-7 -	1E-9 -	- 2E-5	- 2E-4
		Y, see ^{227}Pa	-	6E+2	2E-7	8E-10	-	-
91	Protactinium-234	W, see ^{227}Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{227}Pa	-	7E+3	3E-6	9E-9	-	-
92	Uranium-230	D, UF_6, UO_2F_2, $UO_2(NO_3)_2$	4E+0 Bone surf (6E+0)	4E-1 Bone surf (6E-1)	2E-10 -	- 8E-13	- 8E-8	- 8E-7
		W, UO_3, UF_4, UCl_4	-	4E-1	1E-10	5E-13	-	-
		Y, UO_2, U_3O_8	-	3E-1	1E-10	4E-13	-	-
92	Uranium-231	D, see ^{230}U	5E+3 LLI wall (4E+3)	8E+3 -	3E-6 -	1E-8 -	- 6E-5	- 6E-4
		W, see ^{230}U	-	6E+3	2E-6	8E-9	-	-
		Y, see ^{230}U	-	5E+3	2E-6	6E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
92	Uranium-232	D, see ^{230}U	2E+0	2E-1	9E-11	-	-	-
			Bone surf (4E+0)	Bone surf (4E-1)	-	6E-13	6E-8	6E-7
		W, see ^{230}U	-	4E-1	2E-10	5E-13	-	-
		Y, see ^{230}U	-	8E-3	3E-12	1E-14	-	-
92	Uranium-233	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-234[3]	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-235[3]	D, see ^{230}U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-236	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-237	D, see ^{230}U	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see ^{230}U	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{230}U	-	2E+3	6E-7	2E-9	-	-
92	Uranium-238[3]	D, see ^{230}U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-239[2]	D, see ^{230}U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		W, see ^{230}U	-	2E+5	7E-5	2E-7	-	-
		Y, see ^{230}U	-	2E+5	6E-5	2E-7	-	-
92	Uranium-240	D, see ^{230}U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{230}U	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{230}U	-	2E+3	1E-6	3E-9	-	-
92	Uranium-natural[3]	D, see ^{230}U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ^{230}U	-	8E-1	3E-10	9E-13	-	-
		Y, see ^{230}U	-	5E-2	2E-11	9E-14	-	-
93	Neptunium-232[2]	W, all compounds	1E+5	2E+3	7E-7	-	2E-3	2E-2
			-	Bone surf (5E+2)	-	6E-9	-	-
93	Neptunium-233[2]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4

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)
93	Neptunium-235	W, all compounds	2E+4 LLI wall (2E+4)	8E+2 Bone surf (1E+3)	3E-7 -	- 2E-9	- 3E-4	- 3E-3
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0 Bone surf (6E+0)	2E-2 Bone surf (5E-2)	9E-12 -	- 8E-14	- 9E-8	- 9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3 Bone surf (4E+3)	3E+1 Bone surf (7E+1)	1E-8 -	- 1E-10	- 5E-5	- 5E-4
93	Neptunium-237	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (1E-2)	2E-12 -	- 1E-14	- 2E-8	- 2E-7
93	Neptunium-238	W, all compounds	1E+3 Bone surf -	6E+1 (2E+2)	3E-8 -	- 2E-10	2E-5 -	2E-4 -
93	Neptunium-239	W, all compounds	2E+3 LLI wall (2E+3)	2E+3 -	9E-7 -	3E-9 -	- 2E-5	- 2E-4
93	Neptunium-240[2]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO_2	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO_2	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235[2]	W, see ^{234}Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ^{234}Pu	-	3E+6	1E-3	3E-6	-	-
94	Plutonium-236	W, see ^{234}Pu	2E+0 Bone surf (4E+0)	2E-2 Bone surf (4E-2)	8E-12 -	- 5E-14	- 6E-8	- 6E-7
		Y, see ^{234}Pu	-	4E-2	2E-11	6E-14	-	-
94	Plutonium-237	W, see ^{234}Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see ^{234}Pu	-	3E+3	1E-6	4E-9	-	-
94	Plutonium-238	W, see ^{234}Pu	9E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	-	2E-2	8E-12	2E-14	-	-
94	Plutonium-239	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-240	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -

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)
94	Plutonium-241	W, see ^{234}Pu	4E+1 Bone surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 -	- 8E-13	- 1E-6	- 1E-5
		Y, see ^{234}Pu	- -	8E-1 Bone surf (1E+0)	3E-10 -	- 1E-12	- -	- -
94	Plutonium-242	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-243	W, see ^{234}Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see ^{234}Pu	-	4E+4	2E-5	5E-8	-	-
94	Plutonium-244	W, see ^{234}Pu	8E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see 234Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see ^{234}Pu	-	4E+3	2E-6	6E-9	-	-
94	Plutonium-246	W, see ^{234}Pu	4E+2 LLI wall (4E+2)	3E+2 -	1E-7 -	4E-10 -	- 6E-6	- 6E-5
		Y, see ^{234}Pu	-	3E+2	1E-7	4E-10	-	-
95	Americium-237[2]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238[2]	W, all compounds	4E+4 -	3E+3 Bone surf (6E+3)	1E-6 -	- 9E-9	5E-4 -	5E-3 -
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
95	Americium-242m	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
95	Americium-242	W, all compounds	4E+3 -	8E+1 Bone surf (9E+1)	4E-8 -	- 1E-10	5E-5 -	5E-4 -
95	Americium-243	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
95	Americium-244m[2]	W, all compounds	6E+4 St wall (8E+4)	4E+3 Bone surf (7E+3)	2E-6 -	- 1E-8	- 1E-3	- 1E-2
95	Americium-244	W, all compounds	3E+3 -	2E+2 Bone surf (3E+2)	8E-8 -	- 4E-10	4E-5 -	4E-4 -

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
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

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)
97	Berkelium-250	W, all compounds	9E+3	3E+2 Bone surf	1E-7	-	1E-4	1E-3
			-	(7E+2)	-	1E-9	-	-
98	Californium-244[2]	W, all compounds except those given for Y	3E+4 St wall	6E+2	2E-7	8E-10	-	-
			(3E+4)	-	-	-	4E-4	4E-3
		Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-
98	Californium-246	W, see ^{244}Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see ^{244}Cf	-	9E+0	4E-9	1E-11	-	-
98	Californium-248	W, see ^{244}Cf	8E+0 Bone surf	6E-2 Bone surf	3E-11	-	-	-
			(2E+1)	(1E-1)	-	2E-13	2E-7	2E-6
		Y, see ^{244}Cf	-	1E-1	4E-11	1E-13	-	-
98	Californium-249	W, see ^{244}Cf	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
			(1E+0)	(9E-3)	-	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	- Bone surf	1E-2	4E-12	-	-	-
			-	(1E-2)	-	2E-14	-	-
98	Californium-250	W, see ^{244}Cf	1E+0 Bone surf	9E-3 Bone surf	4E-12	-	-	-
			(2E+0)	(2E-2)	-	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	-	3E-2	1E-11	4E-14	-	-
98	Californium-251	W, see ^{244}Cf	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
			(1E+0)	(9E-3)	-	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	-	1E-2 Bone surf	4E-12	-	-	-
			-	(1E-2)	-	2E-14	-	-
98	Californium-252	W, see ^{244}Cf	2E+0 Bone surf	2E-2 Bone surf	8E-12	-	-	-
			(5E+0)	(4E-2)	-	5E-14	7E-8	7E-7
		Y, see ^{244}Cf	-	3E-2	1E-11	5E-14	-	-
98	Californium-253	W, see ^{244}Cf	2E+2 Bone surf	2E+0	8E-10	3E-12	-	-
			(4E+2)	-	-	-	5E-6	5E-5
		Y, see ^{244}Cf	-	2E+0	7E-10	2E-12	-	-
98	Californium-254	W, see ^{244}Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	-	2E-2	7E-12	2E-14	-	-
99	Einsteinium-250	W, all compounds	4E+4	5E+2 Bone surf	2E-7	-	6E-4	6E-3
			-	(1E+3)	-	2E-9	-	-
99	Einsteinium-251	W, all compounds	7E+3	9E+2 Bone surf	4E-7	-	1E-4	1E-3
			-	(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 LLI wall	1E+1	4E-9	1E-11	-	-
			(3E+2)	-	-	-	4E-6	4E-5

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)
99	Einsteinium-254	W, all compounds	8E+0 Bone surf (2E+1)	7E-2 Bone surf (1E-1)	3E-11 -	- 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 Bone surf (4E+1)	2E-1 Bone surf (2E-1)	7E-11 -	- 3E-13	- 5E-7	- 5E-6
101	Mendelevium-257	W, all compounds	7E+3 -	8E+1 Bone surf (9E+1)	4E-8 -	- 1E-10	1E-4 -	1E-3 -
101	Mendelevium-258	W, all compounds	3E+1 Bone surf (5E+1)	2E-1 Bone surf (3E-1)	1E-10 -	- 5E-13	- 6E-7	- 6E-6
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half- life less than 2 hours	Submersion[1]	-	2E+2	1E-7	1E-9	-	-
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours	. . . .	-	2E-1	1E-10	1E-12	1E-8	1E-7
-	Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known	. . . .	-	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:

[1]"Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2]These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 □Ci/ml for the listed DAC to account for the submersion dose

Atomic Radionuclide No.	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)

prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See A.2.5)

[3]For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see A.2.3(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) □Ci-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 $\geq$ 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

NOTE:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

	If it is known that Ac-227-D and Cm-250-W are not present	-	7E-4	3E-13	-	-	-
	If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present	-	7E-3	3E-12	-	-	-
	If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y,U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present	-	7E-2	3E-11	-	-	-
	If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present	-	7E-1	3E-10	-	-	-
	If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present	-	7E+0	3E-9	-	-	-
	If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present-	-	-		1E-14	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
	If, 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

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 μm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 μCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 μCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B to this Part 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 C_A, C_B, and C_C, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

PART A

APPENDIX C

QUANTITIES[25] OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Hydrogen-3	1,000	Scandium-49	1,000
Beryllium-7	1,000	Titanium-44	1
Beryllium-10	1	Titanium-45	1,000
Carbon-11	1,000	Vanadium-47	1,000
Carbon-14	100	Vanadium-48	100
Fluorine-18	1,000	Vanadium-49	1,000
Sodium-22	10	Chromium-48	1,000
Sodium-24	100	Chromium-49	1,000
Magnesium-28	100	Chromium-51	1,000
Aluminum-26	10	Manganese-51	1,000
Silicon-31	1,000	Manganese-52m	1,000
Silicon-32	1	Manganese-52	100
Phosphorus-32	10	Manganese-53	1,000
Phosphorus-33	100	Manganese-54	100
Sulfur-35	100	Manganese-56	1,000
Chlorine-36	10	Iron-52	100
Chlorine-38	1,000	Iron-55	100
Chlorine-39	1,000	Iron-59	10
Argon-39	1,000	Iron-60	1
Argon-41	1,000	Cobalt-55	100
Potassium-40	100	Cobalt-56	10
Potassium-42	1,000	Cobalt-57	100
Potassium-43	1,000	Cobalt-58m	1,000
Potassium-44	1,000	Cobalt-58	100
Potassium-45	1,000	Cobalt-60m	1,000
Calcium-41	100	Cobalt-60	1
Calcium-45	100	Cobalt-61	1,000
Calcium-47	100	Cobalt-62m	1,000
Scandium-43	1,000	Nickel-56	100
Scandium-44m	100	Nickel-57	100
Scandium-44	100	Nickel-59	100
Scandium-46	10	Nickel-63	100
Scandium-47	100	Nickel-65	1,000
Scandium-48	100	Nickel-66	10

*To convert μCi to kBq, multiply the μCi value by 37.

[25] The quantities listed in this Appendix were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to this Part, 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 C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Copper-60	1,000	Bromine-74	1,000
Copper-61	1,000	Bromine-75	1,000
Copper-64	1,000	Bromine-76	100
Copper-67	1,000	Bromine-77	1,000
Zinc-62	100	Bromine-80m	1,000
Zinc-63	1,000	Bromine-80	1,000
Zinc-65	10	Bromine-82	100
Zinc-69m	100	Bromine-83	1,000
Zinc-69	1,000	Bromine-84	1,000
Zinc-71m	1,000	Krypton-74	1,000
Zinc-72	100	Krypton-76	1,000
Gallium-65	1,000	Krypton-77	1,000
Gallium-66	100	Krypton-79	1,000
Gallium-67	1,000	Krypton-81	1,000
Gallium-68	1,000	Krypton-83m	1,000
Gallium-70	1,000	Krypton-85m	1,000
Gallium-72	100	Krypton-85	1,000
Gallium-73	1,000	Krypton-87	1,000
Germanium-66	1,000	Krypton-88	1,000
Germanium-67	1,000	Rubidium-79	1,000
Germanium-68	10	Rubidium-81m	1,000
Germanium-69	1,000	Rubidium-81	1,000
Germanium-71	1,000	Rubidium-82m	1,000
Germanium-75	1,000	Rubidium-83	100
Germanium-77	1,000	Rubidium-84	100
Germanium-78	1,000	Rubidium-86	100
Arsenic-69	1,000	Rubidium-87	100
Arsenic-70	1,000	Rubidium-88	1,000
Arsenic-71	100	Rubidium-89	1,000
Arsenic-72	100	Strontium-80	100
Arsenic-73	100	Strontium-81	1,000
Arsenic-74	100	Strontium-83	100
Arsenic-76	100	Strontium-85m	1,000
Arsenic-77	100	Strontium-85	100
Arsenic-78	1,000	Strontium-87m	1,000
Selenium-70	1,000	Strontium-89	10
Selenium-73m	1,000	Strontium-90	0.1
Selenium-73	100	Strontium-91	100
Selenium-75	100	Strontium-92	100
Selenium-79	100	Yttrium-86m	1,000
Selenium-81m	1,000	Yttrium-86	100
Selenium-81	1,000	Yttrium-87	100
Selenium-83	1,000	Yttrium-88	10
Bromine-74m	1,000	Yttrium-90m	1,000

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Yttrium-90	10	Ruthenium-94	1,000
Yttrium-91m	1,000	Ruthenium-97	1,000
Yttrium-91	10	Ruthenium-103	100
Yttrium-92	100	Ruthenium-105	1,000
Yttrium-93	100	Ruthenium-106	1
Yttrium-94	1,000	Rhodium-99m	1,000
Yttrium-95	1,000	Rhodium-99	100
Zirconium-86	100	Rhodium-100	100
Zirconium-88	10	Rhodium-101m	1,000
Zirconium-89	100	Rhodium-101	10
Zirconium-93	1	Rhodium-102m	10
Zirconium-95	10	Rhodium-102	10
Zirconium-97	100	Rhodium-103m	1,000
Niobium-88	1,000	Rhodium-105	100
Niobium-89m		Rhodium-106m	1,000
(66min)	1,000	Rhodium-107	1,000
Niobium-89		Palladium-100	100
(122min)	1,000	Palladium-101	1,000
Niobium-90	100	Palladium-103	100
Niobium-93m	10	Palladium-107	10
Niobium-94	1	Palladium-109	100
Niobium-95m	100	Silver-102	1,000
Niobium-95	100	Silver-103	1,000
Niobium-96	100	Silver-104m	1,000
Niobium-97	1,000	Silver-104	1,000
Niobium-98	1,000	Silver-105	100
Molybdenum-90	100	Silver-106m	100
Molybdenum-93m	100	Silver-106	1,000
Molybdenum-93	10	Silver-108m	1
Molybdenum-99	100	Silver-11Om	10
Molybdenum-101	1,000	Silver-111	100
Technetium-93m	1,000	Silver-112	100
Technetium-93	1,000	Silver-115	1,000
Technetium-94m	1,000	Cadmium-104	1,000
Technetium-94	1,000	Cadmium-107	1,000
Technetium-96m	1,000	Cadmium-109	1
Technetium-96	100	Cadmium-113m	0.1
Technetium-97m	100	Cadmium-113	100
Technetium-97	1,000	Cadmium-115m	10
Technetium-98	10	Cadmium-115	100
Technetium-99m	1,000	Cadmium-117m	1,000
Technetium-99	100	Cadmium-117	1,000
Technetium-101	1,000	Indium-109	1,000
Technetium-104	1,000		

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Indium-110 (69.1 min)	1,000	Antimony-128 (10.4 min)	1,000
Indium-110 (4.9 h)	1,000	Antimony-128 (9.01 h)	100
Indium-111	100	Antimony-129	100
Indium-112	1,000	Antimony-130	1,000
Indium-113m	1,000	Antimony-131	1,000
Indium-114m	10	Tellurium-116	1,000
Indium-115m	1,000	Tellurium-121m	10
Indium-115	100	Tellurium-121	100
Indium-116m	1,000	Tellurium-123m	10
Indium-117m	1,000	Tellurium-123	100
Indium-117	1,000	Tellurium-125m	10
Indium-119m	1,000	Tellurium-127m	10
Tin-110	100	Tellurium-127	1,000
Tin-111	1,000	Tellurium-129m	10
Tin-113	100	Tellurium-129	1,000
Tin-117m	100	Tellurium-131m	10
Tin-119m	100	Tellurium-131	100
Tin-121m	100	Tellurium-132	10
Tin-121	1,000	Tellurium-133m	100
Tin-123m	1,000	Tellurium-133	1,000
Tin-123	10	Tellurium-134	1,000
Tin-125	10	Iodine-120m	1,000
Tin-126	10	Iodine-120	100
Tin-127	1,000	Iodine-121	1,000
Tin-128	1,000	Iodine-123	100
Antimony-115	1,000	Iodine-124	10
Antimony-116m	1,000	Iodine-125	1
Antimony-116	1,000	Iodine-126	1
Antimony-117	1,000	Iodine-128	1,000
Antimony-118m	1,000	Iodine-129	1
Antimony-119	1,000	Iodine-130	10
Antimony-120 (16 min)	1,000	Iodine-131	1
		Iodine-132m	100
Antimony-120 (5.76 d)	100	Iodine-132	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

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Xenon-127	1,000	Cerium-137	1,000
Xenon-129m	1,000	Cerium-139	100
Xenon-131m	1,000	Cerium-141	100
Xenon-133m	1,000	Cerium-143	100
Xenon-133	1,000	Cerium-144	1
Xenon-135m	1,000	Praseodymium-136	1,000
Xenon-135	1,000	Praseodymium-137	1,000
Xenon-138	1,000	Praseodymium-138m	1,000
Cesium-125	1,000	Praseodymium-139	1,000
Cesium-127	1,000	Praseodymium-142m	1,000
Cesium-129	1,000	Praseodymium-142	100
Cesium-130	1,000	Praseodymium-143	100
Cesium-131	1,000	Praseodymium-144	1,000
Cesium-132	100	Praseodymium-145	100
Cesium-134m	1,000	Praseodymium-147	1,000
Cesium-134	10	Neodymium-136	1,000
Cesium-135m	1,000	Neodymium-138	100
Cesium-135	100	Neodymium-139m	1,000
Cesium-136	10	Neodymium-139	1,000
Cesium-137	10	Neodymium-141	1,000
Cesium-138	1,000	Neodymium-147	100
Barium-126	1,000	Neodymium-149	1,000
Barium-128	100	Neodymium-151	1,000
Barium-131m	1,000	Promethium-141	1,000
Barium-131	100	Promethium-143	100
Barium-133m	100	Promethium-144	10
Barium-133	100	Promethium-145	10
Barium-135m	100	Promethium-146	1
Barium-139	1,000	Promethium-147	10
Barium-140	100	Promethium-148m	10
Barium-141	1,000	Promethium-148	10
Barium-142	1,000	Promethium-149	100
Lanthanum-131	1,000	Promethium-150	1,000
Lanthanum-132	100	Promethium-151	100
Lanthanum-135	1,000	Samarium-141m	1,000
Lanthanum-137	10	Samarium-141	1,000
Lanthanum-138	100	Samarium-142	1,000
Lanthanum-140	100	Samarium-145	100
Lanthanum-141	100	Samarium-146	1
Lanthanum-142	1,000	Samarium-147	100
Lanthanum-143	1,000	Samarium-151	10
Cerium-134	100	Samarium-153	100
Cerium-135	100	Samarium-155	1,000
Cerium-137m	100	Samarium-156	1,000

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Europium-145	100	Dysprosium-165	1,000
Europium-146	100	Dysprosium-166	100
Europium-147	100	Holmium-155	1,000
Europium-148	10	Holmium-157	1,000
Europium-149	100	Holmium-159	1,000
Europium-150		Holmium-161	1,000
(12.62 h)	100	Holmium-162m	1,000
Europium-150		Holmium-162	1,000
(34.2 y)	1	Holmium-164m	1,000
Europium-152m	100	Holmium-164	1,000
Europium-152	1	Holmium-166m	1
Europium-154	1	Holmium-166	100
Europium-155	10	Holmium-167	1,000
Europium-156	100	Erbium-161	1,000
Europium-157	100	Erbium-165	1,000
Europium-158	1,000	Erbium-169	100
Gadolinium-145	1,000	Erbium-171	100
Gadolinium-146	10	Erbium-172	100
Gadolinium-147	100	Thulium-162	1,000
Gadolinium-148	0.001	Thulium-166	100
Gadolinium-149	100	Thulium-167	100
Gadolinium-151	10	Thulium-170	10
Gadolinium-152	100	Thulium-171	10
Gadolinium-153	10	Thulium-172	100
Gadolinium-159	100	Thulium-173	100
Terbium-147	1,000	Thulium-175	1,000
Terbium-149	100	Ytterbium-162	1,000
Terbium-150	1,000	Ytterbium-166	100
Terbium-151	100	Ytterbium-167	1,000
Terbium-153	1,000	Ytterbium-169	100
Terbium-154	100	Ytterbium-175	100
Terbium-155	1,000	Ytterbium-177	1,000
Terbium-156m		Ytterbium-178	1,000
(5.0 h)	1,000	Lutetium-169	100
Terbium-156m		Lutetium-170	100
(24.4 h)	1,000	Lutetium-171	100
Terbium-156	100	Lutetium-172	100
Terbium-157	10	Lutetium-173	10
Terbium-158	1	Lutetium-174m	10
Terbium-160	10	Lutetium-174	10
Terbium-161	100	Lutetium-176m	1,000
Dysprosium-155	1,000	Lutetium-176	100
Dysprosium-157	1,000	Lutetium-177m	10
Dysprosium-159	100	Lutetium-177	100

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Lutetium-178m	1,000	Rhenium-182	
Lutetium-178	1,000	(12.7 h)	1,000
Lutetium-179	1,000	Rhenium-182	
Hafnium-170	100	(64.0 h)	100
Hafnium-172	1	Rhenium-184m	10
Hafnium-173	1,000	Rhenium-184	100
Hafnium-175	100	Rhenium-186m	10
Hafnium-177m	1,000	Rhenium-186	100
Hafnium-178m	0.1	Rhenium-187	1,000
Hafnium-179m	10	Rhenium-188m	1,000
Hafnium-180m	1,000	Rhenium-188	100
Hafnium-181	10	Rhenium-189	100
Hafnium-182m	1,000	Osmium-180	1,000
Hafnium-182	0.1	Osmium-181	1,000
Hafnium-183	1,000	Osmium-182	100
Hafnium-184	100	Osmium-185	100
Tantalum-172	1,000	Osmium-189m	1,000
Tantalum-173	1,000	Osmium-191m	1,000
Tantalum-174	1,000	Osmium-191	100
Tantalum-175	1,000	Osmium-193	100
Tantalum-176	100	Osmium-194	1
Tantalum-177	1,000	Iridium-182	1,000
Tantalum-178	1,000	Iridium-184	1,000
Tantalum-179	100	Iridium-185	1,000
Tantalum-180m	1,000	Iridium-186	100
Tantalum-180	100	Iridium-187	1,000
Tantalum-182m	1,000	Iridium-188	100
Tantalum-182	10	Iridium-189	100
Tantalum-183	100	Iridium-190m	1,000
Tantalum-184	100	Iridium-190	100
Tantalum-185	1,000	Iridium-192m	
Tantalum-186	1,000	(1.4 min)	10
Tungsten-176	1,000	Iridium-192	
Tungsten-177	1,000	(73.8 d)	1
Tungsten-178	1,000	Iridium-194m	10
Tungsten-179	1,000	Iridium-194	100
Tungsten-181	1,000	Iridium-195m	1,000
Tungsten-185	100	Iridium-195	1,000
Tungsten-187	100	Platinum-186	1,000
Tungsten-188	10	Platinum-188	100
Rhenium-177	1,000	Platinum-189	1,000
Rhenium-178	1,000	Platinum-191	100
Rhenium-181	1,000	Platinum-193m	100

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Platinum-193	1,000	Lead-203	1,000
Platinum-195m	100	Lead-205	100
Platinum-197m	1,000	Lead-209	1,000
Platinum-197	100	Lead-210	0.01
Platinum-199	1,000	Lead-211	100
Platinum-200	100	Lead-212	1
Gold-193	1,000	Lead-214	100
Gold-194	100	Bismuth-200	1,000
Gold-195	10	Bismuth-201	1,000
Gold-198m	100	Bismuth-202	1,000
Gold-198	100	Bismuth-203	100
Gold-199	100	Bismuth-205	100
Gold-200m	100	Bismuth-206	100
Gold-200	1,000	Bismuth-207	10
Gold-201	1,000	Bismuth-210m	0.1
Mercury-193m	100	Bismuth-210	1
Mercury-193	1,000	Bismuth-212	10
Mercury-194	1	Bismuth-213	10
Mercury-195m	100	Bismuth-214	100
Mercury-195	1,000	Polonium-203	1,000
Mercury-197m	100	Polonium-205	1,000
Mercury-197	1,000	Polonium-207	1,000
Mercury-199m	1,000	Polonium-210	0.1
Mercury-203	100	Astatine-207	100
Thallium-194m	1,000	Astatine-211	10
Thallium-194	1,000	Radon-220	1
Thallium-195	1,000	Radon-222	1
Thallium-197	1,000	Francium-222	100
Thallium-198m	1,000	Francium-223	100
Thallium-198	1,000	Radium-223	0.1
Thallium-199	1,000	Radium-224	0.1
Thallium-201	1,000	Radium-225	0.1
Thallium-200	1,000	Radium-226	0.1
Thallium-202	100	Radium-227	1,000
Thallium-204	100	Radium-228	0.1
Lead-195m	1,000	Actinium-224	1
Lead-198	1,000	Actinium-225	0.01
Lead-199	1,000	Actinium-226	0.1
Lead-200	100	Actinium-227	0.001
Lead-201	1,000	Actinium-228	1
Lead-202m	1,000	Thorium-226	10
Lead-202	10	Thorium-227	0.01

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Thorium-228	0.001	Plutonium-240	0.001
Thorium-229	0.001	Plutonium-241	0.01
Thorium-230	0.001	Plutonium-242	0.001
Thorium-231	100	Plutonium-243	1,000
Thorium-232	100	Plutonium-244	0.001
Thorium-234	10	Plutonium-245	100
Thorium-natural	100	Americium-237	1,000
Protactinium-227	10	Americium-238	100
Protactinium-228	1	Americium-239	1,000
Protactinium-230	0.1	Americium-240	100
Protactinium-231	0.001	Americium-241	0.001
Protactinium-232	1	Americium-242m	0.001
Protactinium-233	100	Americium-242	10
Protactinium-234	100	Americium-243	0.001
Uranium-230	0.01	Americium-244m	100
Uranium-231	100	Americium-244	10
Uranium-232	0.001	Americium-245	1,000
Uranium-233	0.001	Americium-246m	1,000
Uranium-234	0.001	Americium-246	1,000
Uranium-235	0.001	Curium-238	100
Uranium-236	0.001	Curium-240	0.1
Uranium-237	100	Curium-241	1
Uranium-238	100	Curium-242	0.01
Uranium-239	1,000	Curium-243	0.001
Uranium-240	100	Curium-244	0.001
Uranium-natural	100	Curium-245	0.001
Neptunium-232	100	Curium-246	0.001
Neptunium-233	1,000	Curium-247	0.001
Neptunium-234	100	Curium-248	0.001
Neptunium-235	100	Curium-249	1,000
Neptunium-236		Berkelium-245	100
(1.15E+5 y)	0.001	Berkelium-246	100
Neptunium-236		Berkelium-247	0.001
(22.5 h)	1	Berkelium-249	0.1
Neptunium-237	0.001	Berkelium-250	10
Neptunium-238	10	Californium-244	100
Neptunium-239	100	Californium-246	1
Neptunium-240	1,000	Californium-248	0.01
Plutonium-234	10	Californium-249	0.001
Plutonium-235	1,000	Californium-250	0.001
Plutonium-236	0.001	Californium-251	0.001
Plutonium-237	100	Californium-252	0.001
Plutonium-238	0.001	Californium-253	0.1
Plutonium-239	0.001	Californium-254	0.001

*To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C
QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Einsteinium-250	100	Fermium-253	1
Einsteinium-251	100	Fermium-254	10
Einsteinium-253	0.1	Fermium-255	1
Einsteinium-254m	1	Fermium-257	0.01
Einsteinium-254	0.01	Mendelevium-257	10
Fermium-252	1	Mendelevium-258	0.01
Any alpha-emitting radio-nuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha- emitting radio-nuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

NOTE: For purposes of A.3.13(e), A.3.16(a), and A.5.12(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.

*To convert μCi to kBq, multiply the μCi value by 37.

PART A

APPENDIX D

REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land-disposal facilities must prepare a Manifest (OMB Control Numbers 3150-0164, -0165, and -0166) reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the Agency to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest. NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-7232. This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by these Regulations.

As used in this appendix, the following definitions apply:

Chelating agent means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the regulatory agency's computer can transfer the information from the medium into its memory.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

APPENDIX D
REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I.

Decontamination facility means a facility operating under an Agency, U.S. Nuclear Regulatory 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.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator means a licensee operating under an Agency, U.S. Nuclear Regulatory Commission or other Agreement State license who (1) is a waste generator as defined in this part, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of 10 CFR 61.56, and to meet Department of Transportation requirements for a Type A package.

Land disposal facility means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes.

NRC Forms 540, 540A, 541, 541A, 542, and 542A are official NRC Forms referenced in this appendix. Licensees need not use originals of these NRC 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, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Physical description means the items called for on NRC Form 541 to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Source material has the same meaning as that given in Subpart A.0 of these Regulations.

Shipper means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means NRC Form 540 and, if required, NRC Form 540A which includes the information required by DOT in 49 CFR part 172.

Special nuclear material has the same meaning as that given in Subpart A.0 of these Regulations.

Uniform Low-Level Radioactive Waste Manifest or uniform manifest means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

APPENDIX D
REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I.

Waste collector means an entity, operating under an Agency, U.S. Nuclear Regulatory Commission or another Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

Waste generator means an entity, operating under an Agency, U.S. Nuclear Regulatory Commission or other Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed 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."

Waste processor means an entity, operating under an Agency, U.S. Nuclear Regulatory Commission, or other Agreement State license, whose principal purpose is to process repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

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).

I. 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 1-129 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.

APPENDIX D
REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I.C

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 cheating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(8) The approximate volume of waste within a container;

(9) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

(10) The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in 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 I of Appendix E to this Part. Waste not meeting the structural stability requirements of Section II(b) of Appendix E to this Part 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 I of Appendix E to this Part. Waste not meeting the structural stability requirements of Section II(b) of Appendix E to this Part must be identified;

I.D.(5)

(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 sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Section II(b) of Appendix E to this Part; 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.

II. 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 Agency, the U.S. Department of Transportation and the U.S. Nuclear Regulatory Commission. 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.

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APPENDIX D
REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

III. CONTROL AND TRACKING

(a) Any licensee 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 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 section. A licensee shall:

(1) Prepare all wastes so that the waste is classified according to Section I of Appendix E to this Part and meets the waste characteristics requirements in Section II(b) of Appendix E to this Part;

(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 I of Appendix E to this Part;

(3) Conduct a quality assurance program to assure compliance with Appendix E to this Part (the program must include management evaluation of audits);

(4) Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

(5) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

(6) Include NRC Form 540 (and NRC Form 540A. if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

(7) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(8) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by C.5.14; and

(9) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

(b) Any waste collector licensee who handles only prepackaged waste shall:

(1) Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

(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: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

(4) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

III.(b)(5)

(5)Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(6)Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by C.5.14;

(7)For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

(8)Notify the shipper and the 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 canceled.

(c) Any licensed waste processor who 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 NRC Form 540;

(2) Prepare a now 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 I of Appendix E to this Part and meets the waste characteristics requirements in Section II of Appendix E to this Part;

(4) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Section I of Appendix E to this Part;

(5) Conduct a quality assurance program to assure compliance with Appendix E to this Part (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; (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

(7) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

(8) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(9) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by C.5.14;

(10) For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

(11) Notify the shipper and the 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 canceled.

APPENDIX D
REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

III.(d)

(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 NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

(2) Maintain copies of all completed manifests and electronically store the information required by this Appendix (except for shipper and carrier telephone numbers and shipper and consignee certifications), the date the shipment of radioactive waste was received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at the disposal site, the containment integrity of the waste disposal containers as received, any discrepancies between materials listed on the manifest and those received, the volume of any pallets, bracing or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated materials or suspect materials, and any evidence of leaking or damaged disposal containers or radiation or contamination limits specified in Agency, U.S. Department of Transportation or U.S. Nuclear Regulatory Commission regulations 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 canceled.

(e) Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

(1) Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

(2) Be traced and reported. The investigation 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 2 weeks of completion of the investigation.

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PART A

APPENDIX E

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

I. Classification of Radioactive Waste for Land Disposal

(a) **Considerations.** Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(b) **Classes of Waste.**

(1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II.(a). If Class A waste also meets the stability requirements set forth in Section II.(b), it is not necessary to segregate the waste for disposal.

(2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

(3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

(c) **Classification Determined by Long-Lived Radionuclides.** If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

(1) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

2) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

(3) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

(4) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

(d) **Classification Determined by Short-Lived Radionuclides.** If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Section I.(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

(1) If the concentration does not exceed the value in Column 1, the waste is Class A.

(2) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

I.(d)(3)

(3) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

(4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

(5) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE I

Radionuclide	Concentration curie/cubic meter[a]	Concentration nanocurie/gram[b]
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

[a]To convert the Ci/m^3 values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m^3 value by 37.

[b]To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

TABLE II

Radionuclide	Concentration [curie/cubic meter]*		
	Column 1	Column 2	Column 3
Total of all radio nuclides with less than 5-year half- life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

NOTE: To convert the Ci/m^3 value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m^3 value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

I.(e)

(e) **Classification Determined by Both Long- and Short-Lived Radionuclides.** If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

(1) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

(2) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

(f) **Classification of Wastes With Radionuclides Other Than Those Listed in Tables I and II.** If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

(g) **The Sum of the Fractions Rule for Mixtures of Radionuclides.** For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m^3 (50 Ci/m^3) and Cs-137 in a concentration of 814 GBq/m^3 (22 Ci/m^3). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33., for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

(h) **Determination of Concentrations in Wastes.** The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

II. Radioactive Waste Characteristics

(a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of Part A, the site license conditions shall govern.

(2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(4) Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

(5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.(a)(8).

II.(a)(7)

(7) Waste must not be pyrophoric. Pyrophoric[26] materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity shall not exceed 3.7 TBq (100 Ci) per container.

(9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

(b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(2) Notwithstanding the provisions in Section II.(a)(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

(3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

III. Labeling

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

[26] See A.0 of these Regulations for definition of pyrophoric

PART A

APPENDIX F

QUANTITIES FOR USE WITH DECOMMISSIONING

Radioactive Material	Microcurie*
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX F
QUANTITIES FOR USE WITH DECOMMISSIONING

Radioactive Material	Microcurie*
Europium-155	10
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10

* To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX F
QUANTITIES FOR USE WITH DECOMMISSIONING

Radioactive Material	Microcurie*
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-llOm	1
Silver-111	100
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur -35	100

* To convert µCi to kBq, multiply the µCi value by 37.

APPENDIX F
QUANTITIES FOR USE WITH DECOMMISSIONING

Radioactive Material	Microcurie*
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)***	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000

* 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.

APPENDIX F
QUANTITIES FOR USE WITH DECOMMISSIONING

Radioactive Material	Microcurie*
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

* To convert µCi to kBq, multiply the µCi 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 A

APPENDIX G

REQUIREMENTS FOR REMOVABLE RADIOACTIVE CONTAMINATION AND EXTERNAL RADIATION LEVELS FROM PACKAGES OFFERED FOR SHIPMENT

I. REMOVABLE RADIOACTIVE CONTAMINATION

(1) The level of removable radioactive contamination on the external surfaces of each package offered for shipment shall be as low as reasonably achievable. The level of removable radioactive contamination shall be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements shall be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as otherwise provided in paragraph 2 below, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, shall not exceed the limits given in Table G-1 below at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used shall be taken into account and in no case shall the removable contamination on the external surfaces of the package exceed 10 times the limits listed in Table G-1.

TABLE G-1
REMOVABLE EXTERNAL RADIOACTIVE CONTAMINATION WIPE LIMITS

Contaminant	Maximum Permissible Limits[271]	
	$\mu Ci/cm^2$	dpm/cm^2
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than ten days; natural uranium; natural thorium; uranium-235; uranium-238; thorium-232; thorium-228 and thorium-230 when contained in ores or physical concentrates	10^{-5}	22
All other alpha emitting radionuclides	10^{-6}	2.2

(2) In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport shall not exceed 10 times the levels prescribed in paragraph 1 above. The levels at the beginning of transport shall not exceed the levels in paragraph 1 above.

[27] To convert microcuries (μCi) to SI units of megabecquerels, multiply the values by 37.

II. EXTERNAL RADIATION LEVELS

External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (2 mSv/h) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10. Notwithstanding these requirements, radiation levels external to a package transported in exclusive use by rail, highway or water may exceed these exceed these limits but shall not exceed any of the following:

(1) 200 millirems per hour (2 mSv/h) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1000 millirems per hour (10 mSv/h);

   (a) The shipment is made in a closed transport vehicle;

   (b) Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and

   (c) There are no loading or unloading operations between the beginning and end of the transportation.

(2) 200 millirems per hour (2 mSv/h) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier[28], at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load [or enclosure, if used], and on the lower external surface of the vehicle;

(3) 10 millirems per hour (0.1 mSv/h) at any point 2 meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and

(4) 2 millirems per hour (0.02 mSv/h) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with Section A.6.3 of these Regulations.

[28] A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 millirems per hour (2 mSv/h) at the surface.

PART A

APPENDIX H

NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

RADIOACTIVE MATERIAL	CATEGORY 1 (TBq)	CATEGORY 1 (Ci)	CATEGORY 2 (TBq)	CATEGORY 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	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

RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART B

REGISTRATION OF X-RAY EQUIPMENT FACILITIES AND RADIATION PHYSICS SERVICES

JUNE 1978

AS AMENDED:

October 1984
August 1991
February 1994
June 1999
September 2004
OCTOBER 2013

PART B
REGISTRATION OF X-RAY EQUIPMENT FACILITIES AND RADIATION PHYSICS SERVICES

B.1 PURPOSE AND SCOPE

B.1.1 This part requires the registration of X-ray equipment facilities and the registration of persons providing installation and/or servicing of X-ray equipment to Agency registrants or radiation physics services to Agency registrants or licensees. For purposes of this part, particle accelerator facilities, whether used primarily for X-ray production or other purposes, shall be considered X-ray equipment facilities.

B.1.2 For purposes of part B of these Regulations, "facility" means the location at which one or more X-ray systems are installed and/or located within one building or vehicle, and are under the same administrative control.

B.1.3 In addition to the requirements of this part, all registrants are subject to the applicable provisions of other parts of these Regulations.

B.2 EXEMPTIONS

B.2.1 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and certification requirements of this part, providing dose equivalent rate averaged over an area of ten square centimeters (10 cm^2) does not exceed 0.5 mrem (5 uSv) per hour at five (5) cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

B.2.2 X-ray equipment while in transit or storage incident to transit is exempt from the requirements of this Part. This exemption does not apply to the providers of X-ray equipment for mobile services.

B.2.3 Domestic television receivers and video display terminals are exempt from the requirements of this Part.

B.2.4 Inoperable X-ray equipment is exempt from the requirements of Part B of these Regulations. For the purposes of Part B, inoperable X-ray equipment means X-ray equipment that cannot be energized when connected to a power supply without repair or modification.

B.3 GENERAL REGULATORY REQUIREMENTS FOR REGISTRATION OF X-RAY EQUIPMENT FACILITIES

B.3.1 **Submission of Application**

(a) Each person who owns or possesses and administratively controls an X-ray equipment facility, unless specifically exempted in B.2, shall apply for registration of such facility with the Agency prior to the operation of an X-ray equipment facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions, including a designated e-mail address for receipt of official Agency correspondence in electronic format. The issuance of a Certificate of Registration for an X-ray equipment facility shall not preclude the Agency from subsequently reassigning the registered X-ray equipment to a more appropriate registration category and/or requiring the facility to periodically reregister all X-ray equipment at the facility. The registration category for an X-ray equipment facility will be determined in accordance with the provisions of Appendix B to Part I of these Regulations.

B.3.1(b)

(b) **Designation of Individual Responsible for Radiation Protection**. An individual to be responsible for radiation protection[29] shall be designated on each application form. The qualifications of that individual shall be submitted to the Agency with the application. The RSO shall meet the applicable requirements of Appendix C and carry out the responsibilities in Appendix D to Part B of these Regulations.

(c) **Designation of Facility Supervisor.**

(1) An individual responsible for directing the operation of the X-ray equipment facility shall be designated on each application form.

(2) The designation of a licensed practitioner of the healing arts shall be required on each healing arts application.

(3) The designation of an individual licensed in accordance with RIGL Chapter 5-25 to engage in veterinary medicine shall be required on each veterinary medicine application.

(d) **Additional Requirements for Medical Research on Humans.** In addition to the requirements of B.3.1(a), (b) and (c), the applicant shall submit, as a minimum, the following information:

(1) A detailed description of the proposed medical research, including a copy of the form that will be used to obtain informed consent from the human subjects and an evaluation of the potential radiation exposure to individuals participating in the medical research; and

(2) (i) Documentation that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects; or

(ii) Documentation of prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

(e) **Additional Requirements for Mobile Service Operations.** In addition to the requirements of B.3.1(a), (b) and (c), the applicant shall submit the following information:

(1) The location where the X-ray equipment, records, etc. will be maintained for inspection. This shall be a street address, not a post office box number.

(2) A sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and

(3) A current copy of the applicant's operating and safety procedures including radiological practices for protection of patients, operators, employees, and the general public.

(f) **Signature.** Each application shall be signed by the applicant or a person duly authorized to act on their behalf.

(g) Financial institutions that take possession of operable X-ray equipment as the result of foreclosure, bankruptcy, or other default of payment are subject to the requirements in this Part. X-ray equipment which is operable for the sole purpose of selling, leasing or transferring shall be registered in the Storage category.

B.3.2 **Shielding Plan Review.** Except as otherwise provided in B.3.2(c), all new facilities and modifications of existing facilities utilizing ionizing radiation machines shall require shielding plan review by

[29] This individual is frequently referred to as the Radiation Safety Officer (RSO).

the Agency.

B.3.2(a)

(a) Prior to construction, the floor plans, shielding specifications and equipment arrangement shall be submitted to the Agency for review and approval. The required information for all ionizing radiation machines, except therapeutic radiation machines, is denoted in Appendix A to Part B of these Regulations. The required information for therapeutic radiation machines is contained in Appendix A to Part H of these Regulations.

(b) The Agency may require the applicant to utilize the services of a person registered to provide General Radiation Physics Services in developing the information required by Appendix A to Part B of these Regulations.

(c) Shielding plan review by the Agency is not required for the following type of X-ray equipment facilities:

(1) Any type of X-ray equipment which provides sufficient self-shielding to reduce the radiation levels at all external surfaces of the equipment below those levels required by A.2.3, A.2.9 and A.2.11 of these Regulations.

(2) Any X-ray equipment facility performing only dental intraoral and/or panoramic procedures whose estimated workload has been evaluated in accordance with NCRP Report 145 ["*Radiation Protection in Dentistry*" (2003)], and it has been documented that existing structural configuration will provide sufficient shielding to reduce the radiation levels to those required by A.2.3, A.2.9 and A.2.11 of these Regulations.

B.3.3 **Shielding Evaluation Required.**

(a) Prior to routine use, but in no case later than thirty (30) days subsequent to installation of the radiation producing equipment and/or modification of the existing facility, the shielding shall be reviewed and evaluated by a person registered with the Agency to provide General Radiation Physics Services.

(b) A written report of the shielding evaluation shall be provided to the facility within ten (10) days of the evaluation. The report shall specifically address any shielding and/or radiation protection deficiencies that were discovered during the evaluation and shall include recommendations for correcting these deficiencies. Any noted deficiencies shall be adequately addressed by the facility.

(c) Facilities shall provide the Agency with a copy of the shielding evaluation report within ten (10) days of receipt of said report.

(d) An Agency finding that an X-ray equipment facility meets appropriate radiation protection standards shall not preclude the requirement of additional modifications, should a subsequent analysis of operating conditions and/or a radiation survey indicate that an individual is likely to receive a dose in excess of the limits prescribed in Sections A.2.3, A.2.9 and A.2.11 of these Regulations.

(e) **Retention of Information Used to Develop Shielding Plan.** After installation of radiation producing equipment, the registrant shall maintain for inspection by the Agency:

(1) The maximum rated technique factors of each machine;

(2) A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. 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.

B.3.3(e)(3)

(3) All information required by B.3.3(e) shall be retained until disposal is authorized by the Agency. All required information shall be retained in an active file from at least the time of generation until the next Agency inspection. Information generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said information can be retrieved until such time as the Agency authorizes final disposal.

B.3.4 Prohibit any person from furnishing X-ray equipment servicing or radiation physics services as described in B.4.4 to their X-ray equipment facility until such person provides evidence that they are registered with the Agency as a provider of services in accordance with subpart B.4 of these Regulations.

B.4 APPLICATION FOR REGISTRATION OF X-RAY EQUIPMENT SERVICING AND RADIATION PHYSICS SERVICES

B.4.1 Each person who is engaged in the business of installing or offering to install X-ray radiation equipment in this State, or is engaged in the business of furnishing or offering to furnish X-ray equipment servicing to an Agency registrant, or is engaged in the business of furnishing or offering to furnish radiation physics services to an Agency registrant or licensee shall apply for registration of such installation and/or servicing or radiation physics services with the Agency prior to furnishing or offering to furnish any such servicing or services.

B.4.2 Application for Registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions, including a designated e-mail address for receipt of official Agency correspondence in electronic format.

(a) An application for registration to provide X-ray equipment servicing will be accepted from either a firm or an individual.

(b) An application for registration to provide radiation physics services will only be accepted from an individual. If a firm employs more than one individual to provide radiation physics services, each individual shall be required to obtain a separate registration.

B.4.3 **Education and Experience Requirements for Providers of Radiation Physics Services.** In addition to the other requirements contained in this subpart, applicants for Radiation Physics Services must include documentation of the education and experience that qualify the applicant to discharge the Radiation Physics Services being requested. The minimum acceptable education and experience requirements are contained in Appendix B to this part. Applicants who do not explicitly meet the requirements contained in Appendix B to this part, but who believe they have a combination of training and/or practical experience equivalent to these requirements, may request special consideration of their situation and/or issuance of a limited Certificate of Registration by the Agency.

B.4.4 For the purpose of this subpart, X-ray equipment servicing and/or radiation physics services may include but shall not be limited to:

(a) Installation and/or servicing of X-ray equipment, and associated components;

(b) Calibration of X-ray equipment used by Agency registrants or radiation survey instruments used by Agency registrants or licensees;

(c) Radiation protection and/or radiation physics consultations or surveys, performed for Agency registrants or licensees;

B.4.4(d)

(d) Personnel dosimetry services.

B.4.5 **Restrictions on Provision of Services.**

(a) Persons offering the services described in B.4.4 shall not provide such services to any operational X-ray equipment facility or any facility utilizing radioactive materials in this state until such facility provides evidence that it has been registered or licensed with the Agency in accordance with Subpart B.3 or Part C of these Regulations. Persons providing the services described in B.4.4 to a preoperational X-ray facility or facility intending to utilize radioactive material shall inform the facility of the registration or licensing requirements of these Regulations.

(b) An individual registered with the Agency as a provider of services in accordance with Subpart B.4 shall only perform services that are specifically authorized for that individual on the Certificate of Registration issued by the Agency.

B.5 CERTIFICATE OF REGISTRATION

B.5.1 No person who is required to be registered under this part shall operate an X-ray equipment facility or radiation physics service without a valid Certificate of Registration.

B.5.2 The Agency may incorporate in the Certificate of Registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation equipment as it deems appropriate or necessary.

B.5.3 A current Certificate of Registration or legible copy thereof shall be posted conspicuously at each registered facility.

B.5.4 Except as provided by B.5.6, each Certificate of Registration shall expire at the end of the specified day in the month and year stated therein.

B.5.5 Application for renewal of registration shall be filed in accordance with subpart B.3 or B.4 of this part.

B.5.6 In any case in which a registrant not less than 30 days prior to the expiration of his existing Certificate of Registration has filed an application in proper form for renewal, and has remitted the renewal fee, such existing Certificate of Registration shall not expire until the application status has been finally determined by the Agency.

B.6 REPORT OF CHANGES

The registrant shall notify the Agency in writing before making any change which would render the information contained in the Application for Registration and/or the Certificate of Registration no longer accurate. In the case of disposition of an X-ray system, such notification should specify the recipient of the system. In the case of modifications involving a structural change, or the addition or relocation of an X-ray system, the Agency may require the registrant to submit the information contained in Appendix A of this part.[1]

B.7 APPROVAL NOT IMPLIED

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency

pursuant to the provisions of subpart B.3 or B.4 of this part and no person shall state or imply that any activity under such registration has been approved by the Agency.

B.8 ASSEMBLER AND/OR TRANSFER OBLIGATION

B.8.1 Any person who sells, leases, transfers, lends, disposes, assembles, or installs X-ray equipment in this State shall notify the Agency within 15 days of:

(a) The name and address of persons who have received this equipment.

(b) The manufacturer, model, and serial number of each X-ray system transferred; and

(c) The date of transfer of each X-ray system.

(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.

B.8.2 No person shall make, sell, lease, transfer, lend, assemble, or install X-ray systems or the supplies used in connection with such system unless such supplies and equipment when properly placed in operation and used in this State shall meet the requirements of these Regulations.

B.9 WAIVER OF REGISTRATION FOR TEMPORARY USE

B.9.1 Whenever any X-ray system is to be brought into the State, for any temporary use, the person proposing to bring such system into the State shall give written notice to the Agency at least two (2) working days before such machine is to be used in the State. The notice shall include the type of X-ray system; the nature, duration, and scope of use; and the exact location(s) where the X-ray system is to be used; and the state(s) in which the X-ray system is registered. Upon receipt of such notification, the Agency shall determine whether a waiver of registration will be granted.

B.9.2 In addition, the out-of-State person shall:

(a) Comply with all applicable regulations of the Agency;

(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 180 calendar days per year.

B.10 REGISTRATION FEES

In accordance with authority granted to the Agency in RIGL Chapter 23-1.3-5, registration fees are payable to the Treasurer, State of Rhode Island by persons applying for registration. A current schedule of fees is available in Appendix B to Part I of these Regulations. Upon approval of the application, the Agency will notify the applicant of the correct fee which is due. A Certificate of Registration will not be issued or renewed until the correct fee has been remitted. Fees which remain unpaid beyond the expiration date of the current Certificate of Registration may result in suspension of registration.

PART B

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. ALL X-RAY EQUIPMENT FACILITIES

(a) Basic facility information including: name, RPS registration number and telephone number of the individual responsible for the shielding specifications; name and telephone number of the facility supervisor; and the street address [including room #(s)] of the facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s). If the facility is currently registered, the Agency registration number shall be provided.

(b) All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

(c) Secondary barriers, when required, shall be provided in all wall, floor, and ceiling areas.

(d) Shielding in walls of diagnostic X-ray facilities shall extend to a minimum height of seven feet above the floor.

II. X-RAY EQUIPMENT FACILITIES UP TO 150 kV

In addition to the requirements listed in Section I above, the plans for all X-ray equipment facilities which produce only photons with a maximum energy less than or equal to 150 kV shall contain, as a minimum, the following additional information:

(a) Equipment specifications including the make and model of the X-ray equipment, the maximum technique factors and the energy waveform (single phase, three phase, etc..

(b) The maximum design workload for the facility in terms of milliamp-minutes or milliamp-seconds per week. The total anticipated number of patients per week or number of exposures per week, as well as the type of examination(s) or treatment(s) which will be performed with the equipment, shall also be provided.

(c) A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of North; normal location of the X-ray system'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 X-ray control panel. If the control panel is located inside the X-ray room, the location of the operator's station shall be noted in the plan and the operator's station at the control panel shall be in compliance with Section A.2.3 of these Regulations.

(d) In X-ray facilities designed for medical use, a window (of lead equivalent at least equal to that required for the adjacent barrier), mirror or other remote viewing system shall be provided and so placed that the operator can see the patient during the exposure without having to leave the protected area.

(e) The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(f) 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.

(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. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

APPENDIX A
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

III. X-RAY EQUIPMENT FACILITIES OVER 150 kV

In addition to the requirements listed in Section I above, the plans for all X-ray equipment/accelerator facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons and/or protons or other subatomic particles shall also contain the following information:

(a) Equipment specifications including: manufacturer and model number of the unit; rad (or rem) per minute at the isocenter; and the energy(s) and type(s) of radiation produced [ie: photon, electron, neutron]. The source to isocenter distance must be specified.

(b) Maximum design workload for the facility including total weekly radiation output [expressed in rad (or rem)/week @ 1 meter], total beam-on time per day or week.

(c) Facility blueprint/drawing (including both floor plan and elevation views) indicating position and orientation of the X-ray/accelerator unit, scale (0.25 inch = 1 foot is typical), type(s) and thickness 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 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.

(f) Description of all assumptions that were used in shielding calculations including, but not limited to, design energy [ie: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], presence of integral beam-stop in unit, workload, occupancy and use(s) of adjacent areas, fraction of time that primary beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

(g) At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [ie: primary and secondary/ leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

IV. NEUTRON SHIELDING

In addition to the requirements listed in Sections I and III above, X-ray equipment/accelerator facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

1. The structural composition, thickness, minimum density and location of all neutron shielding material.
2. 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.
3. 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. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.
4. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. REFERENCES

1. NCRP Report 144 “Radiation Protection for Particle Accelerator Facilities” (2003)
2. NCRP Report 145, “Radiation Protection in Dentistry” (2003).
3. NCRP Report 147, “Structural Shielding Design for Medical X-Ray Imaging Facilities” (2004)
4. NCRP Report 148, “Radiation Protection in Veterinary Medicine” (2004)

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PART B

APPENDIX B

EDUCATION AND EXPERIENCE REQUIREMENTS FOR RADIATION PHYSICS SERVICES

1. **Radiotherapy Physics Services.** [Calibration and surveys of: therapeutic X-ray equipment; medical accelerators; teletherapy units, remote afterloader brachytherapy units and/or stereotactic radiosurgery units utilizing sealed radioactive sources.]

(a) Documentation of training sufficient to qualify as:

(1) An Authorized Medical Physicist pursuant to C.8.71 of these Regulations in the modality(s) for which registration is being requested; or

(2) A Qualified Medical Physicist pursuant to H.3.4 of these Regulations

2. **Diagnostic X-ray Physics Services.** [Calibration and surveys of diagnostic X-ray equipment.]

(a) Certification by the American Board of Radiology in:

(1) Radiological physics;

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Diagnostic radiological physics; or

(5) Diagnostic medical physics; or

(b) Certification by the American Board of Medical Physics in Diagnostic Imaging Physics; or

(c) Hold a master's or doctor's degree in radiological physics and submit documentation of appropriate experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

(d) Hold a master's or doctor's degree in health physics or other related radiation discipline and submit documentation of at least one (1) year of appropriate full time experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

(e) Hold a master's or doctor's degree in a physical science and submit documentation of at least two (2) years of appropriate full time training and experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

(f) Hold a bachelor's degree in health physics or other related radiation discipline and submit documentation of at least two (2) years of appropriate full time experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services; or

(g) Hold a bachelor's degree in a physical science and submit documentation of at least three (3) years of appropriate full time training and experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide Diagnostic X-ray Physics Services.

3. **General Radiation Physics Services.** [All radiation physics services (except calibration of health physics instrumentation) for Agency registrants and/or radioactive materials licensees not covered in Sections 1 or 2 above.]

(a) Comprehensive certification by the American Board of Health Physics; or

(b) Certification by the American Board of Radiology in

(1) Radiological Physics or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Diagnostic radiological physics; or

(5) Medical nuclear physics or nuclear medical physics; or

(c) Certification by the American Board of Medical Physics in Nuclear Medicine Physics or Medical Health Physics; or

(d) Hold a master's or doctor's degree in radiological physics or health physics or other related radiation discipline and submit documentation of appropriate experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide General Radiation Physics Services; or

(e) Hold a master's or doctor's degree in a physical science and submit documentation of at least one (1) year of appropriate full time training and experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide General Radiation Physics Services; or

(f) Hold a bachelor's degree in health physics or other related radiation discipline and submit documentation of at least one (1) year of appropriate full time experience in the area(s) for which registration is being requested. This experience must have been obtained under the supervision of an individual qualified to provide General Radiation Physics Services; or

4. **Instrument Calibration Services.** [Calibration of health physics instrumentation for Agency registrants and/or radioactive materials licensees.]

(a) Compliance with the criteria required to perform any of the services contained in Sections 1, 2, or 3 above; or

(b) Hold at least a bachelor's degree in physics (or a closely related field such as electrical engineering) and submit documentation of at least 6 months of appropriate full time training and experience in the calibration of health physics instrumentation.

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PART B

APPENDIX C

RADIATION SAFETY OFFICER (RSO) REQUIREMENTS

(A) An RSO shall meet the following general requirements, as well as any applicable facility-specific requirements of this Appendix.

(a) Knowledge of potential radiation hazards and emergency precautions;

(b) Completed educational courses related to ionizing radiation safety or a radiation safety officer course;

(c) Experience in the use and familiarity of the type of equipment used.

(B) Specific RSO requirements by facility are as follows.

(a) Healing arts facilities subject to Part F of these Regulations shall have:

(1) A licensed practitioner RSO with documentation of a current unrestricted Rhode Island license; or

(2) A non-practitioner RSO who meets the following requirements:

(i) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-68.1, as a radiologic technologist, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(ii) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-34 as a nurse practitioner, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(iii) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-54, as a physician assistant, and has at least two (2) years of supervised use for the type(s) of radiation machines covered by the registration; or

(iv) An individual who has a current unrestricted license, issued in accordance with RIGL Chapter 5-31.1, as a dental hygienist, and has at least two (2) years of performing radiologic procedures under a dentist's instruction and direction; or;

(v) An individual who has a bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering.

(b) Healing Arts facilities subject to Part H of these Regulations shall have an individual who meets the requirements for either an Authorized User physician or qualified medical physicist, as specified in Part H of these Regulations.

(c) Academic institutions and/or research and development facilities shall have an RSO who is a faculty or staff member with appropriate training in radiation protection, radiation engineering, or related disciplines. (If properly qualified, this individual may also serve as the RSO over the healing arts section of the facility.)]

(d) Industrial radiography facilities shall have an RSO who meets the requirements specified in §E.2.21 of these Regulations.

(e) Other industrial facilities shall have an RSO whose training and experience is sufficient to identify and control the anticipated radiation hazards.

PART B

APPENDIX D

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

Specific duties and responsibilities of the Radiation Safety Officer (RSO) include, but are not limited to, the following:

1. Establishment and oversight of operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and periodic review to ensure that the procedures are current and conform with these Regulations;
2. Ensure that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Part A of these Regulations;
3. Investigate and report to the Agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these Regulations and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;
4. Maintain a thorough knowledge of relevant management policies and administrative procedures of the registrant and keep management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;
5. Authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;
6. Maintain records as required by these Regulations; and
7. Ensure that personnel are adequately trained and complying with these Regulations, the conditions of the Certificate of Registration, and the operating and safety procedures of the registrant.

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RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART C

LICENSING OF RADIOACTIVE MATERIAL AND USE OF RADIONUCLIDES IN THE HEALING ARTS

FEBRUARY 1979

AS AMENDED:

June 1981
October 1984
February 1990
February 1990 (E)
August 1991
December 1993 (E)
February 1994
June 1995
June 1999
September 2004
September 2006
OCTOBER 2013

PART C
LICENSING OF RADIOACTIVE MATERIAL AND USE OF RADIONUCLIDES IN THE HEALING ARTS

C.1 GENERAL PROVISIONS

C.1.1 **Purpose and Scope.**

(a) This part provides for the licensing of radioactive material and use of radionuclides in the healing arts. No person shall 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 this part.

(b) In addition to the requirements of this part, all licensees are subject to the requirements of part A of these Regulations. Licensees engaged in industrial radiographic operations are subject to the requirements of Subpart E.2. Licensees engaged in wireline and/or subsurface tracer studies are subject to the requirements of Subpart E.4.

C.2 EXEMPTIONS

C.2.1 **Source Material.**

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

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

(c) Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers:

(1) Any quantities of thorium contained in:

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

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

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

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

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

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C.2.1(c)(2)

(2) Source material contained in the following products:

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

(ii) 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, glass enamel or ceramic used in construction, or

(iii) piezoelectric ceramic containing not more than 2 percent by weight source material;

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

(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 or any such product or part;

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

(i) 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,

(ii) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "**DEPLETED URANIUM**",[30] and

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

(iv) 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:

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

(ii) the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 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:

[30] The requirements specified in C.2.1(c)(5)(ii) and (iii) need not be met by counterweights manufactured prior to 31 December 1969; provided, that such counterweights are impressed with the legend, "**CAUTION - RADIOACTIVE MATERIAL - URANIUM**", as previously required by the regulations.

C.2.1(c)(7)(i)

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

(ii) 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 microcurie (185 Bq) of uranium; or

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

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

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

(d) The exemptions in C.2.1(c) do not authorize the manufacturer of any of the products described.

C.2.2 **Radioactive Material Other Than Source Material.**

(a) **Exempt Concentrations.**

(1) Except as provided in C.2.2(a)(2), 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 Appendix A.

(2) (i) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in these Regulations to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Appendix B of this Part and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(ii) 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.2.2(a)(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State, except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to §32.11 of 10 CFR Part 32.

(b) **Exempt Quantities.**

(1) (i) Except as provided in C.2.2(b)(2). (3) and (4) any person is exempt from the requirements for a license set forth in these Regulations 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 Appendix B of this part.

(ii) Any person, who possesses byproduct material received or acquired before 25 September 1971, under the general license then provided in 10 CFR 31.4 or similar general license of a State, is exempt from the requirements for a license set forth in 10 CFR Parts 30 through 34, 36 and 39 to the extent that this person possesses, uses, transfers, or owns byproduct material.

C.2.2(b)(2)

(2) This paragraph 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.

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this Part, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.2.2(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the Agency pursuant to C.5.5(b) which license states that the radioactive material may be transferred by the licensee to persons exempt under C.2.2(b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or other Agreement State.

(4) 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 Appendix B, except for radioactive material combined within a device placed in use before 3 May 1999, or as otherwise permitted by the regulations in this part.

(c) **Exempt Items.**

(1)**Certain Items Containing Radioactive Material.** Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these Regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[31]

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

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

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

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

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

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

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

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

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

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

C.2.2(c)(1)(i)(g)(2)

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

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

(h) one microcurie (37 kBq) of radium-226 per timepiece in intact time pieces acquired prior to 30 November 2007.

(ii) (a) Static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

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

(c) Such devices authorized before 23 October 2012 for use under the general license then provided in §31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission.

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

(iv) **[DELETED]**.

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

(vi) **[DELETED]**

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

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

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

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

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

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

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

And provided further, that the radiation dose rate from each electron tube containing 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.[32]

[32] For purposes of C.2.2(c)(1)(vii), "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.

C.2.2(c)(1)(viii)

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

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

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

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

(ix) **[DELETED]**

(2) **Self-luminous products containing radioactive material.**

(i) **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 these Regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, 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.2.2(c)(2) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments.

(ii) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under C.2.2(c)(2)(i) should apply for a license from the U.S. Nuclear Regulatory Commission pursuant to section §32.22 of 10 CFR part 32 and for a certificate of registration in accordance with section 32.210 of 10 CFR part 32.

(iii) The exemption in C.2.2(c)(2)(i) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments.

(3) **Gas and aerosol detectors containing radioactive material.**

(i) 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 for a license set forth in these Regulations 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 , and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission[33] pursuant to section 32.26 of 10 CFR Part 32, which license authorizes the initial transfer of the d product for use under this section.

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

C.2.2(c)(3)(ii)

(ii) This exemption also covers gas and aerosol detectors manufactured or distributed before 30 November 2007 in accordance with a specific license issued by an Agreement State under comparable provisions to section 32.26 of 10 CFR Part 32, authorizing distribution to persons exempt from regulatory requirements.

(iii) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under C.2.2(c)(2)(i), should apply for a license from the U.S. Nuclear Regulatory Commission pursuant to section §32.26 of 10 CFR part 32 and for a certificate of registration in accordance with section 32.210 of 10 CFR part 32

(4) **[DELETED]**

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

(1) Except as provided in Subparagraphs C.2.2(d)(2) and (d)(3), any person is exempt from the requirements for a license pursuant to Subpart C.5 of these Regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in-vivo" use for humans.

(2) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Subpart C.5 of these Regulations.

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

(4) Nothing in Subparagraphs C.2.2(d)(1), (d)(2) &(d)(3) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

(e) **Certain Industrial Devices.**

(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from these Regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.30 of 10 CFR part 32, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(2) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under C.2.2(e)(1) should apply for a license should apply for a license from the U.S. Nuclear Regulatory Commission pursuant to section §32.30 of 10 CFR part 32 and for a certificate of registration in accordance with section 32.210 of 10 CFR part 32.

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C.3 LICENSEES

C.3.1 **Types of Licenses.** Licenses for radioactive materials are of two types: general and specific.

(a) A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these Regulations and any limitations of the general license.

(b) The Agency issues a specific license to a named person who has filed an application for the license under the provisions of this part. The licensee is subject to all applicable portions of these Regulations as well as any limitations specified in the licensing document.

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C.4 GENERAL LICENSES

C.4.1 **General Licenses - Source Material**.

(a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions and Federal, State and Local government agencies to use and transfer not more than fifteen (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.4.1(a) are exempt from the provisions of Subparts A.1 - A.6 of these Regulations 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, possess, use or transfer source material pursuant to the general license in paragraph (a) of this section are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

(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.4.1(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.4.1(e)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to C.5.5(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) (i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by C.4.1(e)(1) shall file Agency Form GEN-1 "Registration Certificate - Use of Depleted Uranium Under General License," with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Agency Form GEN-1 the following information and such other information as may be required by that form:

(a) name and address of the registrant;

(b) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in C.4.1(e)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(c) name and/or tile, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedure identified in C.4.1(e)(3)(i)(b).

C.4.1(e)(3)(ii)

(ii) The registrant possessing or using depleted uranium under the general license established by C.4.1(e)(1) shall report in writing to the Agency any changes in information furnished by him in Agency Form GEN-1 "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.4.1(e)(1):

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

(ii) Shall not abandon such depleted uranium.

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of C.5.14. In the case where the transferee receives the depleted uranium pursuant to the general license established by C.4.1(e)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form GEN-1. In cases where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.4.1(e)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form GEN-1 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation.

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

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to Sections 40.23 and 40.33 of 10 CFR Part 40.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.4.1(e)(1) is exempt from the requirements of Subparts A.1 - A.6 of these Regulations with respect to the depleted uranium covered by that general license.

C.4.2 **General Licenses - Radioactive Material other than Source Material.** This section establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. The general licenses provided in this section are subject to the provisions of C.2.2(a)(2), C.5.6(b), C.5.7(a)-(c), C.5.14, C.5.15, C.7.1 and Subpart A[34] unless indicated otherwise in the specific provision of the general license.

(a) **[RESERVED]**.

[34] Attention is directed particularly to the provisions of part A of these Regulations which relate to the labeling of containers.

C.4.2(b)

(b) **Certain Measuring, Gauging and Controlling Devices.**

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of C.4.2(b)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) (i) The general license in C.4.2(b)(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.5.5(d), a specific license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 31.52, an equivalent specific license issued by another Agreement State or an equivalent specific license issued by a state with provisions comparable to 10 CFR 32.51.

(ii) The devices shall have been received from one of the specific licensees described in C.4.2(b)(2)(i) or through a transfer made under C.4.2(b)(viii).

(3) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in C.4.2(b)(1):

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

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

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

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

(iii) shall assure that the other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

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

(iv) Shall maintain records showing compliance with the requirements of C.4.2(b)(3)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removing from the installation the radioactive material, its shielding or containment. The licensee shall retain these records as follows:

C.4.2(b)(3)(iv)(a)

(a) Each record of a test for leakage or radioactive material required by C.4.2(b)(3)(ii) shall be maintained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(b) Each record of a test of the on/off mechanism and indicator required by C.4.2(b)(3)(ii) shall be maintained for 3 years after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(c) Each record that is required by C.4.2(b)(3)(iii) shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed of.

(v) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding a an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State. The device and any radioactive material from the device shall only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the 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, shall be furnished to the Agency within 30 days. Under these circumstances, the criteria set out in A.2.14, "Radiological Criteria for Unrestricted Use", may be applicable, as determined by the Agency on a case-by-case basis;

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

(vii) Except as provided in C.4.2(b)(3)(viii), (x) and (xi), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State whose specific license authorizes him to receive the device or that authorizes waste collection. Within thirty (30) days after transfer of a device to a specific licensee or export shall furnish to the Agency a report containing:

(a) 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);

(c) The date of the transfer.

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

(a) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device. Within 30 days of the transfer, report to the Agency: the manufacturer's (or initial transferor's) name; the model number and the serial number of device transferred; the transferee's name and mailing address for the location of use; and the name, title, and phone number of the responsible individual identified by the transferee in accordance with C.4.2(b)(5) to have knowledge of and authority to take

actions to ensure compliance with the appropriate regulations and requirements; or

C.4.2(b)(3)(viii)(b)

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

(ix) shall comply with the provisions of A.5.12 and A.5.13 of these Regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Subparts A.1 - A.6 of these Regulations.

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

(xi) Written Agency approval shall be obtained before transferring the device to any other specific licensee not specifically identified in C.4.2(b)(3)(vii). However, a holder of a specific license may transfer a device for possession and use under its own specific license, without prior approval, if the holder:

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

(b) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by C.4.2(b)(3)(i) so that the device is labeled in compliance with A.3.15. 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 C.4.2(b)(3)(vii).

(4) The general license in C.4.2(b)(1) does not authorize the manufacture of devices containing radioactive material.

(5) 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.

(6) (i) Shall register, in accordance with C.4.2(b)(6)(ii) and (iii), devices containing at least 10 millicuries (370 MBq) of Cesium-137, 0.1 millicurie (3.7 MBq) of Strontium-90, 1 millicurie (37 MBq) of Cobalt-60, 0.1 millicurie(3.7 MBq) of radium-226 or 1 millicurie (37 MBq)) of Americium-241 or any other transuranic[35], based on the activity indicated on the label. Each address for a location of use, as described under C.4.2(b)(6)(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.4.2(b)(6)(i), shall register these devices with the Agency and shall pay the fee required by I.3.6. The initial registration shall be submitted to the Agency within 30 days of initial receipt of the device, and shall be updated on an annual basis. Registration shall be done by verifying, correcting, and/or adding to the information provided on Agency Form GEN-4. In addition, a general licensee holding devices meeting the criteria of C.4.2(b)(6)(i) is subject to the bankruptcy notification requirement in C.5.7(f)(1).

[35] element with atomic number greater than uranium (92).

C.4.2(b)(6)(iii)

(iii) In registering devices, the general licensee shall furnish on Agency Form GEN-4 the following information and such other information as may be required by that form:

(a) Name and mailing address of the general licensee, including a designated e-mail address for receipt of official Agency correspondence in electronic format.

(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 C.4.2(b)(5).

(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.

(7) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Agency 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.

(8) Shall not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by C.4.2(b)(3)(ii) 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 shall 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.

(c) **Luminous Safety Devices for Aircraft.**

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

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

(ii) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in section 32.53 of 10 CFR Part 32 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.4.2(c)(1) are exempt from the requirements of Subparts A.1 - A.6 of these Regulations except that they shall comply with the provisions of A.5.12 and A.5.13.

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

C.4.2(c)(4)

(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.7, C.5.7, C.5.14, C.5.15 and C.7.1 of these Regulations.

(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 or use of radioactive material.

(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.4.2(e)(4) and (5), americium-241 in the form of calibration or reference sources:

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

(ii) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of C.4.2(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.4.2(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.4.2(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 source 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 or another Agreement 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.4.2(e)(1), (2) and (3) are subject to the provisions of Part A, C.5.7, C.5.14, C.5.15, and C.7.1 of these Regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

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

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

C.4.2(e)(5)(ii)(a)

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

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (RADIUM-226 or PLUTONIUM or AMERICIUM-241)[36] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer of importer

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

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

(v) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

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

(f) **Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.4.2(e).** An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under C.4.2(e) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirement of C.5.2, and

(2) 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.

(g) **General License for Use of Radioactive Material for Certain In-Vitro Clinical or Laboratory Testing.**[37]

(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.4.2(g)(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 therefrom, to human beings or animals:

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

[37] The New Drug Provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

C.4.2(g)(1)(i)

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

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

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

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

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

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

(vii) Selenium-75 in units not to exceed 10 microcuries (370 kBq) each.

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

(2) A person shall not receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.4.2(g)(1) until that person has:

(i) Filed Agency Form GEN-3 "Certificate - In-Vitro Testing with Radioactive Material Under General License," with the Agency and received from the Agency a validated copy of Agency Form GEN-3 with certification number assigned; or

(ii) A license that authorizes the medical use of radioactive material that was issued pursuant to C.8 of these Regulations

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by C.4.2(g)(1) shall comply with the following:

(i) The general license shall not possess at any one time, pursuant to the general license in C.4.2(g)(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).

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

(iii) The general licensee shall use the radioactive material only for the uses authorized by C.4.2(g)(1).

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

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.4.2(g)(1)(viii) as required by A.4.1 of these Regulations.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.4.2(g)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.5.5(h) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission or another 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.4.2 or its equivalent, and

C.4.2(g)(4)(ii)

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

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

_____
Name of Manufacturer

(b) This radioactive material shall be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in-vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

_____
Name of Manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of C.4.2(g)(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 GEN-3. 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.4.2(g)(1) is exempt from the requirements of Subparts A.1 - A.6 of these Regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in C.4.2(g)(1)(viii) shall comply with the provisions of A.4.1, A.5.12 and A.5.13 of these Regulations.

(h) **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 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.4.2(h)(1):

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of A.4.1 of these Regulations;

(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) Are exempt from the requirements of Subparts A.1 - A.6 of these Regulations except that such persons shall comply with the provisions of A.4.1, A.5.12 and A.5.13.

(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.7, C.5.7, C.5.14, C.5.15, and C.7.1 of these Regulations.

(i) **General License for Radium-226 Contained in Products Manufactured Prior to 30 November 2007**.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of §§4.2(i)(2), (3) and (4), Radium-226 contained in the following products manufactured prior to 30 November 2007.

(i) Antiquities originally intended for use by the general public. For the purposes of §4.2(i), *antiquities* mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads;

(ii) Intact timepieces containing greater than 37 kBq (1 μCi), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;

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

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

(v) Small radium sources containing no more than 37 kBq (1 μCi) of Radium-226. For the purposes of §4.2(i), *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 Agency.

(2) Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in §4.2(i)(1) are exempt from the provisions of Subparts A.1 - A.6 of these Regulations to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license. However, this exemption shall not be deemed to apply to any such person specifically licensed under these Regulations.

(3) Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in §4.2(i)(1):

C.4.2(i)(3)(i)

(i) Shall notify the Agency should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, shall be furnished to the Agency within thirty (30) days.

(ii) Shall not abandon products containing Radium-226. The product, and any radioactive material from the product, may only be disposed of according to §A.4.1 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.

(iii) Shall not export products containing Radium-226 except in accordance with 10 CFR110.

(iv) Shall dispose of products containing Radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive Radium-226 by a specific license issued under these Regulations or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

(v) Shall respond to written requests from the Agency to provide information relating to the general license within thirty (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 with a written justification for the request.

(4) The general license in §4.2(i)(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing Radium-226, except that timepieces may be disassembled and repaired.

C.4.3 **[DELETED]**

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C.5 SPECIFIC LICENSES

C.5.1 **Filing Application for Specific Licenses.**

(a) Applications for specific licenses shall be filed in duplicate on a form prescribed by the Agency, and shall include a designated e-mail address for receipt of official Agency correspondence in electronic format.

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

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

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

(e) In the application, the applicant shall submit the required information to the Agency without reference to previously submitted documents unless permission has been obtained from the Agency, in advance, to incorporate by reference information contained in previous applications, statements, or reports filed with the Agency. All references shall be clear and specific and shall contain all of the information needed for a particular item on the application.

(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.

C.5.2 **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 these Regulations 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.5.3, C.5.4, C.5.5, C.5.16, or C.5.17.

(e) **Bonding Requirements [Reserved].**

(f) **Perpetual Care Requirements [Reserved].**

(g) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Agency determines will significantly affect the quality of the environment, the Agency 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. Commencement of construction, as defined in A.0, may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

C.5.3 **Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.**

(a) **Human Use of Radioactive Material.** In addition to the requirements set forth in C.5.2 and C.8, a specific license for human use of radioactive material in institutions will be issued under the following conditions:

C.5.3(a)(1)

(1) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not cited in a medical institution, the applicant or a person duly authorized to act for and on their behalf may apply.

(2) The application 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).

(3) The application includes procedures required by §§C.8.49, C.8.56, C.8.58, and C.8.59, as applicable.

(4) An application for medical use of radioactive material as described in §C.8.79 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subpart C.8 of these Regulations. The applicant shall also provide specific information on:

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(b) **[DELETED]**.

(c) **Use of Sealed Sources in Industrial Radiography.** In addition to the requirements set forth in C.5.2, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of E.2.10.

(2) 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.

(3) The applicant submits written operating and emergency procedures as described in E.2.11.

(4) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six (6) months as described in E.2.10(e).

(5) 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 delegations of authority and responsibility.

(6) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (E.2.21) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(7) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the:

(i) Instruments to be used;

C.5.3(c)(7)(ii)

(ii) Method(s) of performing the analysis; and

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

(8) If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in E.2.5.

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

(10) The applicant identifies the location(s) where all records required by Subpart E.2 and other parts of these Regulations will be maintained.

(d) **Use of Radioactive Material at Property Not Owned by Applicant.** In addition to the requirements set forth in C.5.2 and/or C.8, a specific license for use of radioactive material where the proposed location of use is not owned by the applicant will be issued under the following conditions:

(1) Each initial application shall include a letter signed by the property owner (or authorized representative) that permits the use of licensed radioactive material at the proposed location of use.

(2) Each amendment request for an additional location of use shall include a letter signed by the property owner (or authorized representative) that permits the use of licensed radioactive material at the proposed location of use.

(e) **Production of PET Radioactive Drugs for Noncommercial Transfer**. An application from a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under C.8 shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under C.5, or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State, 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.5.5(j)(1)(ii).

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an Authorized Nuclear Pharmacist as specified in C.5.5(j)(2)(ii).

(4) Information identified in C.5.5(j)(1)(iii).on the PET drugs to be noncommercially transferred to members of its consortium.

(f) **Use of Radioactive Material in a Sealed Source or in a Device Containing a Sealed Source.**

(1) Except as provided in C.5.3(f)(2), (f)(3), and (f)(4), an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall either:

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

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

C.5.3(f)(2)

(2) For sources or devices manufactured before 23 October 2012 that are not registered with the Agency, with the Nuclear Regulatory Commission under 10 CFR 32.210 or with another Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant shall include:

(i) All available information identified in 10 CFR32.210(c) concerning the source, and, if applicable, the device; and

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

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

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

(g) **Registration of Product Information.** The Agency does not currently administer a sealed source and device registration program. Any manufacturer or initial distributor of a sealed source or device containing a sealed source who is subject to these Regulations shall submit a request for evaluation of radiation safety information about its product and for its registration to the Nuclear Regulatory Commission pursuant to 10 CFR 32.210.

(h) **Inactivation of Certificates of Registration of Sealed Sources and Devices.**

(1) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency and must normally be made no later than two (2) years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two (2) years after that transfer, the certificate holder shall request inactivation of the certificate within ninety (90) days of this determination and briefly describe the circumstances of the delay.

(2) If a distribution license is to be terminated in accordance with these Regulations, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(3) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

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C.5.4

C.5.4 **Special Requirements for Specific Licenses of Broad Scope.** This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses.[38]

(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 multicurie range.

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

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

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

(1) the applicant satisfies the general requirements specified in C.5.2;

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

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

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

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

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

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

C.5.4(b)(3)(iv)(a)

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

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

(c) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with C.5.4(b)(3)(iii)(b) prior to use of the radioactive material.

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

(1) the applicant satisfies the general requirements specified in C.5.2; and

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

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

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

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

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

(c) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with C.5.4(c)(2)(ii)(b) prior to use of the radioactive material.

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

(1) The applicant satisfies the general requirements specified in C.5.2;

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

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

(ii) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

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

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

(1) Unless specifically authorized, persons licensed pursuant to C.5.4 shall not:

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

C.5.4(e)(1)(ii)

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

(iii) Conduct activities for which a specific license issued by the Agency under C.5.3 or C.5.5 is required; or

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

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

(3) Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may 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.5.4(d).

(f) A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of Paragraph C.8.2(e) of these Regulations regarding additions to or changes in the areas of use only at the address specified in the license; and

(2) The provisions of Subparagraph C.8.3(a) of these Regulations for an Authorized User or an Authorized Nuclear Pharmacist.

C.5.5 **Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.**

(a) **[DELETED]**

(b) **[DELETED]**

(c) **[DELETED]**

(d) **Licensing the Manufacture or Initial Transfer of Devices to Persons Generally Licensed Under C.4.2(b).**

(1) An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.4.2(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State will be approved if:

(i) the applicant satisfies the general requirements of C.5.2;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

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

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one (1) calendar quarter a dose in excess of ten percent (10%) of the limits specified in A.2.3(a); and

(c) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

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

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

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

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

(c) the information called for in the following statement in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____[39], Serial No. ____[39], 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)

(iv) 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 A.3.12, and the name of the manufacturer or initial distributor.

[39] 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.

C.5.5(d)(1)(v)

(v) Each device meeting the criteria of C.4.2(b)(6)(i), 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 A.3.12.

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

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six (6) months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

(i) primary containment or (source capsule);

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

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

(3) In the event the applicant desires that the general licensee under C.4.2(b), or under equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of ten percent (10%) of the limits specified in A.2.3(a).

(4) If a device containing radioactive material is to be transferred for use under the general license contained in C.4.2(b), each person that is licensed under C.5.5(d)(1) 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 general license contained in C.4.2(b); if C.4.2(b)(3)(ii) through C.4.2(b)(3)(iv) or C.4.2(b)(6) do not apply to the particular device, those paragraphs may be omitted.

C.5.5(d)(4)(ii)

(ii) A copy of C.4.2 (title paragraph), C.5.15, A.1.3, A.5.12 and A.5.13;

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

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

(5) If a device containing radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission or another Agreement State, each person that is licensed under C.5.5(d)(1) 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 U.S. Nuclear Regulatory Commission or Agreement State regulations (as appropriate) equivalent to C.4.2(b), C.4.2 (title paragraph), C.5.15, A.1.3, A.5.12 and A.5.13,or a copy of C.4.2(b), C.4.2 (title paragraph), C.5.15, A.1.3, A.5.12 and A.5.13. If a copy of the Agency regulations is provided to a prospective general licensee in lieu of the appropriate regulatory authority's regulations, it shall be accompanied by a note explaining that use of the device is regulated by that appropriate regulatory authority. If certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

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

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

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

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

(7) Each device that is transferred after 1 January 2005 shall meet the labeling requirements in C.5.5(d)(1)(iii) through C.5.5(d)(1)(v).

(8) If a notification of bankruptcy has been made under C.5.7(f)(1) or the license is to be terminated, each person licensed under C.5.5(d)(1) shall provide, upon request, to the Agency and to the U.S. Nuclear regulatory Commission or any appropriate Agreement State, records of final disposition required under C.5.5(d)(12).

(9) **Reports to the Agency.** Each person licensed under C.5.5(d)(1) to initially transfer devices to generally licensed persons shall report to the Agency all transfers of such devices to persons for use under the general license in C.4.2(b) and all receipts of devices from persons licensed under C.4.2(b). The report shall be submitted on a quarterly basis on the NRC Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

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

(a) The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(b) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with

the appropriate regulations and requirements;

C.5.5(d)(9)(i)(c)

(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 before its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(iii) For devices received from a C.4.2(b) general licensee, the report shall 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.4.2(b) general licensee, such that the label shall be changed to update required information, the report shall identify the general licensee, the device, and the changes to information on the device label.

(v) The report shall cover each calendar quarter, shall be filed within 30 days of the end of the calendar quarter, and shall clearly indicate the period covered by the report.

(vi) The report shall 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 or from persons generally licensed under C.4.2(b) during the reporting period, the report shall so indicate.

(10) **Reports to NRC and Other Radiation Control Programs**.

(i) Each person licensed under C.5.5(d)(1) to initially transfer devices to generally licensed persons shall also 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 Section 31.5 of 10 CFR Part 31 and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commission's jurisdiction.

(ii) Each person licensed under C.5.5(d)(1) to initially transfer devices to generally licensed persons shall also report to the responsible State agency all transfers of devices manufactured and distributed pursuant to C.5.5(d) for use under a general license in that State's regulations equivalent to C.4.2(b) and all receipts of devices from general licensees in the Agreement State's jurisdiction to the responsible Agreement State agency.

(iii) The required information for reports required by C.5.5(d)(10)(i) and (ii) includes:

(a) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(b) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(c) The date of transfer;

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

(e) The quantity and type of radioactive material contained in the device.

C.5.5(d)(10)(iv)

(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 or from 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.

(11) **Reports - General**. The following requirements are applicable to all reports required by C.5.5(d)(9) and C.5.5(d)(10):

(i) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(ii) For devices received from a general licensee, the report shall 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.

(iii) If the licensee makes changes to a device possessed by a general licensee, such that the label shall be changed to update required information, the report shall identify the general licensee, the device, and the changes to information on the device label.

(iv) The report shall cover each calendar quarter, shall be filed within thirty (30) days of the end of the calendar quarter, and shall clearly indicate the period covered by the report.

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

(12) **Recordkeeping.** Each person licensed under C.5.5(d)(1) to initially transfer devices to generally licensed persons shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section shall be maintained for a period of three (3) years following the date of the recorded event.

(e) **Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft.** An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for uses in aircraft, for distribution to persons generally licensed under C.4.2(c) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirements specified in C.5.2 and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, 32.101 of 10 CFR Part 32 or their equivalent.

(f) **Special Requirements for License to Manufacture or Initially Transfer Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.4.2(e).** An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under C.4.2(e) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirement of C.5.2, and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.60 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

C.5.5(g)

(g) **[DELETED]**

(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.4.2(g) will be approved if:

(1) The applicant satisfies the general requirement specified in C.5.2.

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

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

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

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

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

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

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

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

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

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

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

(ii) Displaying the radiation caution symbol described in A.3.12(a) and the words, **"CAUTION, RADIOACTIVE MATERIAL"**, and **"Not for Internal or External Use in Humans or Animals"**.

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

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

_____
(Name of manufacturer)

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C.5.5(h)(5)

(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 A.4.1 of these Regulations.

(i) **Licensing the Manufacture and Distribution of Ice Detection Devices.** An application for a specific license to manufacture or initially transfer ice detection devices to persons generally licensed under C.4.2(h) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirements of C.5.2, and

(2) The criteria of Sections 32.61, 32.62, 32.63 of 10 CFR Part 32 are met.

(j) **Manufacture and Distribution of Radioactive Drugs for Medical Use Under Subpart C.8.**

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons licensed pursuant to C.5.3(a) will be approved if:

(i) The applicant satisfies the general requirements specified in C.5.2 of this part;

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

(a) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(b) Licensed as a drug manufacturer in accordance with the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors* [*R5-19-PHAR*] of the Rhode Island Department of Health;

(c) Licensed as a pharmacy in accordance with the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributor*s [*R5-19-PHAR*] of the Rhode Island Department of Health; or

(d) A positron emission tomography (PET) drug production facility licensed pursuant to C.5.5(j)(1)(ii)(b) or C.5.5(j)(1)(ii)(b) (as applicable.

(iii) The applicant submits information on the radionuclide, chemical and physical form, maximum activity per vial, syringe, generator or other container of the radioactive drug, and shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

(iv) The applicant satisfies the following labeling requirements:

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

C.5.5(j)(1)(iv)(b)

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

(2) A licensee described by C.5.5(j)(1) of these Regulations:

(i) May prepare radioactive drugs for medical use, as defined by these Regulations, provided that the radioactive drug is prepared by either an Authorized Nuclear Pharmacist as specified in C.5.5(j)(2)(ii) of these Regulations, or an individual under the supervision of an Authorized Nuclear Pharmacist as specified in Section C.8.8 of these Regulations.

(ii) May allow a pharmacist to work as an Authorized Nuclear Pharmacist if:

(a) This individual qualifies as an Authorized Nuclear Pharmacist as defined in these Regulations; and

(b) This individual meets the requirements specified in C.8.76(b) and C.8.74 of these Regulations and the licensee has received an approved license amendment identifying this individual as an Authorized Nuclear Pharmacist.

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

(i) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

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

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

(5) Notwithstanding the foregoing, no license shall be issued pursuant to this section until the applicant has also received all required approvals from the State Board of Pharmacy pursuant to the Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19-PHAR] of the Rhode Island Department of Health.

(k) **[RESERVED]**

(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 C.5.3(a) or C.5.3(b) for use as a calibration or reference source or for the uses listed in C.8.38, C.8.40, C.8.46 and C.8.79 will be approved if:

(1) The applicant satisfies the general requirements in C.5.2 of these Regulations.

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

C.5.5(l)(2(i)

(i) the radioactive material contained, its chemical and physical form, and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Agency has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in C.8.17, C.8.38, C.8.40 and C.8.46, as appropriate, and to persons who hold an 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 (6) months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(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:

(i) primary containment (source capsule),

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

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

(6) The source or device has been registered in the Sealed Source and Device Registry.

C.5.5(m)

(m) **Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.**

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.4.1(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) the applicant satisfies the general requirements specified in C.5.2;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, and transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent (10%) of the limits specified in A.2.3(a); and

(iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under C.5.5(m) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under C.5.5(m) if the end use of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.5.5(m)(1) shall:

(i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) label or mark each unit to:

(a) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(b) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;

(iii) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "**Depleted Uranium**";

(iv) (a) furnish a copy of the general license contained in C.4.1(d) and a copy of Agency Form GEN-1 to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in C.4.1(d), or

C.5.5(m)(4)(iv)(b)

(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.4.1(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.4.1(d) and a copy of Agency Form GEN-1 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in C.4.1(d);

(v) report to the Agency all transfers of industrial products or devices to persons for use under the general license in C.4.1(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 thirty (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.4.1(d) during the reporting period, the report shall so indicate;

(vi) (a) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,

(b) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to C.5.5(m) for use under a general license in that State's regulations equivalent to C.4.1(d),

(c) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

(d) if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission,

(e) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State Agency; and

(vii) keep records showing the name, address, and point of contact for each general licensee to whom the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.4.4(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of two (2) years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

C.5.5(n)

(n) **Serialization of Nationally Tracked Sources.** Each licensee who manufactures a nationally tracked source[40] shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

C.5.6 **Issuance of Specific Licenses.**

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

C.5.7 **Specific Terms and Conditions of License.**

(a) Each licensee issued pursuant to this part shall be subject to all the provisions of the Act, now or thereafter in effect, and to all rules, regulations and orders of the Agency.

(b) (1) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by C.5.16.

(c) Each person licensed by the Agency pursuant to this part shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

(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 Section C.8.31. The licensee shall record the results of each test and retain each record for three (3) years after the record is made.

(e) Each licensee shall notify the Agency in writing when he decides to permanently discontinue all activities involving materials authorized under the license. This notification requirement applies to all specific licenses issued under this part.

[40] The requirement is only applicable to sources manufactured after 6 February 2007.

C.5.7(f)(1)

(f) (1) Each general licensee that is required to register by C.4.2(b)(6) and each specific licensee shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(i) the licensee;

(ii) an entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) an affiliate (as that term is defined in 11 USC 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of filing of the petition.

(g) **Security Requirements For Portable Gauges**. Each portable gauge licensee shall use a minimum of two independent physical controls that form substantial barriers[41] to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(h) **Production of PET Radioactive Drugs for Noncommercial Transfer**.

(1) Authorization under C.5.3(e) to produce Positron Emission Tomography (PET) radioactive drugs for non-commercial 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.5.3(e) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in C.5.5(j)(1)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in C.5.5(j)(3.

(3) A licensee that is a pharmacy authorized under C.5.3(e) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an Authorized Nuclear Pharmacist that meets the requirements in C.5.5(j)(2)(ii), or

(ii) an individual under the supervision of an Authorized Nuclear Pharmacist as specified in C.8.8.

[41] Additional guidance for implementing this requirement is contained in revised Appendix H (July 2005) to NUREG-1556-Volume 1, Revision 1 *Program-Specific Guidance About Portable Gauge Licenses* (November 2001).

C.5.8 **Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.**

(a) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's Final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

(b) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) Limit actions involving radioactive material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

(c) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by C.5.8(f)(1), and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to C.5.8(a); or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

(d) Coincident with the notification required by C.5.8(c), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Section C.5.16 of these Regulations in conjunction with a license issuance or renewal or as required by C.5.8. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to C.5.8(f)(4)(v). Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

(e) The Agency may grant a request to extend the time periods established in C.5.8(c) if the Agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to C.5.8(c). The schedule for decommissioning set forth in C.5.8(c) may not commence until the Agency has made a determination on the request.

(f) (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

C.5.8(f)(1)(i)

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to C.5.8(c) if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in C.5.8(f)(1) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in C.5.8(f).

(5) The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(g) (1) Except as provided in C.5.8(h), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in C.5.8(h), when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(h) The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24-month

period;

C.5.8(h)(2)

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay: and

(5) Other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(i) As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Agency Form MAT-7 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 A.2.13 through A.2.18. The licensee shall, as appropriate:

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters (removable and fixed) for surfaces, mega-becquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instruments used and certify that each instrument is properly calibrated and tested.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

(1) Radioactive material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in A.2.13 through A.2.18.

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in A.2.13 through A.2.18.

(4) Records required by C.5.15(e), (f) and (g) have been received.

C.5.9 **Renewal of Licenses.**

(a) Applications for renewal of specific licenses shall be filed in accordance with C.5.1.

(b) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Agency.

C.5.10

C.5.10 **Amendment of Licenses at Request of Licensee.**

(a) Applications for amendment of a license shall be filed in accordance with C.5.1 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

(b) A licensee, except those licensees subject to Subpart C.8 of these Regulations, may make minor changes in radiation safety procedures that are not potentially important to safety, i.e. ministerial changes, that were described in the application for license, renewal or amendment. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC or Agency Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change is in compliance with the requirements of these Regulations and the license. Procedures for ministerial changes in licenses subject to Subpart C.8 are contained in Section C.8.75 of these Regulations.

(c) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected Authorized Users and of management.

(d) A copy of the record required by Paragraph C.5.10(c) of these Regulations must be submitted to the Agency within thirty days of adopting said change(s).

C.5.11 **Agency Action on Applications to be Renew and Amend.** In considering an application by a licensee to renew or amend his license, the Agency will apply the criteria set forth in C.5.2 and C.5.3, C.5.4 or C.5.5 as applicable.

C.5.12 **[Reserved]**

C.5.13 **[Reserved]**

C.5.14 **Transfer of Material.**

(a) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of C.5.14(c) and (d), any licensee may transfer radioactive material:

(1) to the Agency;[42]

(2) to the U.S. Department of Energy;

(3) to any person exempt from the regulations in this part to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission 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

[42] A licensee may transfer material to the Agency only after receiving prior approval from the Agency.

C.5.14(b)(5)

(5) as otherwise authorized by the Agency in writing.

(c) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, or to a general licensee who is required to register with the Agency, the U.S. 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.5.14(c) are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) the transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the licensee or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission or the licensing agency of another 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.5.14(d)(1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of C.7.1 of this part.

C.5.15 **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 therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

C.5.15(d)

(d) The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

(e) 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 A.4.2, A.4.3, A.4.4 and A.4.5; and

(2) Records required by A.5.3(b)(4).

(f) If licensed activities are transferred or assigned in accordance with C.5.7(b), 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 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 A.4.2, A.4.3, A.4.4 and A.4.5; and

(2) Records required by A.5.3(b)(4).

(g) Prior to license termination, each licensee shall forward the records required by Section C.5.16(g) to the Agency.

C.5.16 **Financial Assurance and Recordkeeping for Decommissioning.**

(a) (1) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix F to Part A of these Regulations shall submit a decommissioning funding plan as described in C.5.16(e). The decommissioning funding plan shall also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F to Part A of these Regulations.

(2) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix F to Part A of these Regulations shall submit a decommissioning funding plan as described in C.5.16(e). The decommissioning funding plan shall also be submitted when a combination of isotopes is involved if R divided by 10^{12} is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F to Part A of these Regulations. The decommissioning funding plan shall be submitted to the Agency by 2 December 2005.

(b) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in C.5.16(d) shall either-

(1) Submit a decommissioning funding plan as described in C.5.16(e)n; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by C.5.16(d)using one of the methods described in C.5.16(f). 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 C.5.16(f) shall be submitted to the Agency before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of C.5.16(f).

C.5.16(c)(1)

(c) (1) **[RESERVED]**.

(2) Each holder of a specific license, which is of a type described in C.5.16(a), shall submit a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this Section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license, which is of a type described in C.5.16(b), shall submit a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this Section.

(4) Waste collectors and waste processors, as defined in Appendix D to Part A of these Regulations, shall provide financial assurance in an amount based on a decommissioning funding plan as described in C.5.16(e). The decommissioning funding plan shall include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of A.2.13 through A.2.18. The decommissioning funding plan shall be submitted to the Agency by 2 December 2005.

(d) (1) Table of required amounts of financial assurance for decommissioning by quantity of material:

QUANTITY OF RADIOACTIVE MATERIAL	**FUNDING REQUIRED**
Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F to Part A of these Regulations in unsealed form. (For a combination of isotopes, if R, as defined in Paragraph (a) above, divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F to Part A of these Regulations in unsealed form. (For a combination of isotopes, if R, as defined in Paragraph (a) above, divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000
Greater than 10^{10} times the applicable quantities of Appendix F to Part A of these Regulations in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in Paragraph (a) above, divided by 10^{10} is greater than 1.)	$113,000

(2) Licensees required to submit the $1,125,000, $113,000 or $225,000 amount shall do so by 2 June 2005. Licensees having possession limits exceeding the upper bounds of the table in Subparagraph (d)(1) above shall base financial assurance on a decommissioning funding plan.

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C.5.16(e)(1)

(e) (1) Each decommissioning funding plan must contain:

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(a) The cost of an independent contractor to perform all decommissioning activities;

(b) The cost of meeting the A.2.14 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of A.2.15, the cost estimate may be based on meeting the A.2.15 criteria;

(c) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(d) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from C.5.16(f), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of C.5.16(f) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed three (3) years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(f) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) **Prepayment.** Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

C.5.16(f)(2)

(2) **A surety method, insurance, or other guarantee method.** These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix E to 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 may be used if the guarantee and test are as contained in Appendix E 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 situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 or more days prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustees and trust must be acceptable to the Agency. An acceptable trustee includes any entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a State or Federal agency.

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

(3) **An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund.** An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operations 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. The surety or insurance provisions must be as stated in Paragraph (f)(2) of this Section.

(4) In the case of State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in Paragraph (d) of this Section, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(g) Each person licensed under Parts C or E of these Regulations shall keep records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with C.5.7, licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records of information important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

C.5.16(g)(1)

(1) Records of spill or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site. These records may be limited to instances where 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, forms, quantities and concentrations.

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

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) of radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years of the following:

(i) All areas designated and formally designated restricted areas as defined in these Regulations; and

(ii) All areas outside of restricted areas that require documentation under C.5.16(g)(1); and

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under A.5.9 of these Regulations; and

(iv) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in A.2.13 through A.2.18,or apply for approval for disposal under A.4.1.

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

(h) 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.5.16(e).

(i) 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:

(1) Submit a decommissioning funding plan as described in C.5.16(e); or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 using one of the methods described in C.5.16(f). 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 C.5.16(f) shall be submitted to the Agency before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of C.5.16(f).

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C.5.17 **Consideration of the Need for an Emergency Plan for Responding to a Release of Radioactive Materials.**

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

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

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

(b) One or more of the following factors may be used to support an evaluation submitted under
(1) The radioactive material is physically separated so that only a portion could be involved in an accident;
(2) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

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

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

(5) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix F to this Part;

(6) Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix F to this Part;

(7) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under C.5.17(a)(2) must include the following information:

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

(2) **Types of Accidents.** An identification of each type of radioactive materials accident for which protective actions may be needed.

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

(4) **Detection of Accidents.** Identification of the means of detecting each type of accident in a timely manner.

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

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

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

C.5.17(c)(8)

(8) **Notification and Coordination.** A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[43]

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

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

(11) **Safe Shutdown**. A brief description of the means of restoring the facility to a safe condition after an accident.

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

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

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

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

C.6 RECIPROCITY

C.6.1 **Reciprocal Recognition of Licenses.**

(a) **Licenses of Radioactive Material.**

(1) Subject to these Regulations, and the limitations contained in C.6.1(a)(4), any person who holds a specific license from the U.S. 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, except for areas under exclusive federal jurisdiction, for a period not in excess of 180 days in any calendar year provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee submits Agency Form MAT-9, a copy of the pertinent licensing document, and the appropriate fee as prescribed in I.3.4 to the Agency at least three (3) days prior to engaging in such activity for the first time in a calendar year. If a submittal cannot be filed three (3) days before engaging in activities under reciprocity, because of an emergency or other reason, the Agency may waive the 3-day time requirement provided the licensee:

(a) Informs the Agency by telephone, facsimile, an Agency Form MAT-9, or a letter of initial activities or revisions to the information submitted on the initial Agency Form MAT-9;

(b) Receives oral or written authorization for the activity from the Agency; and

(c) Within three (3) days after the notification, files an Agency Form MAT-9, a copy of the pertinent licensing document, and the appropriate fee as prescribed in I.3.4.

(iii) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.6.1(a)(1) except by transfer to a person specifically licensed by the Agency, another Agreement State or by the U.S. Nuclear Regulatory Commission to receive such material

(vi) the out-of-state licensee files an amended Agency Form MAT-9 with the Agency to request approval for changes in work locations, radioactive material, or work activities different from the information contained on the initial MAT-9.

(2) Notwithstanding the provisions of C.6.1(a)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in C.4.2(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, except for areas under exclusive federal jurisdiction, provided that:

C.6.1(a)(2)(i)

(i) such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

(iii) such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited;" and

(iv) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.4.2(b).

(3) 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.

(4) The Agency will not accept any applications for reciprocity under this subpart with respect to activities authorized pursuant to regulations that are equivalent to Subpart C.8 ["Use of Radionuclides in the Healing Arts"]. These activities will only be authorized under the provision of a specific license issued by the Agency.

(b) **[DELETED]**

(c) **Generally Licensed Devices .**

(1) Reciprocity requests involving generally licensed devices registered pursuant to C.4.2(b)(6) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State shall be handled in accordance with the procedures contained in C.6.1(a). Applicants for reciprocity shall submit evidence of current registration pursuant to C.4.2(b)(6) (or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State) in lieu of a specific radioactive materials license.

(2) Reciprocity requests involving other generally licensed devices shall also be handled in accordance with the procedures contained in C.6.1(a). In lieu of a specific radioactive materials license, applicants for reciprocity shall submit a copy of the general license authorization for the device and documentation that they are authorized to possess the device under a general license pursuant to the regulations of the U.S. Nuclear Regulatory Commission or another Agreement State that are applicable to the jurisdiction where the reciprocity request originated.

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C.7 TRANSPORTATION OF RADIOACTIVE MATERIAL

C.7.1 Purpose and Scope.

(a) The regulations in this Subpart establish requirements for packaging, preparation for shipment, and transportation of licensed material.

(b) The packaging and transportation of licensed material are also subject to the requirements of other agencies (e.g., the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission and the U.S. Postal Service[44]) having jurisdiction over means of transport. The requirements of this Subpart are in addition to, and not in substitution for, other requirements.

(c) The Regulations in this Subpart apply to any licensee authorized by specific or general license issued by the Agency to receive, possess, use or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Agency license, or transports that material on public highways. No provision of this Subpart authorizes possession of licensed material.

(d) Definition of terms used in this Subpart are those listed in Subpart A.0 of these Regulations, 49 CFR and 10 CFR 71.4, except that whenever a definition refers to evaluation or approval by the U.S. Department of Transportation or NRC, and such evaluation or approval is within the jurisdiction of the State of Rhode Island as an Agreement State, the Agency shall perform the evaluation or approval.

C.7.2 Requirement for License and Opening Instructions.

(a) **Requirement for License.** No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Agency or as exempted in C.7.3.

(b) **Opening Instructions.** Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with A.3.17(e) of these Regulations.

C.7.3 Exemptions.

(a) Common and contract carriers, freight forwarders, and warehouse workers which are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the U.S. Postal Service (Domestic Mail Manual), Section C-023.9.0, and the U.S. Postal Service, are exempt from the requirements of this Subpart to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to C.7.2 and other applicable requirements of these Regulations.

(b) Any licensee is exempt from the requirements of this Subpart to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 70 becquerel per gram (0.002 μCi/g)

(c) Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from C.7.4 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under Subpart C.8 of these Regulations, 10 CFR 35 or the equivalent regulations of another Agreement State.

[44] Postal Service Manual (Domestic Mail Manual), section 124, which is incorporated by reference at 39 CFR 111.1.

C.7.3(d)

(d) A licensee is exempt from all the requirements of this Subpart with respect to shipment or carriage of the following low-level materials:

(1) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed ten (10) times the values specified in Table IV of Appendix G to Part C.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in Table IV of Appendix G to Part C, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table IV of Appendix G to Part C.

(e) Fissile material meeting all the requirements of at least one paragraph in C.7.3(e)(1) through (e)(6) are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of C.7, except as noted.

(1) Individual package containing two (2) grams or less fissile material.

(2) Individual or bulk packaging containing fifteen (15) grams or less of fissile material provided the package has at least two hundred (200) grams of solid nonfissile material for every gram of fissile material. lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

(3) (i) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

(a) There is at least two thousand (2000) grams of solid nonfissile material for every gram of fissile material, and

(b) There is no more than one hundred eighty (180) grams of fissile material distributed within three hundred sixty (360) kg of contiguous nonfissile material.

(ii) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of one percent (1%) by weight, and with total plutonium and uranium-233 content of up to one percent (1%) of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five percent (5%) of the uranium mass.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two percent (2%) by mass, with a total plutonium and uranium-233 content not exceeding two one-thousandth of a percent (0.002%) of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than one-thousand (1000) grams, of which not more than twenty percent (20%) by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

C.7.4 Transportation of Licensed Material.

(a) Each licensee who transports licensed material outside the site of usage, as specified in the Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall:

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C.7.4(a)(1)

(1) Comply with the applicable requirements, appropriate to the mode of transport, of 49 CFR Parts 107, 171-180, 390-397 , appropriate to the mode of transport. The licensee shall particularly note the regulations of the U.S. Department of Transportation in the following areas:

(i) Packaging - 49 CFR Part 173: Subparts A and B and I.

(ii) Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§172.436 through 172.440, and Subpart E.

(iii) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.

(iv) Accident reporting - 49 CFR Part 171: §§171.15 and 171.16.

(v) Shipping papers and emergency information - 49 CFR Part 172: Subpart C and Subpart G.

(vi) Hazardous material employee training - 49 CFR Part 172: Subpart H.

(vii) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

(viii) Security plans, 49 CFR part 172, subpart I;

(2) The licensee shall also comply with applicable U.S. Department of Transportation regulations pertaining to the following modes of transportation:

(i) Rail - 49 CFR Part 174: Subparts A through D and K.

(ii) Air - 49 CFR Part 175.

(iii) Vessel - 49 CFR Part 176: Subparts A through F and M.

(iv) Public Highway - 49 CFR Part 177 and Parts 390 through 397.

(b) If U.S. Department of Transportation regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the U.S. Department of Transportation specified in C.7.4(a) to the same extent as if the shipment was subject to the regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Agency.

C.7.5 General Licenses for Carriers.

(a) A general license is hereby issued to any common or contract carrier not exempt under C.7.3 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[45]

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[45]

[45] Notification of an incident shall be filed with, or made to, the Agency as prescribed in 49 CFR, regardless of and in addition to notification made to the U.S. Department of Transportation or other agencies

C.7.5(c)

(c) Persons who transport radioactive material pursuant to the general licenses in C.7.5(a) or C.7.5(b) are exempt from the requirements of Part A of these Regulations to the extent that they transport radioactive material.

C.7.6 General License: Nuclear Regulatory Commission-Approved Packages.

(a) A general license is hereby issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the Nuclear Regulatory Commission.

(b) This general license applies only to a licensee who:

(1) Has a copy of the certificate of compliance, or other approval of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(2) Complies with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of 10 CFR 71, Subparts A, G and H;

(3) Prior to the licensee's first use of the package, has submitted to the Nuclear Regulatory Commission, in writing, the licensee's name and license number and the package identification number specified in the package approval; and

(4) Has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71, Subpart H.

(c) The general license in C.7.6(a) applies only when the package approval authorizes use of the package under this general license.

(d) For a Type B or fissile material package, the design of which was approved by the Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of C.7.7.

C.7.7 General License: Previously Approved Package.

(a) **[RESERVED]**

(b) A Type B(U) package, a Type B(M) package or a fissile material package, previously approved by the Nuclear Regulatory Commission but without the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of C.7.6 with the following additional conditions:

(1) Fabrication of the package was satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in U.S. Department of Transportation regulations at 49 CFR 173.403; and

(3) A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(c) A Type B(U) package, a Type B(M) package, or a fissile material package previously approved by the Nuclear Regulatory Commission with the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of C.7.6 with the

following additional conditions:

C.7.7(c)(1)

(1) Fabrication of the package was satisfactorily completed by 31 December 2006, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c); and

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403.

C.7.8 General License: Plutonium-Beryllium Special Form Material.

(a) A general license is hereby issued to any licensee of the Agency to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with C.7.8. This material need not be contained in a package which meets the standards of 10 CFR 71 Subparts E and F. However, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) The general license applies only to a licensee who has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71 Subpart H.

(c) The general license applies only when a package's contents:

(1) Contain less than a Type A quantity of material; and

(2) Contain less than one-thousand grams (1000 g) of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than two hundred forty grams (240 g) of the total quantity of plutonium in the package.

(d) The general license applies only to packages labeled with a CSI which:

(1) Has been determined in accordance with C.7.8(e);

(2) Has a value less than or equal to one-hundred (100); and

(3) For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to fifty (50) for shipment on a nonexclusive use conveyance and less than or equal to one-hundred (100) for shipment on an exclusive use conveyance.

(e) (1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$\mathbf{CSI = 10 \left[\frac{Grams\ ^{239}Pu + Grams\ ^{241}Pu}{24} \right]}$$

and

(2)The calculated CSI must be rounded up to the first decimal place.

C.7.9 General License: Use of Foreign Approved Package.

(a) A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

(b) This general license applies only to shipments made to or from locations outside the United States.

(c) This general license applies only to a licensee who:

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C.7.9(c)(1)

(1) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

(2) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of 10 CFR 71, Subparts A, G and H. With respect to the quality assurance provisions of 10 CFR 71, Subpart H, the licensee is exempt from design, construction, and fabrication considerations; and

(3) Except as otherwise provided in C.7.9, the licensee has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71, Subpart H.

C.7.10 General License: Fissile Material, Limited Quantity Per Package.

(a) A general license is hereby issued to any licensee of the Agency to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with C.7.10. The fissile material need not be contained in a package which meets the standards of 10 CFR 71, Subparts E and F; However, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) This general license applies only when a package's contents:

(1) Contain less than a Type A quantity of fissile material; and

(2) Contain less than five hundred (500) total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(3) Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

(c) The general license applies only to a licensee who has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR 71, Subpart H.

(d) The general license applies only to packages containing fissile material that are labeled with a CSI which:

(1) Has been determined in accordance with C.7.10(e);

(2) Has a value less than or equal to ten (10); and

(3) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to fifty (50) [for shipment on a nonexclusive use conveyance] and less than or equal to one hundred (100) [for shipment on an exclusive use conveyance].

(e) (1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$\mathbf{CSI = 10 \left[\frac{Grams\ ^{235}U}{X} + \frac{Grams\ ^{233}U}{Y} + \frac{Grams\ Pu}{Z} \right]}$$

(2) The calculated CSI must be rounded up to the first decimal place;

(3) The values of X, Y, and Z used in the CSI equation must be taken from Tables 1 or 2, as appropriate;

(4) If Table 1 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

C.7.10(e)(5)

(5) Table 1 values for X, Y, and Z must be used to determine the CSI if:

(i) Uranium-233 is present in the package;

(ii) The mass of plutonium exceeds 1 percent of the mass of uranium-235;

(iii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(iv) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table 1 - Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per §C.7.10(e)

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[46] (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

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[46] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O.

Table 2 - Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per §§C.7.10(e)

Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

C.7.11 External Radiation Standards for All Packages.

(a) Except as provided in C.7.11(b), each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.

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C.7/11(b)

(b) A package that exceeds the radiation level limits specified in C.7.11(a) must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):

(i) The shipment is made in a closed transport vehicle;

(ii) The package is secured within the vehicle so that its position remains fixed during transportation; and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(3) 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(4) 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with A.3.3 of these Regulations.

(c) For shipments made under the provisions of C.7.11(b), the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

(d) The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

C.7.12 Assumptions as to Unknown Properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

C.7.13 Preliminary Determinations. Prior to the first use of any packaging for the shipment of radioactive material:

(a) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects which could significantly reduce the effectiveness of the packaging;

(b) Where the maximum normal operating pressure will exceed 35 kilopascal (5 lb/in^2) gauge, the licensee shall test the containment system at an internal pressure at least fifty percent (50 %) higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

C.7.13(d)

(c) Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Nuclear Regulatory Commission; and

(d) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number as assigned by the Nuclear Regulatory Commission.

C.7.14 Routine Determinations. Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of Subpart C.7 and of the license. The licensee shall determine that:

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

(h) The level of non-fixed radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and within the limits specified in U.S. Department of Transportation regulations at, 49 CFR 173.443.

(i) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in C.7.11 at any time during transportation.

(j) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition; and

(k) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

C.7.15 Air Transport of Plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in Subpart C.7 or included indirectly by citation of the U.S. Department of Transportation regulations at 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any for, whether for import, export, or domestic shipment, is not transported by air, or delivered to a carrier for air transport, unless:

(1) The plutonium is contained in a medical device designed for individual human application; or

(2) The plutonium is contained in a material in which the specific activity is not greater than less than or equal to the activity concentration values for plutonium specified in Table IV of Appendix G to Part C, and in which the radioactivity is essentially uniformly distributed; or

(3) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with C.7.4; or

C.7.15(a)(4)

(4) The plutonium is shipped in a package specifically authorized, in the certificate of compliance, issued by the Nuclear Regulatory Commission,

(b) Nothing in C.7.15(a) is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

(c) For a shipment of plutonium by air which is subject to C.7.15(a)(4), the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

C.7.16 Shipment Records. Each licensee shall maintain for a period of three (3) years after shipment a record of each shipment of licensed material not exempt under C.7.3, showing, where applicable:

(a) Identification of the packaging by model number and serial number;

(b) Verification that the packaging, as shipped, had no significant defect;

(d) Volume and identification of coolant;

(e) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(e) Date of the shipment;

(f) Name and address of the transferee;

(g) Address to which the shipment was made;

(h) Results of the determinations required by C.7.14 and by the conditions of the package approval;

(i) For each item of irradiated fissile material:

(1) Identification by model number and serial number;

(2) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(3) Any abnormal or unusual condition relevant to radiation safety; and

(j) For fissile packages and for Type B packages, any special controls exercised.

C.7.17 Reports.

(a) The licensee, after requesting the certificate holder's input, shall submit a written report to the Agency of:

(1) Instances in which there is significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use;

(2) Details of any defects with safety significance in any NRC-approved Type B or fissile material packaging after first use;

(3) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

(b) The licensee shall submit a written report to the Agency of instances in which the conditions in the certificate of compliance were not followed during a shipment.

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C.7.17(c)

(c) Each licensee shall submit a written report required by C.7.17(a) or (b) within sixty (60) days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the Agency to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. These written reports must include the following:

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2) A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of 10 CFR 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.

(i) Status of components or systems that were inoperable at the start of the event and that contributed to the event;

(ii) Dates and approximate times of occurrences;

(iii) The cause of each component or system failure or personnel error, if known;

(iv) The failure mode, mechanism, and effect of each failed component, if known;

(v) A list of systems or secondary functions that were also affected for failures of components with multiple functions;

(vi) The method of discovery of each component or system failure or procedural error;

(vii) For each human performance-related root cause, a discussion of the cause(s) and circumstances;

(viii) The manufacturer and model number (or other identification) of each component that failed during the event; and

(ix) For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

(3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

(4) A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

(6) The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

(7) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(d) **Report Legibility.** The reports submitted by licensees and/or certificate holders under C.7.17 must be of sufficient quality to permit reproduction and micrographic processing.

C.7.18 Advance Notification of Shipment of Nuclear Waste.

(a) (1) As specified in C.7.18(b), (d) and (e), each licensee shall provide advance notification to the governor of a State, or governor's designee[47], of the shipment of licensed material, within, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(2) As specified in C.7.18(b), (d) and (e), each licensee shall provide advance notification to the Tribal official of participating Tribes*, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is required under C.7.18 for shipment of licensed material, other than irradiated fuel, meeting the following three (3) conditions:

(1) The licensed material is required by C.7 to be in Type B packaging for transportation;

(2) The licensed material is being transported to or across a state boundary enroute to a disposal facility or to a collection point for transport to a disposal facility; and

(3) The quantity of licensed material in a single package exceeds the least of the following:

(i) Three thousand (3000) times the A_1 value of the radionuclides as specified in Table I of Appendix G to Part C for special form radioactive material;

(ii) Three thousand (3000) times the A_2 value of the radionuclides as specified in Table I of Appendix G to Part C for normal form radioactive material; or

(iii) One thousand (1000) terabecquerel (27,000 Ci).

(c) **Information to be Furnished in Advance Notification of Shipment.** Each advance notification required by C.7.18(a) shall contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the nuclear waste shipment;

(2) A description of the nuclear waste contained in the shipment as specified by the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the seven (7)-day period during which departure of the shipment is estimated to occur;

(4) The seven (7)-day period during which arrival of the shipment at state boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the seven (7)-day period during which arrival of the shipment is estimated to occur; and

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

[47] A list of the names and mailing addresses of the governors' designees and Tribal official's designees of participating Tribes is available upon request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

C.7.18(d)

(d) **Procedures for Submitting Advance Notification.** The notification required by C.7.18(a) shall be made in writing to the office of each appropriate governor, or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, to the Agency and to the Director, NRC Division of Security Policy, Office of Nuclear Security and Incident Response.

(1) A notification delivered by mail shall be postmarked at least seven (7) days before the beginning of the seven (7)-day period during which departure of the shipment is estimated to occur.

(2) A notification delivered by any other means than mail shall reach the office of the governor, or governor's designee or the Tribal official or Tribal official's designee at least four (4) days before the beginning of the seven (7)-day period during which departure of the shipment is estimated to occur.

(3) The licensee shall retain a copy of the notification shall be retained by the licensee for three (3) years.

(e) **Revision Notice.** A licensee who finds that schedule information previously furnished to a governor, or governor's designee or a Tribal official or Tribal official's designee, pursuant to C.7.18(a) will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain for three (3) years a record of the name of the individual contacted.

(f) **Cancellation Notice.** Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor, or governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, to the Agency and to the Director, NRC Division of Security Policy, Office of Nuclear Security and Incident Response. A copy of the notice shall be retained by the licensee as a record for three (3) years.

C.7.19 Quality Assurance Requirements.

(a) **Purpose**. C.7.19 describes quality assurance requirements applying to purchase, handling, shipping, storing, cleaning, assembly, inspection, operation, maintenance, and repair of components of packaging that are important to safety. As used in C.7.19, *quality assurance* comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes *quality control*, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to C.7.

(b) **Establishment of Program.** Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of C.7.19 and 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirements importance to safety.

(c) **Approval of Program.** Before the use of any package for the shipment of licensed material subject to this C.7.19, each licensee shall obtain Agency approval of its quality assurance program by submitting a description of its quality assurance program, including a discussion of which requirements of C.7.19 are applicable and how they will be satisfied.

C.7.19(d)

(d) **Previously Approved Programs**. A NRC-approved quality assurance program that satisfies the applicable criteria of 10 CFR 71 Subpart H, 10 CFR 50 Appendix B or 10 CFR 72 Subpart G, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of C.7.19(b). Before first use, the licensee shall notify the Agency of its intent to apply its previously approved 10 CFR 71 Subpart H, 10 CFR 50 Appendix B or 10 CFR 72 Subpart G quality assurance program to transportation activities. The licensee shall identify the program by date of submittal to the NRC, Docket Number, and date of NRC approval.

(e) **Radiography Containers.** A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of E.2.9(b) of these Regulations, 10 CFR 34.31(b) or equivalent requirement of another Agreement State, is deemed to satisfy the requirements of C.7.6(b) and C.7.19(b).

(f) **Quality Assurance Organization.** Each licensee shall establish a quality assurance organization in accordance with 10 CFR 71.103.

(g) **Quality Assurance Program.** Each licensee shall establish a quality assurance program in accordance with 10 CFR 71.105(a) through (d).

(h) **Handling, Storage and Shipping Control.** Each licensee shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

(i) **Inspection, Test and Operating Status.**

(1) Each licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

(2) Each licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

(j) **Nonconforming Materials, Parts or Components.** Each licensee, shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(k) **Corrective Action.** Each licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(l) **Quality Assurance Records.** The licensee shall maintain sufficient written records to describe the activities affecting quality.

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C.7.19(l)(1)

(1) The records must include the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment.

(2) The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility.

(3) The licensee shall retain these records for three (3) years beyond the date when the licensee last engaged in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee shall retain the superseded material for three (3) years after it is superseded.

(m) **Audits.** The licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

(1) The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited;

(2) Audited results must be documented and reviewed by management having responsibility in the area audited; and

(3) Follow up action, including re-audit of deficient areas, must be taken where indicated.

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C.8 USE OF RADIONUCLIDES IN THE HEALING ARTS

C.8.1 **Scope, Provisions for Research Involving Human Subjects and FDA, Other Federal and State Requirements.**

(a) **Scope.** This subpart contains the requirements and provisions for the use of radioactive material in the healing arts (medical use of radioactive 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 subpart are in addition to, and not in substitution for, others in these Regulations. The requirements and provisions of these Regulations apply to applicants and licensees subject to this subpart unless specifically exempted.

(b) **Provisions for Research Involving Human Subjects.** A licensee may conduct research involving human subjects using radioactive material provided:

(1) That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(2) The research involving human subjects authorized in C.8.1(b)(1) shall be conducted using radioactive material authorized for medical use in the license; and

(3) Nothing in this section relieves licensees from complying with the other requirements in this Subpart.

(c) **FDA, Other Federal and State Requirements.** Nothing in this Subpart relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

(d) **License Required.** A person shall manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State, or as allowed by C.8.8(a) and C.8.8(b) of these Regulations. A specific license is not needed for an individual who:

(1) Receives, possesses, uses, or transfers radioactive material in accordance with these Regulations under the supervision of an Authorized User as provided in C.8.8, unless prohibited by license condition; or

(2) Prepares unsealed radioactive material for medical use in accordance with these Regulations under the supervision of an Authorized Nuclear Pharmacist or Authorized User as provided in C.8.8, unless prohibited by license condition.

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C.8.1(e)

(e) **Maintenance of Records.** Each record required by this Subpart shall be legible throughout the specified retention period specified by each Agency regulation.. 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, shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

C.8.2 **License Amendments.** A licensee shall apply for and receive a license amendment:

(a) Before it receives or uses radioactive material for a type of use that is permitted under this subpart, but that is not authorized on the licensee's current license issued pursuant to this Subpart;

(b) Before permitting anyone, except a Visiting Authorized User, Visiting Authorized Medical Physicist or Visiting Authorized Nuclear Pharmacist as described C.8.9, to work as an Authorized User, Authorized Medical Physicist or Authorized Nuclear Pharmacist under the license;

(c) Before changing a Radiation Safety Officer, except as provided in C.8.4(c), or Authorized Medical Physicist;

(d) Before ordering radioactive material in excess of the amount, or radionuclide or form different than authorized on the license;

(e) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license;

(f) Before changing statements, representations, and procedures which are incorporated into the license, except as provided for in C.8.75 of these Regulations;

(g) Before it releases licensed facilities for unrestricted use.

(h) In addition to the requirements specified above, a Therapeutic Medical Unit licensee shall apply for and receive a license amendment before:

(1) Making any change in the treatment room shielding;

(2) Making any change in the location of the therapeutic medical unit within the treatment room;

(3) Using the therapeutic medical unit in a manner that could result in increased radiation levels in areas outside the treatment room;

(4) Relocating the therapeutic medical unit; or

(5) Allowing an individual not listed on the licensee's license to perform the duties of the Authorized Medical Physicist, except as provided in C.8.9(b).

C.8.3 **Notifications.** A licensee shall notify the Agency by letter no later than thirty (30) days after:

(a) An Authorized User, an Authorized Nuclear Pharmacist, Radiation Safety Officer, or Authorized Medical Physicist permanently discontinues performance of duties under the license or has a name change; or

(b) The licensee's mailing address changes; or

(c) The licensee’s name changes, but the name change does not constitute a transfer of control of the license as described in C.5.7(b) of these Regulations; or

C.8.4 **Authority and Responsibilities for the Radiation Protection Program.**

(a) In addition to the radiation protection program requirements of A.2.2 of these Regulations, a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendments before submittal to the Agency;

(2) Any individual before allowing that individual to work as a Visiting Authorized User, Visiting Authorized Medical Physicist, or Visiting Authorized Nuclear Pharmacist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under C.8.75;

(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 sixty days each year, a licensee may permit an Authorized User or an individual qualified to be a Radiation Safety Officer under C.8.62 and C.8.74, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in C.8.4(e), if the licensee takes the actions required in C.8.4(b), (d), (e) and (h), and notifies the Agency in accordance with C.8.3.

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer, 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 use of radioactive material permitted by the license.

(e) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(f) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(g) Licensees that are authorized for two or more different types of uses of radioactive material under C.8.34, C.8.40 or C.8.46, or two or more types of units under C.8.46, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee shall include an Authorized User of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an Authorized User nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(h) A licensee shall retain a record of actions taken by the licensee's management in accordance with C.8.4(a) for 5 years. The record shall include a summary of the actions taken and a signature of licensee management.

(i) The licensee shall retain a copy of both authority, duties and responsibilities of the Radiation Safety Officer as required by C.8.4(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by C.8.4(b), for the duration of the license. The records shall include the signature of the Radiation Safety Officer and licensee management.

C.8.4(j)

(j) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six (6) months. The licensee shall maintain minutes of each Radiation Safety Committee meeting which shall include the date of the meeting, members present, members absent and a summary of deliberations and discussions.

C.8.5 **Duties of Authorized User and Authorized Medical Physicist.**

(a) A licensee shall ensure 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 C.8.6 and C.8.8, 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 C.8.1(d)(1), C.8.1(d)(2) and C.8.8.

(b) A licensee shall ensure that only Authorized Medical Physicists perform, as applicable:

(1) Full calibration measurements as described in C.8.52, C.8.53 and C.8.55;

(2) Periodic spot-checks as described in C.8.56, C.8.58 and C.8.59; and

(3) Radiation surveys as described in C.8.57.

C.8.6 **Written Directives.**

(a) A written directive shall be dated and signed by an Authorized User prior to administration of I-131 sodium iodide greater than 1.11 MBq (30 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 shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

(b) The written directive shall contain the patient or human research subject's name and the following information:

(1) For an administration of a dosage of radioactive drug containing radioactive material: the radioactive drug containing radioactive material, dosage, and route of administration;

(2) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(3 For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(4) For high dose rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(5) For all other brachytherapy including low, medium and pulsed dose rate remote afterloaders:

(i) Prior to implantation: treatment site, the radionuclide and dose; and

(ii) After implantation but before completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).

C.8.6(c)

(c) A written revision to an existing written directive may be made provided that the revision is dated and signed by an Authorized User prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next fractional dose.

(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. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the Authorized User within forty-eight (48) hours of the oral revision.

(d) The licensee shall retain a copy of each written directive for 3 years.

C.8.7 **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 C.8.7(a) shall address the following items that are applicable for the licensee's use of radioactive material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by C.8.46.

(c) A licensee shall retain a copy of the procedures required under C.8.7(a) for the duration of the license.

C.8.8 **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 C.8.1(d)(1), shall:

(1) In addition to the requirements in A.6.3 of these Regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this Subpart and license conditions with respect to the use of radioactive material;

(2) Require the supervised individual to follow the instructions of the supervising Authorized User for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, these Regulations, and license conditions with respect to the medical use of radioactive material; and;

(3) If the individual is involved in administration of radiation/radioactive materials to humans, ensure that the individual possesses a current license in accordance with the Rules and Regulations for the Licensure of Radiographers, Nuclear Medicine Technologists and Radiation Therapists [R5-68-RAD] of the Rhode Island Department of Health, unless the individual is specifically exempted from licensure by Section 6.0 of said regulations;

C.8.8(b)

(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 C.8.1(d)(2), shall:

(1) In addition to the requirements in A.6.3 of these Regulations, 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, these Regulations, and license conditions.

(c) A licensee that permits supervised activities under C.8.8(a) and (b) is responsible for the acts and omissions of the supervised individual.

(d) Unless physical presence is otherwise required by license condition, a licensee who permits supervised activities for which a written directive is required under this Section shall require an Authorized User to be immediately available[48] to communicate with the supervised individual, and able to be physically present within one hour of notification.

C.8.9 **Visiting Authorized User, Visiting Authorized Medical Physicist and Visiting Authorized Nuclear Pharmacist.**

(a) A licensee may permit any Visiting Authorized User to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The Visiting Authorized User has the prior written permission of the licensee's management and Radiation Safety Committee if one is required;

(2) The licensee has a copy of an Agency, Agreement State or U.S. Nuclear Regulatory Commission license that identifies the Visiting Authorized User by name as an Authorized User for medical use; and

(3) Only those procedures for which the Visiting Authorized User is specifically authorized by an Agency, Agreement State or U.S. Nuclear Regulatory Commission license are performed by that individual.

(b) A licensee may permit a medical physicist to act as a Visiting Authorized Medical Physicist, and perform the duties of a medical physicist under the terms of the licensee's license for sixty (60) days each calendar year if:

(1) The medical physicist is registered with the Agency, under the provisions of Subpart B.4 of these Regulations, as a provider of Radiation Physics Services in the area of calibration and compliance surveys of therapeutic medical units; and

(2) The Visiting Authorized Medical Physicist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and

(3) The licensee has a copy of:

[48] For the purpose of this requirement, "immediately available" may include availability by telephone within ten (10) minutes.

C.8.9(b)(3)(i)

(i) An Agency, NRC or Agreement State license that identifies the individual as an Authorized Medical Physicist; or

(ii) A permit issued by an Agency, NRC or Agreement State specific license of broad scope that identifies the medical physicist by name as an Authorized Medical Physicist.

(c) A licensee may permit a nuclear pharmacist to act as a Visiting Authorized Nuclear Pharmacist, and to perform the duties of a nuclear pharmacist under the terms of the licensee's license for sixty (60) days each calendar year if:

(1) The nuclear pharmacist possesses a current license as a pharmacist in accordance with the Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19-PHAR] of the Rhode Island Department of Health; and

(2) The visiting Authorized Nuclear Pharmacist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and

(3) The licensee has a copy of:

(i) An Agency, NRC or Agreement State license that identifies the individual as an Authorized Nuclear Pharmacist; or

(ii) A permit issued by an Agency, NRC or Agreement State specific license of broad scope that identifies the nuclear pharmacist by name as an Authorized Nuclear Pharmacist.

(d) A licensee need not apply for a license amendment in order to permit:

(1) A Visiting Authorized User to use licensed material as described in C.8.9(a);

(2) A Visiting Authorized Medical Physicist to perform licensed duties as described in C.8.9(b);

(3) A Visiting Authorized Nuclear Pharmacist to perform licensed duties as described in C.8.9(c).

(e) A licensee shall retain copies of the records specified in C.8.9(a), C.8.9(b) and C.8.9(c) for three (3) years from the date of the last visit.

C.8.10 **Mobile Nuclear Medicine Service Requirements.** The Agency shall license mobile nuclear medicine services or clients of such services. The mobile nuclear medicine service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by a 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 mobile nuclear medicine service and the client. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile nuclear medicine service;

(2) Inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(3) Maintain all records required by Part A and Subpart C.8 of these Regulations at a location within the Agency's jurisdiction that is:

(i) A single address of use:

C.8.10(a)(3)(i)(a)

(a) Identified as the records retention location; and

(b) Staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or

(ii) When no address of use is identified on the license for records retention, the mobile unit:

(a) Identified in the license; and

(b) Whose current client's address schedule and location schedule is reported to the Agency.

(4) 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, this check for proper function shall include a constancy check;

(5) Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

(6) Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(7) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

(8) 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 shall include a constancy check;

(9) Check survey instruments for consistent response with a dedicated check source before use at each client's address;

(10) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with the requirements in Part A of these Regulations;

(11) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency pursuant to C.8.32; and,

(b) A mobile nuclear medical service shall not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(c) A licensee providing mobile nuclear medical services shall retain a copy of each letter required by C.8.10(a)(1). Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for 3 years after the last provision of service.

(d) A licensee providing mobile nuclear medical services shall retain the record of each survey required by C.8.10(a)(8) for 3 years. The record shall 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.

(e) A licensee providing mobile nuclear medical services shall, at a minimum, maintain the following documents on each mobile unit:

(1) The current operating and emergency procedures;

(2) A copy of the license;

(3) Copies of the letter(s) required by C.8.10(a)(1);

C.8.10(e)(4)

(4) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

(5) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding thirty (30) calendar days.

C.8.11 **Report and Notification of a Misadministration.**

(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:

(1) A dose that differs from the prescribed dose 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 either

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

(iii) 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:

(i) An administration of a wrong radioactive drug;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) 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) A licensee shall notify the Agency by telephone[49] no later than the next calendar day after discovery of the misadministration.

[49] During normal business hours, the Agency may be contacted at (401) 222-2566. At other times, this number will allow you to leave a message on the answering machine. In case of an emergency when it is necessary to immediately contact the Agency, utilize the RI Department of Health's 24-hour number [(401) 272-5952] and indicate the nature of your emergency. FAX communications may be sent 24 hours a day to (401) 222-5901.

C.8.11(d)

(d) The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration.

(1) The written report shall include:

(i) The licensee's name;

(ii) The prescribing physician's name;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken, or are planned, to prevent recurrence;

(vii) Verification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report shall not contain the individual's name or 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 misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he/she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee 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, individuals affected by the misadministration, or that individual's responsible relatives or guardians.

(g) A licensee shall retain a record of misadministrations reported in accordance with this section for 3 years. The record shall contain:

(1) The licensee's name;

(2) Names of the individuals involved;

(3) The social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration;

(4) A brief description of the event; why it occurred; the effect, if any, on the individual;

(5) The actions, if any, taken, or planned, to prevent recurrence; and

(6) Whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(h) The licensee shall provide a copy of the record required by C.8.11(g) to the referring physician, if other than the licensee, no later than 15 days after the discovery of the misadministration.

C.8.12

C.8.12 **Suppliers for Sealed Sources or Devices for Medical Use.** A licensee shall use for medical use only:

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to C.5.5(l) of these Regulations or the equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Sealed sources or devices non-commercially transferred from a license issued pursuant to C.8 of these Regulations or the equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to C.5.5(l) of these Regulations or the equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission.

C.8.13 **Quality Control of Diagnostic Equipment.** Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. The licensee shall conduct quality control procedures in accordance with written procedures.

C.8.14 **Possession, Use, Calibration and Check of Dose Calibrators (Photon-Emitting Radio-nuclides) and Instruments to Measure Dosages (Alpha- and Beta- Emitting Radionuclides) .**

(a) **Possession and Use.** For direct measurements performed in accordance with C.8.16:

(1) A licensee shall possess a dose calibrator and use it to measure the activity of photon-emitting unsealed radioactive material before it is administered to each patient or human research subject.

(2) For other than unit dosages of alpha- and beta- emitting unsealed radioactive material that has been obtained from a manufacturer or preparer licensed pursuant to C.5.5(j) of these Regulations or the equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission, a licensee shall possess and use instrumentation to measure the activity of alpha- or beta- emitting unsealed radioactive material before it is administered to each patient or human research subject. The licensee shall have procedures for use of the instrumentation.

(b) (1) For dose calibrators, a licensee shall:

(i) Check each instrument for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on the most frequently used setting(s) with a sealed source of not less than 50 microcuries (1.85 MBq) of any photon-emitting radionuclide with a half-life greater than 90 days;

(ii) Test each instrument for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying a reference source of the most frequently used radionuclide. This radionuclide source must be either a primary standard obtained from the National Institute for Standards and Technology or a calibration source that has been specifically prepared for dose calibrator accuracy determination by the radionuclide manufacturer/distributor. The actual activity of any such calibration source must be within 5 percent of its stated activity and must have been assayed by the radionuclide manufacturer/distributor in a dose calibrator whose calibration for that radionuclide is traceable to the National Institute for Standards and Technology within the previous six months. Upon completion of dose calibrator accuracy determination, the licensee shall also perform the constancy determination described in C.8.14(b)(1)(i) and use the values obtained as the reference points for the daily constancy checks.

C.8.14(b)(1)(iii)

(iii) Test each instrument for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 1.11 megabecquerels (30 μCi) and the highest dosage that will be administered to a patient or human research subject; and

(iv) Test each instrument for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(2) For instruments used to measure dosages of unsealed alpha- and beta- emitting radioactive material, a licensee shall:

(i) Perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, geometric dependence, as appropriate;

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

(iii) Make any necessary adjustment(s) to each instrument.

(c) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(d) A licensee shall also perform checks and tests required by C.8.14(b) following adjustment or repair of the dose calibrator or other instrument used to measure dosage.

(e) A licensee shall retain a record of dose calibrator and instrument calibrations required by this section for 3 years. The records shall include the model and serial number of the instrument, the identity and calibrated activity of the radionuclide contained in the calibration source, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

C.8.15 **Calibration of Survey Instruments.**

(a) A licensee shall ensure that the survey instruments used to show compliance with this subpart and Part A have been calibrated before first use, at intervals not to exceed 12 months, and following any repair that will affect the calibration.

(b) To satisfy the requirements of C.8.15(a), the licensee shall:

(1) Calibrate all required scale readings up to 10 mSv per hour or 1000 mR per hour with a radiation source;

(2) Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 mSv per hour or 2 and 1000 mR per hour; and

(iii) So that an accuracy within ± 20 percent of the true rate can be demonstrated at each point checked.

(3) Conspicuously note on the instrument the reading from a dedicated check source as determined at the time of calibration, and the date of calibration.

C.8.15(c)

(c) A licensee shall not use survey instruments if the difference between the indicated rate and calculated rate[50] is more than 20 percent.

C.8.15(d)

(d) A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each calibration required in C.8.15(a) for 3 years. The record shall include:

(1) The model and serial number of the instrument;

(2) The results of the calibration;

(3) The name of the individual who performed the calibration; and

(4) The date of calibration.

(f) To meet the requirements of C.8.15(a), (b) and (c), the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to perform calibrations of survey instruments.

C.8.16 **Determination of Dosages of Unsealed Radioactive Materials for Medical Use.** A licensee shall determine and record the activity of each dosage prior to medical use.

(a) For a unit dosage, this determination shall be made by:

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer or preparer licensed pursuant to C.5.5(j) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State; or

(ii) An Agency, U.S. Nuclear Regulatory Commission or another Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under C.5.3(e) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

(b) For other than unit dosages, this determination shall 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:

(i) A manufacturer or preparer licensed pursuant to C.5.5(j) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State; or

(ii) An Agency, U.S. Nuclear Regulatory Commission or another Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

[50] Energy dependent instruments shall have appropriate correction factor(s) attached to the instrument.

C.8.16(b)(iii))

(iii) A PET radioactive drug producer licensed under C.5.3(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

(c) Retain a record of the dosage determinations required by C.8.16(a) and (b) for 3 years. To satisfy this requirement, the record shall contain:

(1) The radiopharmaceutical;

(2) Patient's or human research subject's name, and identification number if one has been assigned;

(3) Prescribed dosage and determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

(4) Date and time of the dosage determination; and

(5) Name of the individual who determined the dosage.

(d) Unless otherwise directed by the Authorized User, a licensee shall 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.

C.8.17 **Authorization for Calibration, Transmission and Reference Sources.** Any person authorized by this subpart for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission[51] and reference use:

(a) Sealed sources manufactured and distributed by a person specifically licensed pursuant to C.5.5(l) of these Regulations or equivalent provisions of the U.S. Nuclear Regulatory Commission or another Agreement State and that do not exceed 1.11 GBq (30 mCi) each;

(b) Any radioactive material with a half-life of one hundred twenty (120) days or less in individual amounts not to exceed 555 MBq (15 mCi);

(c) Any radioactive material with a half life greater than one hundred twenty (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 A of these Regulations;

(d) Technetium-99m in amounts as needed.

C.8.18 **Requirements for Possession of Sealed Sources and Brachytherapy Sources.**

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall assure that:

(1) The source is tested for leakage in accordance with A.3.1; and

(2) The source is tested for leakage at intervals not to exceed six (6) months or at intervals approved by the Agency, another Agreement State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

[51] This general license is not applicable to any transmission source whose Sealed Source & Device Registry Sheet recommends distribution only to a specific licensee and/or recommends that source replacement be conducted only by source manufacturer or other specifically authorized licensed person.

C.8.18(c)

(c) If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of these Regulations; and

(2) File a written report with the Agency within 5 days of receiving the leak test results. The written report shall include, the model number and serial number if assigned, of the leaking source, the radionuclide and its estimated activity, the results of the test, the date of the test and the action taken.

(d) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory of all such sources at intervals not to exceed 6 months. The licensee shall retain each inventory record for 3 years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer or the individual who performed the inventory.

C.8.19 **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 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 the Agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in C.8.19(a) or (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 C.8.19(a) or (b).

(1) The written report shall include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) 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.

C.8.19(e)

(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 C.8.19(a) or (b), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. 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 Agency with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) 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.

C.8.20 **Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.**

(a) 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 an effective dose equivalent in excess of A.2.11 of these Regulations as a result of the deceased's body.

(b) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in C.8.19(a). has died. The written report shall include:

(1) The licensee's name;

(2) The date of death;

(3) The radionuclide, chemical and physical form and calculated activity at time of death; and,

(4) The names (or titles) and address(es) of known individuals who might have received a TEDE exceeding 5 mSv (0.5 rem).

C.8.21 **Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

C.8.22 **Labeling of Vials and Syringes.** Each syringe shield and vial shield that contains a radioactive drug shall be labeled to identify the radioactive drug unless the label on the syringe or vial is visible when shielded.

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C.8.23 **Surveys for Contamination and Ambient Radiation Dose Rate.**

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material were prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs containing radioactive material or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by C.8.23(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 C.8.23(a) and (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 at least once each week all areas where generators and radioactive drugs containing radioactive material are prepared for use or administered or radioactive materials are stored.

(f) A licensee shall conduct the surveys required by C.8.23(e) so as to be able to detect contamination on each wipe sample 33.3 Bq (2000 dpm).

(g) A licensee shall establish removable contamination action levels for the surveys required by C.8.23(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by C.8.23(a) in an area(s) where patients or human research subjects are confined when they cannot be released pursuant to C.8.24.

(i) A licensee shall retain a record of each survey for 3 years. The record shall 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.

C.8.24 **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 radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[52]

(b) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as 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 breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the consequences, if any, of failure to follow the guidance.

[52] NRC 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).

C.8.24(c)

(c) For patients administered radioactive material for which a written directive is required, the licensee shall maintain a record, for 3 years after the date of release, of the basis for authorizing the release of an individual.

(d) The licensee shall maintain a record, for 3 years after the date of release, that instructions required by C.8.24(b) were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 1 mSv (0.1 rem).

(e) The licensee shall immediately notify the Agency in accordance with C.8.26 if a patient departs prior to an authorized release.

(f) The licensee shall notify the Agency in accordance with C.8.20:

(1) When they are aware that a patient containing radioactive material and who has been released in accordance with C.8.24 dies; and

(2) If it is possible that any individual could receive an effective dose equivalent in excess of 5 mSv (0.5 rem) as a result of the deceased's body.]

C.8.25 **Survey Instruments.**

(a) Licensees authorized for radioactive material use under C.8.28, C.8.30, C.8.34, C.8.40 and/or C.8.46 shall possess an operable survey instrument that has been calibrated in accordance with C.8.15 and meets the following criteria:

<table>
<tr><th>AUTHORIZED USE</th><th>SURVEY INSTRUMENT</th></tr>
<tr><td>C.8.28 - Uptake, dilution, and excretion studies</td><td>Portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 500 μSv (50 mrems) per hour</td></tr>
<tr><td>C.8.30 - Imaging & localization studies</td><td rowspan="3">Portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 500 μSv (50 mrems) per hour; and
Portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour.</td></tr>
<tr><td>C.8.34 - Unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required</td></tr>
<tr><td>C.8.40 - Manual brachytherapy</td></tr>
<tr><td>C.8.46- Remote afterloader unit, teletherapy unit and/or gamma stereotactic radiosurgery unit</td><td>Portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour.</td></tr>
</table>

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C.8.25(b)

(b) A licensee authorized to use radioactive material as a sealed source for diagnostic purposes pursuant to C.8.38 shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 500 μSv (50 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with C.8.15.

C.8.26 **Reports of Patient Departure Prior to Authorized Release.**

(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 C.8.24(a).

(b) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

(1) The licensee's name;

(2) The date and time of the unauthorized departure;

(3) The projected date and time when release would have occurred;

(4) The address of the patient's or human research subject's home or anticipated destination following departure;

(5) The radionuclide, chemical and physical form and calculated activity at time of release;

(6) The apparent reason(s) for the departure prior to authorized release; and

(7) 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.

C.8.27 **Decay-In-Storage.**

(a) A licensee may hold radioactive material with a physical half-life of less than or equal to one hundred twenty (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 an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(2) Removes or obliterates all radiation labels, except for material that will be managed as biomedical waste after release; and

(3) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(b) For radioactive material disposed in accordance with C.8.27(a), the licensee shall retain a record of each disposal for 3 years. The record shall include the date of the disposal, the model and serial number of 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.

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C.8.28

C.8.28 **Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for Which a Written Directive is Not Required.** A licensee may use any unsealed radioactive material, in quantities that do not require a written directive pursuant to C.8.6(b), for a diagnostic use involving measurements of uptake, dilution or excretion studies that is:

(a) Obtained from:

(1) A manufacturer or preparer licensed pursuant to C.5.5(j) of these Regulations or the equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under C.5.3(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another 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 C.8.65 or C.8.66 and C.8.65(c)(1)(ii)(g); or

(3) An individual under the supervision of either as specified in C.8.8; or

(c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research .

C.8.29 **[RESERVED]**

C.8.30 **Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required**. A licensee may use, for imaging and localization studies, any unsealed radioactive material (except aerosol or gaseous forms) prepared for medical use, in quantities that do not require a written directive pursuant to C.8.6(b), that is:

(a) Obtained from:

(1) A manufacturer or preparer licensed pursuant to C.5.5(j) of these Regulations or the equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under C.5.3(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another 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 C.8.65 or C.8.66 and C.8.65(c)(1)(ii)(g); or

(3) An individual under the supervision of either as specified in C.8.8 of these Regulations; or

(c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or other Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or.

C.8.30(d)

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(e) Provided the conditions of C.8.32 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

(f) Technetium-99m pertechnetate as an aerosol for lung function studies is not subject to the restrictions in C.8.30(e).

C.8.31 **Radionuclide Contaminants.**

(a) A licensee shall not administer to humans a radioactive drug containing:

(1) More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m);

(2) More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride);

(3) More than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

(b) To demonstrate compliance with C.8.31(a), 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;

(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 for 3 years. The record shall include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

C.8.31(d)

(d) A licensee shall report immediately to the Agency each occurrence of radio-nuclide contaminant concentration exceeding the limits specified in C.8.31(a).

C.8.32 **Control and Storage of Volatiles, Aerosols and Gases.**

(a) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by A.2.3 and A.2.11 of these Regulations.

(b) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(c) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(d) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix A of Part A of these Regulations. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

C.8.32(e)

(e) A licensee shall post the time calculated in C.8.32(d) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(f) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 3 years.

(g)A copy of the calculations required in C.8.32(d) shall be recorded and retained for the duration of the license.

(h) A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.

(i) A licensee shall store and use a multidose container in a properly functioning fume hood.

C.8.33 **[RESERVED]**

C.8.34 **Use of Unsealed Radioactive Material for Which a Written Directive is Required.**

(a) A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

(1) Obtained from a manufacturer or preparer licensed pursuant to C.5.5(j) of these Regulations or the equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(2) Prepared by an Authorized Nuclear Pharmacist, a physician who is an Authorized User and who meets the requirements specified in C.8.65 or C.8.66 or an individual under the supervision of either as specified in C.8.8 of these Regulations; or

(3) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or another Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(4) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

C.8.35 **Safety Instruction.** In addition to the requirements of A.6.3 of these Regulations:

(a) A licensee shall provide radiation safety instruction for all personnel caring for patients or human research subjects that have received therapy with a radioactive drug and cannot be released in accordance with C.8.24. The training must be provided initially and at intervals not to exceed twelve (12) months.

(b) To satisfy C.8.35(a), the instruction shall be appropriate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including:

(i) Routine visitation to hospitalized individuals in accordance with A.2.11(a)(1); and

(ii) Visitation authorized in accordance with A.2.11(f);

(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's or human research subject has a medical emergency or dies.

C.8.35(c)

(c) A licensee shall keep a record of individuals receiving instruction required by C.8.35(a) for 3 years. The record shall include a list of the topic(s) covered, the date of instruction or training the name(s) of the attendees, and the name(s) of the individual(s) who provided the instruction.

C.8.36 **Safety Precautions.**

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with C.8.24, a licensee shall:

(1) Quarter the patient or human research subject either in:

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who also cannot be released in accordance with C.8.24;

(2) Visibly post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

(3) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of A.2.3 and A.2.11 of these Regulations and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (microsieverts) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(4) 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 an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(5) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters;

(b) The Radiation Safety Officer, or his or her designee, and an Authorized User shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Agency in accordance with C.8.20 if it is possible that any individual could receive an effective dose equivalent in excess of A.2.11 of these Regulations as a result of the deceased's body.

C.8.37 **[RESERVED]**

C.8.38 **Use of Sealed Sources for Diagnosis.** A licensee shall use only sealed sources for diagnostic medical use as approved in the Sealed Source and Device Registry, and in accordance with the manufacturer's radiation safety instructions.

C.8.39 **[RESERVED]**

C.8.40 **Use of Sources for Manual Brachytherapy.** A licensee shall use only brachytherapy sources for therapeutic medical uses:

C.8.40(a)

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of C.8.12(a) are met.

C.8.41 **Safety Instruction.** In addition to the requirements of A.6.3 of these Regulations:

(a) A licensee shall provide radiation safety instruction, initially and at intervals not to exceed twelve (12) months, for all personnel caring for patients or human research subjects who are undergoing implant therapy and cannot be released in accordance with C.8.24 of these Regulations.

(b) To satisfy C.8.41(a), the instruction shall 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) Procedures for patient or human research subject control;

(4) Procedures for visitor control, including both:

(i) Routine visitation to hospitalized individuals in accordance with A.2.11(a)(1); and

(ii) Visitation authorized in accordance with A.2.11(f);

(5) Notification of the Radiation Safety Officer and an Authorized User if the patient or human research subject dies or has a medical emergency. The licensee shall also notify the Agency in accordance with C.8.20 if it is possible that any individual could receive an effective dose equivalent in excess of 5 mSv (500 mrem) as a result of the deceased's body.

(c) A licensee shall maintain a record of individuals receiving instruction required by C.8.41(a) for 3 years. The record shall include a list of the topic(s) covered, the date of instruction or training, the name(s) of the attendees, and the name(s) of the individual(s) who provided the instruction.

C.8.42 **Safety Precautions and Required Surveys for Patients or Human Research Subjects Receiving Brachytherapy.**

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released in accordance with C.8.24, a licensee shall:

(1) Quarter the patient or human research subject either in:

(i) A private room; or

(ii) A room with another individual who is also receiving brachytherapy and who also can not be released in accordance with C.8.24;

(2) Visibly post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an Authorized User immediately if the patient or human research subject dies or has a medical emergency.

(c) A licensee shall have applicable emergency response equipment readily available near each treatment room to respond to a source that inadvertently becomes:

(1) Dislodged from the patient; or

C.8.42(c)(2)

(2) Lodged within the patient following removal of the source applicators.

(d) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

(e) 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.

(f) A licensee shall retain a record of the surveys required by C.8.42(d) and (e) for 3 years. Each record shall include the date and results of the survey, the serial number and the model number of the survey instrument used, and the name of the individual who made the survey.

C.8.43 **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 as follows:

(1) For temporary implants, the record shall include:

(i) 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;

(ii) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage; and

(iii) The number and activity of sources temporarily implanted in the patient or human research subject.

(2) For permanent implants, the record shall include:

(i) 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;

(ii) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(iii) The number and activity of sources permanently implanted in the patient or human research subject.

(d) A licensee shall maintain the records required in C.8.43(c) for three (3) years.

C.8.44 **Calibration Measurements of Brachytherapy Sealed Sources.**

(a) Prior to the first medical use of a brachytherapy sealed source, a licensee shall perform the following:

(1) Determine the source output or activity using a dosimetry system that meets the requirements of C.8.54(a);

(2) Determine source positioning accuracy within applicators; and

(3) Use published protocols accepted by nationally recognized bodies to meet the requirements of C.8.44(a)(1) and (a)(2).

C.8.44(b)(1)

(b) (1) For surface applicators, 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 C.8.44(a);

(2) For permanently implanted sources, the licensee may establish a quality assurance program, consistent with recommendations of nationally recognized bodies, to validate the activity of implanted sources.

(c) A licensee shall mathematically correct the outputs or activities determined in C.8.44(a) for physical decay at intervals consistent with one percent (1%) physical decay.

(d) An Authorized Medical Physicist shall perform or review the calculation measurements made pursuant to C.8.44(a), (b)(1), (b)(2) or (c).

(e) Only an Authorized Medical Physicist shall calculate the output or activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the output or activity determined in accordance with C.8.44(a), (b)(1) and (c).

(f) A licensee shall retain a record of each calibration of brachytherapy sources required by C.8.44(a) for 3 years after the last use of the source. The record shall 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) Source positioning accuracy within applicators;

(5) The signature of the Authorized Medical Physicist; and

(6) For surface applicators where the calibration was performed by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists, a complete copy of all calibration measurements provided for that source.

(g) A licensee shall retain a record of decay calculations required by C.8.44(e) for 3 years after the last use of the source. The record shall include:

(1) The date and initial source output or activity as determined under C.8.44(a), (b) and (c);

(2) For each decay calculation, the date and the source output or activity as determined under C.8.44(e); and

(3) The signature of the Authorized Medical Physicist.

C.8.45 **[RESERVED]**

C.8.46 **Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radio-surgery Unit**. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of C.8.12(a) of these Regulations are met.

C.8.47

C.8.47 **Installation, Maintenance, Adjustment and Repair.**

(a) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform such services shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on 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 U.S. Nuclear Regulatory Commission or another Agreement State to perform such services shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services, 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 for three (3) years. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

C.8.48 **[RESERVED]**

C.8.49 **Safety Procedures, Instructions and Survey Protocols 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 simultaneous operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure shall include:

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the Authorized Users, the Authorized Medical Physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by C.8.49(a)(4) shall be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

C.8.49(c)(1)

(1) The location of the procedures required by C.8.49(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 intervals not to exceed twelve (12) months, to all individuals who the unit, as appropriate to the individual's assigned duties, in:

(1) The procedures identified in C.8.49(a)(4); and

(2) The operating procedures for the unit.

(e) The licensee shall ensure that operators, Authorized Medical Physicists, and Authorized Users participate in drills of the emergency procedures, initially and at intervals not to exceed twelve (12) months.

(f) A licensee shall maintain a record of individuals receiving instruction required by C.8.49(d) for 3 years. The record shall include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(g) A licensee shall retain a copy of the procedures required by C.8.49(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

(h) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(i) A licensee shall retain a record of the surveys required by C.8.49(h) for 3 years. Each record shall include the date and results of the survey, the serial number and the model number of the survey instrument used, and the name of the individual who made the survey.

C.8.50 **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 shall:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded promptly when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and irradiation is reinitiated by manual action at the control panel.

(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 C.8.50(a) through (e), a licensee shall:

C.8.50(f)(1)

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(i) An Authorized Medical Physicist and either an Authorized User or a physician, under the supervision of an Authorized User, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An Authorized Medical Physicist and either an Authorized User or an individual, under the supervision of an Authorized User, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require:

(i) An Authorized User and an Authorized Medical Physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An Authorized Medical Physicist and either an Authorized User or a physician, under the supervision of an Authorized User, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an Authorized User and an Authorized Medical Physicist to be physically present throughout all patient treatments involving the unit.

(4) For teletherapy units, require:

(i) Each entrance to the teletherapy room to be equipped with a beam condition indicator light;

(ii) The beam control mechanism to be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure;

(iii) The closing device to be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and stay in the "off" position until activated from the control panel;

(iv) A warning device at the housing and at the control panel that plainly indicates whether the beam is "on" or "off";

(v) The equipment be provided with a locking device to prevent unauthorized use; and

(vi) The control panel be provided with a timer that automatically terminates the exposure after a pre-set time. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated.

(5) Notify the Radiation Safety Officer, or his or her designee, and an Authorized User as soon as possible, if the patient or human research subject has a medical emergency and, immediately if the patient or human research subject dies during treatment.

(g) A licensee shall have applicable emergency response equipment readily 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.

C.8.51

C.8.51 **[RESERVED]**

C.8.52 **Full Calibration Measurements on Remote Afterloader Units.**

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of C.8.52(a), full calibration measurements shall 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 C.8.54(a) to measure the output.

(d) A licensee shall make full calibration measurements required by C.8.52(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 C.8.52(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 C.8.52(a) through (e).

(g) A licensee shall mathematically correct the outputs determined in C.8.52(b)(1) for physical decay at intervals consistent with one percent (1%) physical decay.

(h) Full calibration measurements required by C.8.52(a) and physical decay corrections required by C.8.52(g) shall be performed by or under the direct supervision of an Authorized Medical Physicist.

(i) A licensee shall retain a record of each calibration for 3 years. The record shall include:

(1) The date of the calibration;

C.8.52(i)(2)

(2) The manufacturer's name, model number, and serial number for both the remote afterloader unit and the source(s), and the model number and serial number of the instrument used to calibrate the unit;

(3) The results and assessments 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 reviewed or performed the full calibration.

C.8.53 **Full Calibration Measurements on Gamma Stereotactic Radiosurgery Unit.**

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of C.8.53(a), full calibration measurements shall 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 microswitchs;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in C.8.54(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in C.8.53(b)(1) may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by C.8.53(a) in accordance with

published protocols accepted by nationally recognized bodies.

C.8.53(e)

(e) A licensee shall mathematically correct the outputs determined in C.8.53(b)(1) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent (1%) physical decay for all other radionuclides.

(f) Full calibration measurements required by C.8.53(a) and physical decay corrections required by C.8.53(e) shall be performed by or under the direct supervision of an Authorized Medical Physicist.

(g) A licensee shall retain a record of each calibration for 3 years. The record shall include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for both the gamma stereotactic radiosurgery unit and the sources, and the model number and serial number of the instrument used to calibrate the unit;

(3) The results and assessments of the full calibrations; and

(4) The signature of the Authorized Medical Physicist who reviewed or performed the full calibration.

C.8.54 **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 shall 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 shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system shall have been calibrated within the previous 4 years. Eighteen to thirty (18 to 30) months after that calibration, the system shall 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. This intercomparison shall be performed by or under the direct supervision of an Authorized Medical Physicist. The results of the intercomparison shall have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall 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 meet this requirement, the system may be compared with a system that has been calibrated in accordance with C.8.54(a). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in C.8.54(a).

(c) The licensee shall maintain a record of each calibration, intercomparison, and comparison of its dosimetry equipment for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

(1) The date;

C.8.54(c)(2)

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared or compared as required by C.8.54(a) and (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, and evidence that the intercomparison was performed by or under the direct supervision of an Authorized Medical Physicist.

C.8.55 **Full Calibration Measurements on Teletherapy Units.**

(a) Any 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;

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; and

(iii) Following any repair of the teletherapy unit that includes removal of the radiation source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of C.8.55(a), full calibration measurements shall include determination of:

(1) The radiation 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 constancy 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 C.8.54 to measure the output for one set of exposure conditions. The remaining radiation measurements required in C.8.55(b)(1) may then be made using a dosimetry system that indicates relative output.

(d) A licensee shall make full calibration measurements required by C.8.55(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall correct mathematically the outputs determined in C.8.55(b)(1) for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent (1%) decay for all other nuclides.

(f) Full calibration measurements required by C.8.55(a) and physical decay corrections required by C.8.55(e) shall be performed by or under the direct supervision of an Authorized Medical Physicist.

C.8.55(g)

(g) A licensee shall maintain a record of each calibration for 3 years. The record shall include:

(1) The date of the calibration;

(2) The manufacturer's name, model number and serial number for both the teletherapy unit and the source, and the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit;

(3) The results and assessments of the full calibrations; and

(4) The signature of the Authorized Medical Physicist who reviewed or performed the full calibration.

C.8.56 **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 at intervals not to exceed 1 month.

(b) To satisfy the requirement of C.8.56(a), spot-checks shall 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; and

(6) The difference between the measurement made in C.8.56(b)(5) and the anticipated radiation output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay.

(c) A licensee shall use the dosimetry system described in C.8.54 to make the spot-check required in C.8.56(b)(5).

(d) A licensee shall perform spot-checks required by C.8.56(a) in accordance with written procedures established by the Authorized Medical Physicist. The Authorized Medical Physicist does not need to actually perform the spot-check measurements.

(e) A licensee shall have the Authorized Medical Physicist review the results of each spot-check within 15 days. The Authorized Medical Physicist shall promptly notify the licensee in writing of the results of each spot-check.

(f) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility at intervals not to exceed 1 month and after each source installation.

(g) To satisfy the requirement of C.8.56(f), safety spot-checks shall 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

C.8.56(g)(6)

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(h) If the results of the checks required by C.8.56(g) 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. A licensee shall promptly repair any system identified in C.8.56(g) that is not operating properly.

(i) A licensee shall maintain a record of each spot-check required by C.8.56(a) and (f), and a copy of the procedures required by C.8.56(d), for 3 years. The record shall include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the teletherapy unit, source and the instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer constancy and linearity;

(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 or 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 signature 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.8.57 **Radiation Surveys.**

(a) In addition to the survey requirement in A.3.2 of these Regulations, a licensee authorized to use radioactive material in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit shall conduct surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by C.8.57(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(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall maintain a record of the surveys required by C.8.57(a) and (b) for the duration of the license. The record shall include:

(1) The date of the measurements;,

(2) The manufacturer's name, model number and serial number of the treatment unit, the source, and the instrument used to measure radiation levels;

(3) Each dose rate measured around the source while in the "off" position and the average of all measurements, and

(4) The signature of the Authorized Medical Physicist who reviewed or performed the survey.

C.8.58 **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) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

(2) Prior to each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) The licensee shall have the Authorized Medical Physicist establish written procedures for performing the spot-checks required in C.8.58(a). The Authorized Medical Physicist need not actually perform the spot-check measurements.

(c) A licensee shall have the Authorized Medical Physicist review the results of each 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 C.8.58(a), spot-checks shall, 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 C.8.58(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 C.8.58(d), and a copy of the procedures required by C.8.58(b), for 3 years. The record shall 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 signature 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.8.59 **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) At the beginning of each day of use; and

(3) After each source installation.

(b) The licensee shall have the Authorized Medical Physicist:

(1) Establish written procedures for performing the spot-checks required in C.8.59(a). The Authorized Medical Physicist need not actually perform the spot-check measurements; and

(2) Review the results of each spot-check required by C.8.59(a)(1) within 15 days. The Authorized Medical Physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of C.8.59(a)(1), spot-checks shall, at a minimum:

(1) Assure proper operation of:

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine :

(i) The output for one typical set of operating conditions measured with the dosimetry system described in C.8.54(b);

(ii) The difference between the measurement made in C.8.59(c)(2)(i) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of C.8.59(a)(2) and (a)(3), spot-checks shall 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

C.8.59(d)(6)

(6) Emergency off buttons.

(e) A licensee shall arrange for prompt repair of any system identified in C.8.59(c) that is not operating properly.

(f) If the results of the checks required in C.8.59(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 C.8.59(c) and (d), and a copy of the procedures required by C.8.59(b), for 3 years. The record shall 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 signature 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.8.60 **Additional Technical Requirements for Mobile Remote Afterloader Units.**

(a) A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by C.8.58, 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 shall be made to verify the operation of :

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

C.8.60(b)(7)

(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 C.8.60(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 C.8.60(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 C.8.60(b) for 3 years. The record shall 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 and source transfer tubes, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

C.8.61 **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 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.
C.8.61(b)

(b) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Agency, another Agreement State, or the U.S. Nuclear Regulatory Commission.

(c) A licensee shall maintain a record of the inspection and servicing for the duration of use of the unit. The record shall contain:

(1) The inspector's name;

(2) The inspector's radioactive materials license number;

(3) The date of inspection;

(4) The manufacturer's name and model number and serial number for both the treatment unit and source;

(5) A list of components inspected and serviced, and the type of service; and

(6) The signature of the inspector.

C.8.62 **Training for Radiation Safety Officer.** Except as provided in C.8.63, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in C.8.4 to be an individual who:

C.8.62(a)

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[53], and who meets the requirements in C.8.62(d) and (e). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) (i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have five (5) or more years of professional experience in health physics (graduate training may be substituted for no more than two (2) years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2) (i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have two (2) years of full-time practical training and/or supervised experience in medical physics:

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for Authorized Users in C.8.65 C.8.66 or C.8.72;

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety;

OR

(b) (1) Has completed a structured educational program consisting of both:

(i) Two hundred (200) hours of didactic 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; and

(e) Radiation dosimetry; and

[53] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.62(b)(1)(ii)

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, an Agreement State or U.S. Nuclear Regulatory Commission license 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;

OR

(2) [**RESERVED**]

(c) (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency under C.8.71(a) [or the equivalent requirement of an Agreement State or the U.S. Nuclear Regulatory Commission] and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in C.8.62(d) and (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) (1) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements[54] in C.8.62(e);

AND

(2) C.8.62 (a)(1)(i) and (a)(1)(ii);

OR

(3) C.8.62(a)(2)(i) and (a)(2)(ii);

OR

(4) C.8.62(b)(1);

OR

(5) C.8.62(c)(1);

OR

[54] Or the equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission.

C.8.62(d)(6)

(6) C.8.62(c)(2);

AND

(7) 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 types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, Authorized Medical Physicist, Authorized Nuclear Pharmacist, or Authorized User, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval

C.8.63 **Training for Experienced Radiation Safety Officer.** An individual identified as a Radiation Safety Officer on an Agency, Agreement State or U.S. Nuclear Regulatory Commission license on 27 September 2004 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of C.8.62 of these Regulations. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

C.8.64 **Training for Uptake, Dilution and Excretion Studies.** Except as provided in C.8.72, the licensee shall require the Authorized User of an unsealed radioactive material for the uses authorized under C.8.28 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[55] and who meets the requirements in C.8.64(c)(2). 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 C.8.64(c)(1)(i) and (c)(1)(ii); 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 C.8.65 or C.8.66 [or the equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission];

OR

(c) (1) Has completed sixty (60) hours of training and experience, including a minimum of eight (8) hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include:

(i) Classroom and laboratory training in the following areas:

[55] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.64(e)(1)(i)(a))

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology;

AND

(ii) Work experience, under the supervision of an Authorized User who meets the requirements in C.8.64, C.8.65, C.8.66 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(f) 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 C.8.64, C.8.65, C.8.66 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] that the individual has satisfactorily completed the requirements in C.8.64(a)(1) or (c)(1) and has achieved a level of competency sufficient to function independently as an Authorized User for the medical uses authorized under C.8.28.

C.8.65 **Training for Imaging and Localization Studies.** Except as provided in C.8.72, the licensee shall require an Authorized User of unsealed radioactive material for the uses authorized under C.8.30 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[56] and who meets the requirements in C.8.65(c)(2). 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 C.8.65(c)(1)(i) and (c)(1)(ii); and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses

[56] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

knowledge and competence in radiation safety, radionuclide handling, and quality control;

C.8.65(b)

OR

(b) Is an Authorized User under C.8.66 and meets the requirements in C.8.65(c)(1)(ii)(f) [or the equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission];

OR

(c) (1) Has completed seven hundred (700) hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use;

(e) Radiation biology;

AND

(ii) Work experience, under the supervision of an Authorized User who meets the requirements in C.8.65, or C.8.66 and C.8.65(c)(1)(ii)(f) or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator[57] 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

[57] Generator-related training requirements are not applicable to facilities which do not routinely utilize generators to obtain radioactive material for imaging and localization studies.

C.8.65(c)(2)

(2) Has obtained written attestation, signed by a preceptor Authorized User who meets the requirements in C.8.65, or C.8.66 and C.8.65(c)(1)(ii)(f) or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] that the individual has satisfactorily completed the requirements in C.8.65 (a)(1) or C.8.65(c)(1) and has achieved a level of competency sufficient to function independently as an Authorized User for the medical uses authorized under C.8.28 and C.8.30.

C.8.66 **Training for Unsealed Radioactive Material for Which a Written Directive is Required.** Except as provided in C.8.72, the licensee shall require an Authorized User of unsealed radioactive material for the uses authorized under C.8.34 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[58] and who meets the requirements in C.8.66(b)(1)(ii)(f) and C.8.66(b)(2). 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 shall include seven hundred (700) hours of training and experience as described in C.8.66(b)(1)(i) through (b)(1)(ii)(e). Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required;

OR

(b) (1) Has completed seven hundred (700) hours of training and experience, including a minimum of two hundred (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 shall include:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology;

AND

[58] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.66(b)(1)(ii)

(ii) Work experience, under the supervision of an Authorized User who meets the requirements in C.8.66 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission]. A supervising Authorized User, who meets the requirements in C.8.66(b) shall also have experience in administering dosages in the same dosage category or categories (i.e., C.8.66(b)(1)(ii)(f)) as the individual requesting Authorized User status. The work experience shall involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(f) 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:

(1) 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;

(2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131[59]

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(4) Parenteral administration of any other radionuclide, for which a written directive is required;

AND

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.66(a)(1) and (b)(1)(ii)(f) or C.8.66(b)(1) [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission], and has achieved a level of competency sufficient to function independently as an Authorized User for the medical uses authorized under C.8.66. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission. The preceptor Authorized User, who meets the requirements in C.8.66(b) shall have experience in administering dosages in the same dosage category or categories (i.e., C.8.66(b)(1)(ii)(f)) as the individual requesting Authorized User status.

C.8.67 **Training for Use of Manual Brachytherapy Sources.** Except as provided in C.8.72, the licensee shall require the Authorized User of a manual brachytherapy source for the uses authorized under C.8.40 to be

[59] Experience with at least 3 cases in Category (f)(2) also satisfies the requirement in Category (f)(1).

a physician who:

C.8.67(a)

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[60] and who meets the requirements in C.8.67(b)(3). To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three (3) years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy;

OR

(b) (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) Two hundred (200) hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology;

AND

(ii) Five hundred (500) hours of work experience, under the supervision of an Authorized User who meets the requirements in C.8.67 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] at a medical institution, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(f) Using emergency procedures to control radioactive material;

AND

[60] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.67(b)(2)

(2) Has completed three (3) years of supervised clinical experience in radiation oncology, under an Authorized User who meets the requirements in C.8.67 orC.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission], 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 C.8.67(b)(1)(ii);

AND

(3) Has obtained written attestation, signed by a preceptor Authorized User who meets the requirements in C.8.67 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission], that the individual has satisfactorily completed the requirements in paragraphs C.8.67(a)(1), or C.8.67(b)(1) and C.8.67(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 C.8.67.

C.8.68 **Training for Ophthalmic Use of Strontium-90.** Except as provided in C.8.72, the licensee shall require the Authorized User of strontium-90 for ophthalmic radiotherapy to be a physician who:

(a) Is an Authorized User under C.8.67 [or equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission];

OR

(b) (1) Has completed twenty-four (24) hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

AND

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an Authorized User at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five (5) individuals. This supervised clinical training shall involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history;

AND

(3) Has obtained written attestation, signed by a preceptor Authorized User who meets the requirements in C.8.67, C.8.68 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission], that the individual has satisfactorily completed the requirements in C.8.68(b)(1) and (b)(2) and has achieved a level of competency sufficient to function independently as an Authorized User of strontium-90 for ophthalmic use.

C.8.69

C.8.69 **Training for Use of Sealed Sources for Diagnosis.** Except as provided in C.8.72, the licensee shall require the Authorized User of a diagnostic sealed source for use in a device authorized under C.8.38 to be a physician, dentist, or podiatrist who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[61] and who meets the requirements in C.8.69(b) and (c).

OR

(b) Has completed eight (8) hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology; and

(3) Radiation protection.

AND

(c) Has completed training in the use of the device for the uses requested.

C.8.70 **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.** Except as provided in C.8.72, the licensee shall require an Authorized User of a sealed source for a use authorized under C.8.46 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission [62]and who meets the requirements in C.8.70(b)(3) and (c). To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three (3) years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the 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:

(i) Two hundred (200) hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

[61] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

[62] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.70(b)(1)(i)(d)

(d) Radiation biology;

AND

(ii) Five hundred (500) hours of work experience, under the supervision of an Authorized User who meets the requirements in C.8.70 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] at a medical institution, involving:

(a) Reviewing full calibration measurements and periodic spot-checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered;

AND

(2) Has completed three (3) years of supervised clinical experience in radiation therapy, under an Authorized User who meets the requirements in C.8.70 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission], 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 C.8.70(b)(1)(ii);

AND

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.70(a)(1) or C.8.70(b)(1) and C.8.70(b)(2), and C.8.70(c), 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 shall be signed by a preceptor Authorized User who meets the requirements in C.8.70 or C.8.72 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] for an Authorized User for each type of therapeutic medical unit for which the individual is requesting Authorized User status;

AND

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an Authorized User or Authorized Medical Physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

C.8.71 **Training for Authorized Medical Physicist.** Except as provided in C.8.73, the licensee shall require the Authorized Medical Physicist to be an individual who:

C.8.71(a)

(a) Is registered with the Agency, under the provisions of Subpart B.4, as a provider of Radiation Physics Services for the therapeutic modality(s) in which the individual is seeking approval as an Authorized Medical Physicist; and

AND

(b) Is certified by a specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[63] and who meets the requirements in C.8.71(c)(2) and (d). 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 (2) years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for Authorized Users in C.8.67, C.8.70 or C.8.72; 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

(c) (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an Authorized Medical Physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

AND

[63] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.71(c)(2)

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.71(d) and C.8.71(b)(1) and (2), or C.8.71(c)(1) and (d), and has achieved a level of competency sufficient to function independently as an Authorized Medical Physicist for each type of therapeutic medical unit for which the individual is requesting Authorized Medical Physicist status. The written attestation shall be signed by a preceptor Authorized Medical Physicist who meets the requirements in C.8.71 or C.8.73 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] for an Authorized Medical Physicist for each type of therapeutic medical unit for which the individual is requesting Authorized Medical Physicist status;

AND

(d) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an Authorized Medical Physicist authorized for the type(s) of use for which the individual is seeking authorization.

C.8.72 **Training for Experienced Authorized Users.** Physicians, dentists, or podiatrists identified as Authorized Users for the medical, dental or podiatric use of radioactive material on an Agency, Nuclear Regulatory Commission or another Agreement State license or on a permit issued by an Agency Nuclear Regulatory Commission or another Agreement State broad scope licensee that authorizes medical use, before 27 September 2004, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of C.8.64, C.8.65, C.8.66, C.8.67, C.8.68, C.8.69 and C.8.70. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

C.8.73 **Training for Experienced Medical Physicists.**

(a) An individual identified as a teletherapy physicist, medical physicist or Authorized Medical Physicist on an Agency, another Agreement State or Nuclear Regulatory Commission license or on a permit issued by an Agency, Nuclear Regulatory Commission or another Agreement State broad scope licensee that authorizes medical use, before 24 October 2004, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of C.8.71 of these Regulations. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized

(b) An individual who does not qualify as an Experienced Medical Physicist pursuant to C.8.73(a), but has, prior to 24 October 2004, registered with the Agency, under the provisions of Subpart B.4, as a provider of Radiation Physics Services for the therapeutic modality(s) in which the individual is seeking approval as an Authorized Medical Physicist need not comply with the training requirements of C.8.71 of these Regulations. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

C.8.74 **Recentness of Training.** The training and experience specified in this Subpart shall have been obtained within the seven (7) years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

C.8.75

C.8.75 **Radiation Safety Program Changes.**

(a) A licensee may make minor changes[64] in radiation safety procedures without prior Agency approval if:

(1) The revision does not require an amendment under C.8.2;

(2) The revision is in compliance with these Regulations and the license;

(3) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change for five (5) years. The record shall include the effective date of the change, a copy of the old and new procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change and the signature of the licensee management representative that reviewed and approved the change.

(c) A copy of the record required by C.8.75(b) of these Regulations shall be submitted to the Agency within thirty (30) days of adopting said change(s).

C.8.76 **Training for an Authorized Nuclear Pharmacist**. Except as provided in C.8.77, the licensee shall require the Authorized Nuclear Pharmacist to be a pharmacist who:

(a) Possesses a current license as a pharmacist in accordance with the Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19-PHAR] of the Rhode Island Department of Health;

AND

(b) Be certified by a specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[65] and who meets the requirements in C.8.76(c)(2). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least four thousand (4,000) hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than two thousand (2,000) hours of the required training and experience; and

[64] Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC or Agency Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys.

[65] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.76(b)(4)

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development;

OR

(c) (1) Has completed seven hundred (700) hours in a structured educational program consisting of both:

(i) Two hundred (200) hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology;

AND

(ii) Supervised experience in a nuclear pharmacy 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, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to prevent the misadministration of radioactive material;

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

AND

(2) Has obtained written attestation, signed by a preceptor Authorized Nuclear Pharmacist, that the individual has satisfactorily completed the requirements in C.8.76(b)(1), C.8.76(b)(2), and C.8.76(b)(3) or C.8.76(c)(1), and that the individual has achieved a level of competency sufficient to function independently as an Authorized Nuclear Pharmacist.

C.8.77 **Training for Experienced Nuclear Pharmacists.** A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an Authorized Nuclear Pharmacist before it allows this individual to work as an Authorized Nuclear Pharmacist. An individual identified as a nuclear pharmacist on an Agency, Agreement State or U.S. Nuclear Regulatory Commission license or on a permit issued by an Agency, Nuclear Regulatory Commission or another Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, before 27 September 2004 need not comply with the training requirements of C.8.76(b) or (c). Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

C.8.78

C.8.78 **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 shall 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 radioactive source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

C.8.79 **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 elsewhere in this Subpart if:

(a) The applicant or licensee has submitted:

(1) Information regarding any radiation safety aspects of the medical use of the material that is not addressed elsewhere in this Subpart; and

(2) Specific information on:

(i) Radiation safety precautions and instructions;

(ii) Training and experience of proposed users;

(iii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iv) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(3) Any other information requested by the Agency in its review of the application; 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.8.80 **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 C.8.72, 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 includes all of the requirements in C.8.80(c)(1) and (c)(2), and whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[66], and who meets the requirements in C.8.80(c)(3);

OR

[66] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.80(b)

(b) Is an Authorized User under C.8.66(a), C.8.66(b) for uses listed in C.8.66(b)(1)(ii)(f)(1) or (2), or C.8.81 [or equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission];

OR

(c) (1) Has successfully completed eighty (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 shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology;

AND

(2) Has work experience, under the supervision of an Authorized user who meets the requirements in C.8.66 (a), C.8.66(b), C.8.72, C.8.80 or C.8.81 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission]. A supervising Authorized User who meets the requirements in C.8.66(b) shall also have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(1) or (2). The work experience shall involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

AND

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.80(c)(1) and (c)(2), and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized under C.8.34. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66, C.8.72, C.8.80, or C.8.81 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission]. A preceptor Authorized User, who meets the requirement in C.8.66(b), shall also have experience in administering dosages as specified in C.8.66 (b)(1)(ii)(f)(1) or (2).

C.8.81

C.8.81 **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 C.8.72, 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 includes all of the requirements in C.8.81(c)(1) and (c)(2), and whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission[67], and who meets the requirements in C.8.81(c)(3);

OR

(b) Is an Authorized User under C.8.66(a), C.8.66(b) for uses listed in C.8.66(b)(1)(ii)(f)(2), or C.8.81 [or equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission];

OR

(c) (1) Has successfully completed eighty (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 shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology;

AND

(2) Has work experience, under the supervision of an Authorized User who meets the requirements in C.8.66(a), C.8.66(b), C.8.72 or C.8.81 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission]. A supervising Authorized User, who meets the requirements in C.8.66(b), shall also have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(2). The work experience shall involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of Radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

[67] The names of board certifications which have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC Web page.

C.8.81(c)(3)

AND

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in C.8.81(c)(1) and (c)(2), and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized under C.8.34. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66, C.8.72 or C.8.81 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission]. A preceptor Authorized User, who meets the requirements in C.8.66(b), shall also have experience in administering dosages as specified in C.8.66(b)(1) (ii)(f)(2).

C.8.82 **Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.** Except as provided in C.8.72, 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 C.8.66 for uses listed in C.8.66(b)(1)(ii)(f)(3) or (f)(4) [or equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission];

OR

(b) Is an Authorized User under C.8.67 or C.8.70 [or equivalent requirements of an Agreement State or the U.S. Nuclear Regulatory Commission], and who meets the requirements in C.8.82(d);

OR

(c) Is certified by a medical specialty board whose certification process has been recognized by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission under C.8.67 or C.8.70, and who meets the requirements in C.8.82(d);

OR

(d) (1) Has successfully completed eighty (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 shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology;

AND

(2) Has work experience, under the supervision of an Authorized User who meets the requirements in C.8.66, C.8.72 or C.8.82 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission] 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 C.8.66 shall have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(3) and/or (f)(4). The work experience shall involve:

C.8.82(d)(2)(i)

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 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 (3) 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 C.8.82(b) or (c), and has achieved a level of competency sufficient to function independently as an Authorized User for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation shall be signed by a preceptor Authorized User who meets the requirements in C.8.66, C.8.72 or C.8.82 [or equivalent requirements of another Agreement State or the U.S. Nuclear Regulatory Commission]. A preceptor Authorized User, who meets the requirements in C.8.66 shall have experience in administering dosages as specified in C.8.66(b)(1)(ii)(f)(3) and/or (f)(4).

C.8.83 through C.8.92 **[Removed and Reserved]**

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PART C

APPENDIX A

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml[1]	Column II Liquid and solid µCi/ml[2]
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1x10^{-3}$
Argon (18)	Ar-37	$1x10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1x10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1x10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1x10^{-3}$

[1] Values are given in Column I only for those materials normally used as gases.

[2] µCi/gm for solids.

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml[1]	Column II Liquid and solid µCi/ml[2]
Cobalt (27)	Co-60		$5X10^{-4}$
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165		$4X10^{-3}$
Dysprosium (66)	Dy-166		4X10-4
Erbium (68)	Er-169		9X10-4
	Er-171		1x10-3
Europium (63)	Eu-152		$6X10^{-4}$
	($T_{1/2}$=9.2 h)		
	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		$2X10^{-4}$

[1] Values are given in Column I only for those materials normally used as gases.

[2] µCi/gm for solids.

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml[1]	Column II Liquid and solid µCi/ml[2]
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		$3X10^{-3}$
Mercury (80)	Hg-203		$2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147		$6X10^{-4}$
Neodymium (60)	Nd-149		$3X10^{-3}$
Nickel (28)	Ni-65		$1x10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1x10^{-3}$
	Nb-97		$9X10^{-3}$
Osmium (76)	Os-185		$7X10^{-4}$
	Os-191m		$3X10^{-2}$
	Os-191		$2X10^{-3}$
	Os-193		$6X10^{-4}$
Palladium (46)	Pd-103		$3X10^{-3}$
	Pd-109		$9X10^{-4}$
Phosphorus (15)	P-32		$2X10^{-4}$
Platinum (78)	Pt-191		$1x10^{-3}$
	Pt-193m		$1x10^{-2}$
	Pt-197m		$1x10^{-2}$
	Pt-197		$1x10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142		$3X10^{-4}$
	Pr-143		$5X10^{-4}$
Promethium (61)	Pm-147		$2X10^{-3}$
	Pm-149		$4X10^{-4}$
Rhenium (75)	Re-183		$6X10^{-3}$
	Re-186		$9X10^{-4}$
	Re-188		$6X10^{-4}$
Rhodium (45)	Rh-103m		$1x10^{-1}$

[1] Values are given in Column I only for those materials normally used as gases.

[2] µCi/gm for solids.

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml[1]	Column II Liquid and solid µCi/ml[2]
Rhodium (45)	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		$1x10^{-3}$
Strontium (38)	Sr-89		$1x10^{-4}$
	Sr-91		$7X10^{-4}$
	Sr-92		$7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$
Technetium (43)	Tc-96m		$1x10^{-1}$
	Tc-96		$1x10^{-3}$
Tellurium (52)	Te-125m		$2X10^{-3}$
	Te-127m		$6X10^{-4}$
	Te-127		$3X10^{-3}$
	Te-129m		$3X10^{-4}$
	Te-131m		$6X10^{-4}$
	Te-132		$3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$
Thallium (81)	Tl-200		$4X10^{-3}$
	Tl-201		$3X10^{-3}$
	Tl-202		$1x10^{-3}$

[1] Values are given in Column I only for those materials normally used as gases.

[2] µCi/gm for solids.

APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml[1]	Column II Liquid and solid µCi/ml[2]
Thallium (81)	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 radio-active material not listed above with half-lives less than 3 years.		$1x10^{-10}$	$1x10^{-6}$

[1] Values are given in Column I only for those materials normally used as gases.

[2] µCi/gm for solids.

NOTES:

1. Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Appendix A, the activity stated is that of the parent isotope and takes into account the daughters.
2. For purposes of Section C.2.2 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Appendix A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

NOTES [cont.]:

EXAMPLE: $\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$

3. To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

   EXAMPLE: Zirconium-97 (2×10^{-4} μCi/ml multiplied by 37 is equivalent to 74×10^{-4} MBq/l).

PART C

APPENDIX B

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb-122)	100
Antimony-124 (Sb-124)	10
Antimony-125 (Sb-125)	10
Arsenic-73 (As-73)	100
Arsenic-74 (As-74)	10
Arsenic-76 (As-76)	10
Arsenic-77 (As-77)	100
Barium-131 (Ba-131)	10
Barium-133 (Ba-133)	10
Barium-140 (Ba-140)	10
Bismuth-207 (Bi-207)	0.1
Bismuth-210 (Bi-210)	1
Bromine-82 (Br-82)	10
Cadmium-109 (Cd-109)	10
Cadmium-115m (Cd-115m)	10
Cadmium-115 (Cd-115)	100
Calcium-45 (Ca-45)	10
Calcium-47 (Ca-47)	10
Carbon-11 (C-11)	0.1
Carbon-14 (C-14)	100
Cerium-139 (Ce-139)	0.1
Cerium-141 (Ce-141)	100
Cerium-143 (Ce-143)	100
Cerium-144 (Ce-144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs-131)	1,000
Cesium-134m (Cs-134m)	100
Cesium-134 (Cs-134)	1
Cesium-135 (Cs-135)	10
Cesium-136 (Cs-136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-56 (Co-56)	0.1

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152m (Eu-152m) [$T_{1/2}$=9.2h]	100
Europium-152 (Eu-152) [$T_{1/2}$=13 yr]	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Fluorine-18 (F-18)	1,000
Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au-195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Iodine-135 (I-135)	10
Iridium-192 (Ir-192)	10
Iridium-194 (Ir-194)	100
Iron-52 (Fe-52)	10
Iron-55 (Fe-55)	100
Iron-59 (Fe-59)	10
Krypton-85 (Kr-85)	100
Krypton-87 (Kr-87)	10
Lanthanum-140 (La-140)	10
Lutetium-177 (Lu-177)	100
Manganese-52 (Mn-52)	10
Manganese-54 (Mn-54)	10
Manganese-56 (Mn-56)	10
Mercury-197m (Hg-197m)	100
Mercury-197 (Hg-197)	100
Mercury-203 (Hg-203)	10
Molybdenum-99 (Mo-99)	100
Neodymium-147 (Nd-147)	100
Neodymium-149 (Nd-149)	100
Nickel-59 (Ni-59)	100
Nickel-63 (Ni-63)	10
Nickel-65 (Ni-65)	100
Niobium-93m (Nb-93m)	10
Niobium-95 (Nb-95)	10
Niobium-97 (Nb-97)	10
Nitrogen-13 (N-13)	0.1
Osmium-185 (Os-185)	10
Osmium-191m (Os-191m)	100
Osmium-191 (Os-191)	100
Osmium-193 (Os-193)	100
Oxygen-15 (O-15)	0.1
Palladium-103 (Pd-103)	100
Palladium-109 (Pd-109)	100
Phosphorus-32 (P-32)	10
Platinum-191 (Pt-191)	100
Platinum-193m (Pt-193m)	100
Platinum-193 (Pt-193)	100
Platinum-197m (Pt-197m)	100
Platium-197 (Pt-197)	100

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Polonium-210 (Po-210)	0.1
Potassium-42 (K-42)	10
Potassium-43 (K-43)	10
Praseodymium-142 (Pr-142)	100
Praseodymium-143 (Pr-143)	100
Promethium-147 (Pm-147)	10
Promethium-149 (Pm-149)	10
Rhenium-186 (Re-186)	100
Rhenium-188 (Re-188)	100
Rhodium-103m (Rh-103m)	100
Rhodium-105 (Rh-105)	100
Rubibium-81 (Rb-81)	10
Rubidium-86 (Rb-86)	10
Rubidium-87 (Rb-87)	10
Ruthenium-97 (Ru-97)	100
Ruthenium-103 (Ru-103)	10
Ruthenium-105 (Ru-105)	10
Ruthenium-106 (Ru-106)	1
Samarium-151 (Sm-151)	10
Samarium-153 (Sm-153)	100
Scandium-46 (Sc-46)	10
Scandium-47 (Sc-47)	100
Scandium-48 (Sc-48)	10
Selenium-75 (Se-75)	10
Silicon-31 (Si-31)	100
Silver-105 (Ag-105)	10
Silver-110m (Ag-110m)	1
Silver-111 (Ag-111)	100
Sodium-22 (Na-22)	10
Sodium-24 (Na-24)	10
Strontium-85 (Sr-85)	10
Strontium-89 (Sr-89)	1
Strontium-90 (Sr-90)	0.1
Strontium-91 (Sr-91)	10
Strontium-92 (Sr-92)	10
Sulphur-35 (S-35)	100
Tantalum-182 (Ta-182)	10
Technetium-96 (Tc-96)	10
Technetium-97m (Tc-97m)	100

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Technetium-97 (Tc-97)	100
Technetium-99m (Tc-99m)	100
Technetium-99 (Tc-99)	10
Tellurium-125m (Te-125m)	10
Tellurium-127m (Te-127m)	10
Tellurium-127 (Te-127)	100
Tellurium-129m (Te-129m)	10
Tellurium-129 (Te-129)	100
Tellurium-131m (Te-131m)	10
Tellurium-132 (Te-132)	10
Terbium-160 (Tb-160)	10
Thallium-200 (Tl-200)	100
Thallium-201 (Tl-201)	100
Thallium-202 (Tl-202)	100
Thallium-204 (Tl-204)	10
Thulium-170 (Tm-170)	10
Thulium-171 (Tm-171)	10
Tin-113 (Sn-113)	10
Tin-125 (Sn-125)	10
Tungsten-181 (W-181)	10
Tungsten-185 (W-185)	10
Tungsten-187 (W-187)	100
Vanadium-48 (V-48)	10
Vanadium-49 (V-49)	1
Xenon-131m (Xe-131m)	1,000
Xenon-133 (Xe-133)	100
Xenon-135 (Xe-135)	100
Ytterbium-169 (Yb-169)	0.1
Ytterbium-175 (Yb-175)	100
Yttrium-87 (Y-87)	10
Yttrium-88 (Y-88)	10
Yttrium-90 (Y-90)	10
Yttrium-91 (Y-91)	10
Yttrium-92 (Y-92)	100
Yttrium-93 (Y-93)	100
Zinc-65 (Zn-65)	10
Zinc-69m (Zn-69m)	100
Zinc-69 (Zn-69)	1,000
Zirconium-93 (Zr-93)	10

APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	**Microcuries**
Zirconium-95 (Zr-95)	10
Zirconium-97 (Zr-97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

NOTES:

1. For purposes of C.2.2(b)(1) 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" (i.e., "unity).

EXAMPLE:

$$\frac{\text{Amt. of Isotope A possessed}}{\text{1000 x Appendix B quantity for Isotope A}} + \frac{\text{Amt. of Isotope B possessed}}{\text{1000 x Appendix B quantity for Isotope B}} \leq 1$$

2. To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE:

Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq)

PART C

APPENDIX C

[RESERVED]

PART C

APPENDIX D

LIMITS FOR BROAD LICENSES (C.5.4)

Radioactive Material	Column I Curies	Column II Curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-75	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01

APPENDIX D
LIMITS FOR BROAD LICENSES (C.5.4)

Radioactive Material	Column I Curies	Column II Curies
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 [$T_{1/2}$=9.2h]	10	0.1
Europium-152 [$T_{1/2}$=13 y]	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1
Krypton-87	10	0.1

APPENDIX D
LIMITS FOR BROAD LICENSES (C.5.4)

Radioactive Material	Column I Curies	Column II Curies
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1
Platinum-193	10	0.1
Platinum-197m	100	1
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-166	10	0.1
Rhenium-168	10	0.1

APPENDIX D
LIMITS FOR BROAD LICENSES (C.5.4)

Radioactive Material	Column I Curies	Column II Curies
Rhodium-105	10	0.1
Rodium-103m	1,000	10
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1

APPENDIX D
LIMITS FOR BROAD LICENSES (C.5.4)

Radioactive Material	Column I Curies	Column II Curies
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above	0.1	0.001

NOTE:

To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE:

Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq).

PART C

APPENDIX E

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. INTRODUCTION

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this Appendix The terms of the self-guarantee are in Section III of this Appendix. This Appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. FINANCIAL TEST

(A) To pass the financial test, a company must meet all of the following criteria:

(1) A current rating for its most recent bond issuance of AAA, AA or A as issued by Standard and Poor's or Aaa, Aa or A as issued by Moody's; and

(2) Tangible net worth each at least ten times the current decommissioning cost estimates (or current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(3) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the current decommissioning cost estimates (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(B) To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(C) If the licensee no longer meets the requirements of Section II.A. of this Appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

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APPENDIX E
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

III. COMPANY SELF-GUARANTEE

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

(B) The licensee shall provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the Agency of the notice of cancellation of the guarantee.

(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

(E) 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 II.A. of this Appendix.

(F) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

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PART C

APPENDIX F

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (Curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9[68]
Carbon-14 (Non CO_2)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000

[68] Equivalent to 20 milligrams

APPENDIX F
QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (Curies)
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	0.0001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulphur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000

APPENDIX F
QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (Curies)
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[69]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[69]	.0001	20
Combinations of radioactive materials listed above[70]		

[69] Waste packaged in Type B containers does not require an emergency plan.

[70] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material above exceeds unity (i.e. one).

PART C

APPENDIX G

DETERMINATION OF A_1 AND A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these Regulations, are given in Table I. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. (a) For individual radionuclides whose identities are known, but which are not listed in Table I, the A_1 and A_2 values contained in Table II may be used. Otherwise, the licensee shall obtain prior Agency approval of the A_1 and A_2 values for radionuclides not listed in Table I, before shipping the material.

(b) For individual radionuclides whose identities are known, but which are not listed in Table IV, the exempt material activity concentration and exempt consignment activity values contained in Table II may be used. Otherwise, the licensee shall obtain prior Agency approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table IV, before shipping the material.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table I, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than ten (10) days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten (10) days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i, and $A_1(i)$ is the A_1 value for radionuclide i.

(b) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i and $A_2(i)$ is the A_2 value for radionuclide i

(c) Alternatively, an A_1 value for mixtures of special form material may be determined as follows:

$$A_1 = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and $A_1(i)$ is the appropriate A_1 value for radionuclide i.

(d) An A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide i.

(e) The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$[A] = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide i in the mixture, and [A] is the activity concentration for exempt material containing radionuclide i.

(f) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$A = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture, and A is the activity limit for exempt consignments for radionuclide i.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

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APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195		$1.0X10^{1}$	$2.7X10^{2}$	6.0	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Ba-133		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	9.4	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	8.1	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	1.9	$5.2X10^{1}$
Bi-210		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$
Bk-247	Berkelium (97)	8.0	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	8.1	$6.1X10^{1}$	$1.6X10^{3}$
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6
Cf-252 (h)		$5.0X10^{-2}$	1.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	4.0	$1.1X10^{2}$	4.0	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	3.2	$8.7X10^{1}$
Cu-64	Copper (29)	6.0	$1.6X10^{2}$	1.0	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	8.1	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Eu-147	Europium (63)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short lived)		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192 (c)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-81	Krypton (36)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		8.0	$2.2X10^{2}$	8.0	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		9.0	$2.4X10^{2}$	9.0	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	1.1
Mo-99 (a) (i)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{7}$	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	8.8	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	6.0	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^{1}$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	5.4	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	5.2	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	1.4	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-1}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (medium lung absorption) (a)(e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	See Table A-4
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	(See Table A-3)
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$

APPENDIX G -TABLE I
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (70)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$
Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days.

[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq) (see Appendix A to Part 71—Determination of A_1 and A_2, Section I).

[c] The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

[h] A_1 = 0.1 TBq (2.7 Ci) and A_2 = 0.001 TBq (0.027 Ci) for Cf-252 for domestic use.

[i] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

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APPENDIX G -TABLE II & TABLE III

TABLE II
GENERAL VALUES FOR A_1 AND A_2

	A_1		A_2	
Contents	**TBq**	**Ci**	**TBq**	**Ci**
Only beta- or gamma-emitting nuclides are known to be present.	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available.	0.10	2.70	$2x10^{-5}$	$5.4x10^{-4}$

TABLE III
ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment[71]	Specific Activity	
weight % U-235 present	**Ci/g**	**TBq/g**
0.45	$1.8x10^{-8}$	$5.0x10^{-7}$
0.72	$2.6x10^{-8}$	$7.1x10^{-7}$
1.0	$2.8x10^{-8}$	$7.6x10^{-7}$
1.5	$3.7x10^{-8}$	$1.0x10^{-6}$
5.0	$1.0x10^{-7}$	$2.7x10^{-6}$
10.0	$1.8x10^{-7}$	$4.8x10^{-6}$
20.0	$3.7x10^{-7}$	$1.0x10^{-5}$
35.0	$7.4x10^{-7}$	$2.0x10^{-5}$
50.0	$9.3x10^{-7}$	$2.5x10^{-5}$
90.0	$2.2x10^{-6}$	$5.8x10^{-5}$
93.0	$2.6x10^{-6}$	$7.0x10^{-5}$
95.0	$3.4x10^{-6}$	$9.1x10^{-5}$

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[71] The figures for uranium include representative values for the activity of the uranium-235 which is concentrated during the enrichment process.

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-81	Krypton (36)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b),(d)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
U-235 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less) (g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a] [Reserved]

[b] Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214

APPENDIX G -TABLE IV
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic Number	Activity Concentration for Exempt Material (Bq/g)	Activity Concentration for Exempt Material (Ci/g)	Activity Limit for Exempt Consignment (Bq)	Activity Limit for Exempt Consignment (Ci)
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)				
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209				
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)				
Th-234	Pa-234m				
U-230	Th-226, Ra-222, Rn-218, Po-214				
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)				
U-235	Th-231				
U-238	Th-234, Pa-234m				
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210				
U-240	Np-240m				
Np-237	Pa-233				
Am-242m	Am-242				
Am-243	Np-239				

[c] [Reserved]

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART D

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

JUNE 1978

As Amended:

June 1981
October 1984
February 1990 (E)
August 1991
February 1994
JUNE 1999

PART D
RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

D.1 PURPOSE AND SCOPE

D.1.1 This part establishes procedures for the registration (or licensing) and the use of particle accelerators intended for other than healing arts use. Requirements for registration and use of particle accelerators for healing arts use are contained in Part H of these Regulations.

D.1.2 In addition to the requirements of this part, all registrants are subject to the requirements of Parts A and B. Registrants engaged in industrial radiographic operations are subject to the requirements of Part E. Registrants (or licensees) whose operations result in the production of radioactive material are also subject to the requirements of Part C of these Regulations.

D.2 REGISTRATION PROCEDURE

D.2.1 **Registration (or Licensing) Requirement.** No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration (or license) issued pursuant to these Regulations or as otherwise provided for in these Regulations. The general procedures for registration (or licensing) of particle accelerator facilities are included in Part B (or C) of these Regulations.

D.2.2 **General Requirements for the Issuance of a Registration (or License) for Particle Accelerators.**

In addition to the requirement of Part B (or C), a registration (or licensing) 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 Part A of these Regulations in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed 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 registration (or license) will not be inimical to the health and safety of the public;

(d) The applicant has appointed a radiation safety officer;

(e) The applicant and/or his staff has substantial experience in the use of particle accelerators for the 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 particle accelerator operators.

D.2.3 **[RESERVED]**.

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D.3 RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

D.3.1 **[RESERVED]**.

D.3.2 **Limitations.**

(a) No registrant (or licensee) shall permit any person to act as a particle accelerator operator until such person:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instructions in this part and the applicable requirements of Part A, pertinent registration (or license) conditions and the registrant's (or 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 in his assignment.

(b) Either the radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

D.3.3 **Shielding and Safety Design Requirements.**

(a) A qualified expert, registered with 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 Sections A.2.3 and A.2.11 of these Regulations.

D.3.4 **Particle Accelerator Controls and Interlock System.**

(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 a safety interlock that shuts down the machine under conditions of barrier penetration.

(c) When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped, and lastly at the main control console.

(d) Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

(e) All safety interlocks shall be fail safe (i.e., designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator).

(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.

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D.3.5 **Warning Devices.**

(a) All locations designated as high radiation areas, and entrances to such locations shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

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.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with Section A.3.12 of these Regulations.

D.3.6 **Operating Procedures.**

(a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) Only a switch on the accelerator control console shall be routinely used to run the accelerator beam on and off. 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 for inspection at the accelerator facility.

(d) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the Agency and 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.

D.3.7 **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 regularly and prior to use, and calibrated at intervals not to exceed one year, and after each servicing and repair which could affect the calibration.

(b) A radiation protection survey shall be performed and documented by a qualified expert registered with the Agency when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(c) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

(d) All area monitors shall be calibrated quarterly.

(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.

D.3.7(f)

(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

(g) All area surveys shall be made in accordance with the written procedures established by a qualified expert, or the radiation safety officer of the particle accelerator facility.

(h) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.

D.3.8 **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 A, Appendix A, Table I of these Regulations.

(b) A registrant (or licensee), as required by Section A.2.11, shall not vent, release or otherwise discharge airborne radioactive material to an uncontrolled area which exceed the limits specified in Part A, Appendix A, Table II, except as authorized pursuant to Section A.4.2 or Paragraph A.2.11(c) of these Regulations. For purposes of this paragraph, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas, as far below these limits as practicable.

D.4 [RESERVED]

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RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OR WIRELINE SERVICE OPERATIONS AND INDUSTRIAL RADIATION MACHINES

JUNE 1978

As Amended:

June 1981
October 1984
August 1991
February 1994
June 1999
September 2004
OCTOBER 2013

PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OR WIRELINE SERVICE OPERATIONS AND INDUSTRIAL RADIATION MACHINES

E.1 PURPOSE

The regulations in this part establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography or wireline service operations (including mineral logging, radioactive markers and subsurface tracer studies), and provides special requirements for industrial radiation machines. The requirements of this part are in addition to and not in substitution for the other requirements of these Regulations.

E.2 INDUSTRIAL RADIOGRAPHY

E.2.1 **Scope.** Except for industrial radiation machines regulated pursuant to Subpart E.3 of these Regulations, the regulations in this subpart apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however, that nothing in this subpart shall apply to the use of sources of radiation in the healing arts.

E.2.2 **Limits on External Levels of Radiation from Storage Containers and Source Changers.** The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

E.2.3 **Locking of Sources of Radiation, Storage Containers, and Source Changers.**

(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized removal of the sealed source from its shielded position. The exposure device and/or its container shall be kept locked (and if a keyed lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in E.2.13. In addition, during radiographic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(b) Each sealed source storage container and source changer shall 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 shall 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) The control panel of each radiation machine shall be equipped with a lock 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 or a radiographer’s assistant.

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E.2.4 **Labeling, Storage, and Transportation.**

(a) The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors (i.e., magenta, purple or black on a yellow background) having a minimum diameter of 25 mm, and the wording:

CAUTION[72]
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")

(b) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR 71.

(c) Radiographic exposure devices, source changers, storage containers, and radiation machines must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner which will minimize danger from explosion or fire.

(d) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the radioactive material from the vehicle.

(e) The licensee's or registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

E.2.5 **Radiation Survey Instruments.**

(a) The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this subpart and A.3.2 of these Regulations. Instrumentation required by this section shall 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 energies appropriate for use and at intervals not to exceed 6 months and after instrument servicing, except for battery changes;

(2) Such that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked; and

(3) (i) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale;

(ii) For logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and

(iii) For digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour.

[72] or "DANGER"

E.2.5(c)

(c) The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with E.2.25.

E.2.6 **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 shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State.

(b) The opening, repair or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State.

(c) Testing and record keeping requirements.

(1) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source shall be performed using a method approved by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample shall be analyzed for radioactive contamination. The analysis shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on the test sample and shall be performed by a person specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

(2) The licensee shall maintain records of the leak tests in accordance with E.2.26.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but shall be tested before use or transfer to another person if the interval of storage exceeds 6 months.

(d) Any test conducted pursuant to paragraphs (a) and (c) of this section which reveals the presence of 185 Bq (0.005 μCi) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with regulations of the Agency. Within 5 days after obtaining results of the test, the licensee shall file a report with the Agency describing the equipment involved, the test results, and the corrective action taken.

(e) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. The analysis shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on the test sample and shall be performed by a person specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform the analysis. Should such testing reveal the presence of 185 Bq (0.005 μCi) or more of removable DU contamination, the exposure device shall be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however the device shall be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test shall be made in accordance with E.2.26.

E.2.7 **Quarterly Inventory.**

(a) Each licensee shall conduct a quarterly physical inventory to account for all sources of radiation and for devices containing depleted uranium received and possessed under this license.

E.2.7(b)

(b) The licensee or registrant shall maintain records of the quarterly inventory in accordance with E.2.27.

E.2.8 **Utilization Logs.**

(a) Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

(1) A description, including the make, model and serial number of the radiation machine or the radiographic exposure device, transport or storage container in which the sealed source is located;

(2) The identity or signature of the radiographer to whom assigned;

(3) Locations where used and dates of use, including the dates removed and returned to storage; and

(4) For permanent radiographic installations, the dates each radiation machine is energized.

(b) The licensee or registrant shall retain the logs required by paragraph (a) of this section for 3 years after the log is made.

E.2.9 **Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.**

(a) Each licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, and source changers before each day's use, or work shift, to ensure that:

(1) The equipment is in good working condition;

(2) The sources are adequately shielded; and

(3) Required labeling is present.

(b) 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.

(c) Each licensee or registrant shall have written procedures for and perform:

(1) Inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

(2) Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(d) Records of equipment problems and of any maintenance performed under this section must be made in accordance with E.2.28.

E.2.10 **Training and Testing.**

(a) The licensee or registrant shall not permit any individual to act as a radiographer until the individual:

E.2.10(a)(1)

(1) Has received at least 40 hours of training in the subjects outlined in Paragraph (g) of this section, in addition to on-the-job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A to Part E. The on-the-job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours); or

(2) The licensee or registrant may, until 27 June 2000, allow an individual who has not met the requirement of paragraph (a)(1) of this section, to act as a radiographer after the individual has received at least 40 hours of training in the subjects outlined in paragraph (g) of this section and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Agency, the Nuclear Regulatory Commission, or another Agreement State, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer. The on the job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours).

(b) In addition, the licensee or registrant shall not permit any individual to act as a radiographer until the individual:

(1) Has received copies of and instruction in RCA regulations as contained in this part and applicable sections of Parts A and C, in applicable DOT regulations as referenced in 10 CFR 71, in the license(s) and/or certificate(s) of registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures.

(2) Has demonstrated understanding of the items in subparagraph (b)(1) of this section by successful completion of a written or oral examination.

(3) Has received training in the use of the registrant's radiation machines or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(4) Has demonstrated understanding of the use of the equipment described in subparagraph (b)(3) of this section by successful completion of a practical examination.

(c) The licensee or registrant shall not permit any individual to act as a radiographer's assistant until the individual:

(1) Has received copies of and instruction in RCA regulations as contained in this part and applicable sections of Parts A and C, in applicable DOT regulations as referenced in 10 CFR 71, license(s) and/or certificate(s) of registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

(2) Has demonstrated an understanding of items in subparagraph (b)(1) of this section by successful completion of a written or oral examination;

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E.2.10(c)(3)

(3) Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments;

(4) Has demonstrated understanding of the use of the equipment described in subparagraph (b)(1) of this section by successful completion of a practical examination.

(d) The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in paragraph (e)(4), the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency's regulations, license and/or certificate of registration requirements, and the applicant's operating and emergency procedures are followed. The inspection program shall:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of E.2.10(b)(3) and the radiographer's assistant must re-demonstrate knowledge of the training requirements of E.2.10(c)(2) by a practical examination 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.

(f) The licensee or registrant shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with E.2.30.

(g) The licensee or registrant shall include the following subjects required in paragraph (a) of this section:

(1) Fundamentals of radiation safety including:

(i) Characteristics of gamma and X-radiation;

(ii) Units of radiation dose and quantity of radioactivity;

(iii) Hazards of exposure to radiation;

(iv) Levels of radiation from sources of radiation; and

(v) Methods of controlling radiation dose (time, distance, and shielding);

(2) Radiation detection instruments including:

(i) Use, operation, calibration, and limitations of radiation survey instruments;

(ii) Survey techniques; and

(iii) Use of personnel monitoring equipment.

(3) Equipment to be used including:

(i) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

E.2.10(g)(3)(ii)

(ii) Operation and control of radiation machines;

(iii) Storage, control, and disposal of sources of radiation; and

(iv) Inspection and maintenance of equipment.

(4) The requirements of pertinent Agency and Federal regulations; and

(5) Case histories of accidents in radiography.

(h) Licensees and registrants will have until 27 June 2000 to comply with the certification requirements specified in paragraph (a)(1) of this section. Records of radiographer certification maintained in accordance with E.2.30(a) provide appropriate affirmation of certification requirements specified in paragraph (a)(1) of this section.

E.2.11 **Operating and Emergency Procedures.**

(a) The licensee's or registrant's operating and emergency procedures shall include, as a minimum, instructions in the following:

(1) Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Subpart A.2 Standards for Protection Against Radiation;

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for posting and controlling access to radiographic areas;

(4) Methods and occasions for locking and securing sources of radiation;

(5) Personnel monitoring and the use of personnel monitoring equipment;

(6) Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the equipment during transportation (refer to 49 CFR Parts 171-173);

(7) The inspection, maintenance and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers; and

(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by Section E.2.19;

(10) The procedure for notifying proper personnel in the event of an accident or incident;

(11) Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

(12) Source recovery procedure if licensee will perform source recovery; and

(13) Maintenance of records.

(b) The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with Sections E.2.17 and E.2.31.

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E.2.12 **Personnel Monitoring.**

(a) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters shall have a range from zero to 2 mSv (200 mrem) and shall be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(2) Each personnel dosimeter shall be assigned to and worn by only one individual.

(3) Film badges shall be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at periods not to exceed three months.

(4) After replacement, each personnel dosimeter shall be processed as soon as possible.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, shall be read and the exposures recorded at the beginning and end of each shift, and records shall be maintained in accordance with E.2.32.

(c) Pocket dosimeters, or electronic personal dosimeters, shall be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with E.2.32. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 mSv (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter shall 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 shall be made by the RSO or the RSO's designee. The results of this determination shall be included in the records maintained in accordance with E.2.32.

(e) If the personnel dosimeter required by E.2.12(a) is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements of E.2.12(a) is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged shall be included in the records maintained in accordance with E.2.32.

(f) Dosimetry reports received from the accredited NVLAP personnel dosimeter processor shall be retained in accordance with E.2.32.

(g) Each alarm ratemeter must:

(1) Be checked to ensure that the alarm functions properly (i.e. sounds) prior to use at the start of each shift;

(2) Be set to give an alarm signal at a pre-set dose rate of 5 millisieverts (500 mrem) per hour, with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the pre-set alarm function; and

E.2.12(g)(4)

(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 E.2.32.

E.2.13 **Surveillance.** During each radiographic operation the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Part A, except at permanent radiographic installations where all entryways are locked and the requirements of E.2.16 are met.

E.2.14 **Posting.** All areas in which industrial radiography is being performed must be conspicuously posted as required by A.3.13(a) and (b). Exceptions listed in A.3.14(b) do not apply to industrial radiographic operations.

E.2.15 **Radiation Surveys.** The licensee or registrant shall:

(a) Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of E.2.5.

(b) Conduct a survey 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. Radiation machines shall be surveyed after each exposure to determine that the machine is off.

(c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in A.0), to ensure that the sealed source is in its shielded position.

(d) Maintain records in accordance with E.2.33.

E.2.16 **Permanent Radiographic Installations.**

(a) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have either:

(1) An entrance control of the type described in Subparagraph A.3.4(a)(1) that causes the radiation level upon entry into the area to be reduced; or

(2) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

(b) The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in paragraph (a)(1) of this section) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of E.2.13 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarm must be maintained in accordance with E.2.29.

E.2.17 **Records Required at Temporary Jobsites.** Each licensee or registrant shall maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:

E.2.17(a)

(a) Appropriate license, certificate of registration or equivalent document authorizing the use of sources of radiation.

(b) Operating and emergency procedures required by E.2.31.

(c) A copy of these Regulations.

(d) Survey records as required by E.2.33, for the period of operation at the site.

(e) Records of dosimeter readings as required by E.2.32.

(f) Utilization log for each source of radiation dispatched from that location as required by E.2.8.

(g) Records of equipment problems identified in daily checks of equipment as required by E.2.28(a);

(h) Records of alarm system and entrance control checks required by E.2.29, if applicable;

(i) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by E.2.25;

(j) Evidence of the latest calibrations of alarm ratemeters and operability checks of dosimeters as required by E.2.32;

(k) The shipping papers for the transportation of radioactive materials required by 10 CFR 71.5; and

(l) When operating under reciprocity pursuant to Subpart C.6, a copy of the applicable State license or certificate of registration, or U.S. Nuclear Regulatory Commission license authorizing the use of sources of radiation.

E.2.18 **Performance Requirements for 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 Standards Institute (ANSI), N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" [published as NBS Handbook 136, issued January 1981][73].

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model or product code and serial number of the sealed source;

(iv) Manufacturer's identity of the sealed source; and

(v) Licensee's name, address and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR 71.

[73] This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone: (212) 642-4900.

E.2.18(b)(3)

(3) Modification of exposure devices, source changers, source assemblies and associated equipment is prohibited, unless approved by the Agency or other approval body.

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers:

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) 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) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces 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 assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All radiographic exposure devices and associated equipment in use after 10 January 1996 must comply with the requirements of this section.

(e) Notwithstanding paragraph (a)(1) of this section, equipment used in industrial radiographic operations need not comply with Sec. 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

E.2.19 **Reporting Requirements.**

(a) In addition to the reporting requirements specified under other sections of these Regulations, each licensee shall provide a written report to the Agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

E.2.19(a)(1)

(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; or

(4) An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

(b) The licensee or registrant shall include the following information in each report submitted under paragraph (a) of this section:

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Name of the manufacturer and model number of equipment involved in the incident;

(4) Place, 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 overexposure submitted under Section A.5.14 of these Regulations which involve failure of safety components of radiography equipment must also include the information specified in paragraph (b) of this section.

(d) Any licensee or registrant conducting radiographic operations or storing sources of radiation material at any location not listed on the license and/or certificate of registration for a period in excess of 180 days in a calendar year, shall notify the Agency prior to exceeding the 180 days.

E.2.20 **Conducting Industrial Radiographic Operations.**

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of E.2.10(c). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(b) All radiographic operations shall be conducted in a permanent radiographic installation, unless otherwise specifically authorized by the Agency.

(c) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(d) A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State.

(e) 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;

E.2.20(e)(2)

(2) A current whole body personnel monitor (TLD or film badge) for each person performing radiographic operations;

(3) An operable, calibrated pocket dosimeter with a range of zero to 2 millisieverts (200 mrem) for each person performing radiographic operations;

(4) An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and

(5) The appropriate barrier ropes and signs.

(f) Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

(g) Industrial radiographic operations shall not be performed if any of the items in E.2.20(e) and E.2.20(f) are not available at the job site or are inoperable.

(h) During an inspection, the Agency may terminate an operation if any of the items in E.2.20(e) and E.2.20(f) are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

E.2.21 **Radiation Safety Officer for Industrial Radiography.** The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

(a) The minimum qualifications, training, and experience for RSOs for industrial radiography are as follows:

(1) Completion of the training and testing requirements of E.2.10(a);

(2) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(3) Formal training in the establishment and maintenance of a radiation protection program.

(b) The 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 A of these Regulations, and reviewing them regularly to ensure that they conform to Agency regulations and to the license and/or certificate of registration conditions.

(2) Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated, if applicable and used properly; that records are kept of the monitoring results, and that timely notifications are made as required by Part A of these Regulations; and

(5) Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

E.2.21(d)

(d) Licensees and registrants will have until 27 June 2000 to meet the requirements of paragraph (a) or (b) of this section.

E.2.22 **Supervision of Radiographers' Assistants.** The radiographer's assistant shall be under the personal supervision of a radiographer when using sources of radiation or conducting radiation surveys required by E.2.15(b) to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

(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 assistant's performance of the operations referred to in this section.

E.2.23 **Records for Industrial Radiography.** Each licensee or registrant shall maintain a copy of its license/ certificate of registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license and/or certificate of registration.

E.2.24 **Records of Receipt and Transfer of Sources of Radiation.**

(a) Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding and radiation machines, and retain each record for 3 years after it is made.

(b) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

E.2.25 **Records of Radiation Survey Instruments.** Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under E.2.5 and retain each record for 3 years after it is made.

E.2.26 **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 3 years after it is made or until the source in storage is removed.

E.2.27 **Records of Quarterly Inventory.**

(a) Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by E.2.7 and retain each record for 3 years after it is made.

(b) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

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E.2.28

E.2.28 **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 or registrant shall maintain records specified in E.2.8 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments. Each record shall be maintained for 3 years after it is made.

(b) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

E.2.29 **Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations.** Each licensee or registrant shall maintain records of alarm system and entrance control device tests required under E.2.16 and retain each record for 3 years after it is made.

E.2.30 **Records of Training and Certification.** Each licensee or registrant shall maintain the following records (of training and certification) for 3 years after the record is made:
E.2.30(a)

(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, names of individuals conducting and receiving the oral and practical examinations, a list of items tested and the results of the oral and practical examinations; and

(b) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliances observed by the RSO or designee.

E.2.31 **Copies of Operating and Emergency Procedures.** Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license and/or certificate of registration. Superseded material must be retained for 3 years after the change is made.

E.2.32 **Records of Personnel Monitoring Procedures.** Each licensee or registrant shall maintain the following exposure records specified in E.2.12:

(a) Direct reading dosimeter readings and yearly operability checks required by E.2.12(b) and (c) for 3 years after the record is made.

(b) Records of alarm ratemeter calibrations for 3 years after the record is made.

(c) Personnel dosimeter results received from the accredited NVLAP processor until the Agency terminates the license and/or certificate of registration.

(d) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters, until the Agency terminates the license and/or certificate of registration.

E.2.33 **Records of Radiation Surveys.** Each licensee or registrant shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in E.2.15(c). Each record must be maintained for 3 years after it is made.

E.2.34

E.2.34 **Form of Records.** Each record required by this subpart must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

E.2.35 **Location of Documents and Records.**

(a) Each licensee or registrant shall maintain copies of records required by this subpart and other applicable parts of these Regulations at the location specified in C.5.3(c)(10).

(b) Records shall also be maintained at each applicable field station and each temporary jobsite, as specified by E.2.17.

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E.3 INDUSTRIAL RADIATION MACHINES

E.3.1 **Purpose**. This Subpart establishes requirements for the use of industrial radiation machines not otherwise covered by these Regulations. For the purposes of this Subpart:

(a) **Category A Industrial Radiation Machine**: A device capable of generating or emitting fields of radiation in an open beam configuration during normal conditions of use. This includes, but is not limited to, portable/handheld fluorescence x-ray, fluoroscopy hand held intensified, fluoroscopy x-ray, flash x-ray, flash x-ray for bomb detection, spectrography x-ray, diffraction x-ray and uncertified cabinet x-ray.

(b) **Category B Industrial Radiation Machine:** A device capable of generating or emitting fields of radiation where the beam is contained during normal conditions of use. This includes, but is not limited to, package x-ray, certified and certifiable cabinet x-ray, x-ray fluorescence units and similar devices.

E.3.2 **Exemptions**. Uses of portable/handheld fluorescence x-ray (open beam) devices that are manufactured without safety devices are exempt from the requirements of §E.3.4(a) of these Regulations.

E.3.3 **General Requirements – All Industrial Radiation Machines.**

(a) **Radiation Levels.** The local components of an industrial radiation machine 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 in the area in excess of the dose limits given in §A.2.11 of these Regulations.

(b) **Warning Devices.**

(1) The x-ray control shall provide visual indication whenever x rays are produced.

(2) All ancillary warning devices shall be labeled so that their purpose is easily identified and shall have fail-safe characteristics.

(c) **Posting.** Each area or room containing industrial radiation machines 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.

(d) **Ports.** Unused ports on industrial radiation machine source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.

(e) **Labeling.** Each registrant shall ensure that each industrial radiation machine is labeled in a conspicuous manner to caution individuals that radiation is produced when it is energized. This label shall be affixed in a clearly visible location on the face of the control unit. If the industrial radiation machine is not visible from the control unit, the industrial radiation machine shall have a visible indication that it is energized.

(f) **Radiation Source Housing**. Each radiation source 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.

E.3.4 **Additional Requirements – Category A Industrial Radiation Machines.**

(a) **Safety Device.** A safety device shall be provided on all open-beam configurations 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.

(1) A registrant may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

(i) A description of the various safety devices that have been evaluated,

E.3.4(a)(1)(ii)

(ii) The reason each of these devices cannot be used, and

(iii) 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. O**pen-beam configurations shall be provided with a visible indication of:

(1) X-ray tube status (**ON-OFF**) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(2) Shutter status (**OPEN-CLOSED**) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) **Shutters.** On open-beam configurations 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.

(d) **Surveys.**

(1) Radiation surveys, as required by §A.3.2 of these Regulations, of industrial radiation machines sufficient to show compliance with §E.3.3(a) of these regulations shall be performed:

(i) Upon installation of the equipment, and at least once every twelve (12) months thereafter;

(ii) Following any change in the initial arrangement, number, or type of local components in the system;

(iii) Following any maintenance requiring the disassembly or removal of a local component in the system;

(iv) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed; and

(v) Any time a visual inspection of the local components in the system reveals an abnormal condition.

(vi) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

(2) Radiation survey measurements shall not be required if a registrant can demonstrate, to the satisfaction of the Agency, compliance with §E.3.3(a) of these regulations in some other manner.

(e) **Generator Cabinet.** Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five (5) cm from its surface such that it is not capable of producing a dose in excess of 0.5 mrem (5 μSv) in any one (1) hour.

E.3.5 **Additional Requirements – Category B Industrial Radiation Machines.**

(a) All Category B industrial radiation machines shall be evaluated in accordance with the following requirements:

(1) The registrant shall perform an evaluation of the radiation dose limits to determine compliance with §§A.2.11(a), (b) and (c) of these Regulations at intervals not to exceed twelve (12) months. The registrant shall ensure that radiation emitted five (5) centimeters from the external surface of the cabinet x-ray system does not exceed 0.5 millirem (5.0 μSv) in any one (1) hour;

E.3.5(a)(2)

(2) Tests for proper operation of interlocks shall be conducted and recorded at intervals not to exceed twelve (12) months;

(3) Records that demonstrate compliance with §E.3.5(a) of these Regulations shall be maintained by the registrant for ten (10) years for inspection by the Agency.

(b) **Certified and Certifiable Cabinet X-ray Systems**. Certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals shall also 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.

E.3.6 **Operating Requirements.**

(a) **Procedures.** Operating and safety procedures shall be written and made available to all industrial radiation machine operators. No individual shall be permitted to operate an industrial radiation machine in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

(b) **Bypassing.** No individual shall bypass a safety device or interlock unless such individual has obtained the written approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words **"SAFETY DEVICE NOT WORKING"**, or words having a similar intent, shall be placed on the radiation source housing.

(c) **Repair or Modification of Industrial Radiation Machines.** Except as specified in §E.3.6(b), no operation involving removal of covers, shielding materials or tube housing 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.

E.3.7 **Personnel Requirements.**

(a) **Instruction.** No individual shall be permitted to operate or maintain an industrial radiation machine unless the individual has received instruction in and demonstrated competence in the following:

(1) Identification of radiation hazards associated with the use of the industrial radiation machine;

(2) Radiation warning and safety devices incorporated into the industrial radiation machine, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Operating and safety procedures for the industrial radiation machine; and

(4) Proper procedures for reporting an actual or suspected exposure in excess of the limits specified in §A.2.11 of these Regulations.

(b) **Instructions for Bomb Detection Radiation Machines**. All personnel operating bomb detection radiation machines shall be trained in the set-up and operation of the radiation machine and in establishing a restricted area.

(c) **Individual Monitoring.** In addition to the requirements of §A.3.3(a)(1), finger dosimetric devices shall be provided to and shall be used by:

(1) Industrial radiation machine workers using systems having an open-beam configuration and not equipped with a safety device; and

E.3.7(c)(2)

(2) Personnel maintaining industrial 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.

(d) Reported dose values shall not be used for the purpose of determining compliance with §A.2.3 of these Regulations unless evaluated by an individual registered with the Agency to provide General Radiation Physics Services.

(e) **Records and Documentation**. Records that demonstrate compliance with §§E.3.7(a)-(c) of these Regulations shall be maintained by the registrant for ten (10) years for inspection by the Agency. In addition to complying with the requirements of §§E.3.7(a)-(c), records of individual monitoring results shall be maintained by the registrant in accordance with §A.5.7 of these Regulations.

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E.4 WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

E.4.1 **Scope.** The regulations in this part apply to all licensees or registrants who use sources of radiation for wireline service operations including mineral logging, radioactive markers, or subsurface tracer studies.

E.4.2 **Prohibition.** No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner that:

(a) in the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

(b) in the event a decision is made to abandon the sealed source downhole, the requirements of Paragraph E.4.23 shall be met.

EQUIPMENT CONTROL

E.4.3 **Limits on Levels of Radiation.** Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Subpart C.7 and the dose limitation requirements of Subpart A.2 of these Regulations are met.

E.4.4 **Storage Precautions.**

(a) Each source of radiation, except accelerators, shall be provided with a storage and/or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

(b) Sources of radiation shall be stored in a manner which will minimize danger from explosion and/or fire.

E.4.5 **Transport Precautions.** Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

E.4.6 **Radiation Survey Instruments.**

(a) The licensee or registrant shall maintain a calibrated and operable radiation survey instrument at each field station and temporary jobsite to make radiation surveys as required by this part and by Section A.3.2 of these Regulations. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.001 mSv (0.1 mrem) per hour through at least 0.5 mSv (50 mrem) per hour.

(b) Each radiation survey instrument shall be calibrated:

(1) at intervals not to exceed 6 months and after each instrument servicing;

(2) for linear scale instruments, at two points located at approximately 1/3 and 2/3 of full scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(3) so that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained for a period of 2 years for inspection by the Agency.

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E.4.7 **Leak Testing of Sealed Sources.**

(a) **Requirements.** Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency for 3 years after the next required leak test is performed or until transfer or disposal of the sealed source.

(b) **Method of Testing.** The wipe of a sealed source shall be performed using a leak test kit or method approved by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State. The wipe sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample shall be analyzed for radioactive contamination. The analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and shall be performed by a person approved by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform the analysis.

(c) **Interval of Testing.**

(1) Each sealed source of radioactive material (except an energy compensation source (ECS)) shall be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within the 6 months before the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(2) Each ECS that is not exempt from testing in accordance with E.4.7(e) shall be tested at intervals not to exceed 3 years. In the absence of a certificate from a transferor that a test has been made within the 3 years before the transfer, the ECS may not be used until tested.

(d) **Removal of Leaking Source From Service.** If the test conducted pursuant to E.4.7(a) and (b) reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these Regulations. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of in accordance with these Regulations. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the Agency within 5 days of receiving the test results.

(e) **Exemptions.** The following sources are exempted from the periodic leak test requirements of E.4.7(a) through (d).

(1) hydrogen-3 (tritium) sources;

(2) sources of radioactive material with a half-life of 30 days or less;

(3) sealed sources of radioactive material in gaseous form;

(4) sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

(5) sources of alpha-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

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E.4.8

E.4.8 **Quarterly Inventory.** Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 2 years from the date of the inventory for inspection by the Agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

E.4.9 **Utilization Records.** Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the Agency for 2 years from the date of the recorded event, showing the following information for each source of radiation:

(a) make, model number, and a serial number or a description of each source of radiation used;

(b) the identity of the well-logging supervisor or field unit to whom assigned;

(c) locations where used and dates of use; and

(d) in the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

E.4.10 **Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.**

(a) A licensee may use a sealed source for use in downhole operations if:

(1) The sealed source is doubly encapsulated;

(2) The sealed source contains radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and

(3) Meets the requirements of E.4.10(b), (c) or (d).

(b) For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in downhole operations if it meets the requirements of USASI N5.10–1968, ‘‘Classification of Sealed Radioactive Sources,’’ or the requirements in E.4.10(c) or (d).

(c) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in downhole operations if it meets the oil-well logging requirements of ANSI/HPS N43.6–1997, "Sealed Radioactive Sources-Classification".

(d) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in downhole operations, if the sealed source’s prototype has been tested and found to maintain its integrity after each of the following tests:

(1) **Temperature.** The test source shall be held at -40° C for 20 minutes, 600° C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds.

(2) **Impact test.** A 5 kg steel hammer, 2.5 cm in diameter, shall be dropped from a height of 1 m onto the test source.

(3) **Vibration test.** The test source shall be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.

(4) **Puncture test.** A 1 gram hammer and pin, 0.3 cm pin diameter, shall be dropped from a height of 1 m onto the test source.

(5) **Pressure test.** The test source shall be subject to an external pressure of 1.695×10^7 pascals [24,600 pounds per square inch absolute].

E.4.10(e)

(e) The requirements in E.4.10(a), (b), (c) and (d) do not apply to sealed sources that contain licensed material in gaseous form.

(f) The requirements in E.4.10(a), (b), (c) and (d) do not apply to energy compensation sources (ECS). ECSs shall be registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210, or registered pursuant to the equivalent regulations of the Agency or another Agreement State.

E.4.11 **Labeling.**

(a) Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER[74]

RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

(b) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER[55]

RADIOACTIVE
NOTIFY CIVIL AUTHORITIES (OR "NAME OF COMPANY")

E.4.12 **Inspection and Maintenance.**

(a) Each licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of 2 years for inspection by the Agency.

(b) If any inspection conducted pursuant to Paragraph E.4.11(a) reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

(c) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State.

(d) If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting or chiseling, on the source holder unless the licensee is specifically approved by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform this operation.

E.4.13 **Training Requirements.**

(a) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in these Regulations until such individual has:

(1) received, in a course recognized by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State, instruction in the subjects outlined in Appendix B of this part and demonstrated an understanding thereof;

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[74] or **CAUTION**

E.4.13(a)(2)

(2) read and received instruction in the regulations contained in this subpart and the applicable sections of Parts A, and C of these Regulations or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

(3) demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(b) No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(1) read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

(2) demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(c) The licensee or registrant shall maintain employee training records for inspection by the Agency for 2 years following termination of employment.

E.4.14 **Operating and Emergency Procedures.** The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Subpart A.2 of these Regulations;

(b) methods and occasions for conducting radiation surveys;

(c) methods and occasions for locking and securing sources of radiation;

(d) personnel monitoring and the use of personnel monitoring equipment;

(e) transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

(f) minimizing exposure of individuals in the event of an accident;

(g) procedure for notifying proper personnel in the event of an accident;

(h) maintenance of records;

(i) use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(j) procedure to be followed in the event a sealed source is lodged downhole; and

(k) procedures to be used for picking up, receiving, and opening packages containing radioactive material.

(l) for the use of tracers, decontamination of the environment, equipment and personnel;

(m) maintenance of records generated by logging personnel at temporary jobsites; and

(n) actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by Section E.4.6.

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E.4.15 **Personnel Monitoring.**

(a) No licensee or registrant shall permit any individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of sources of radiation, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be replaced at least monthly and other personnel dosimeters replaced at least quarterly. After replacement, each personnel dosimeter shall be promptly processed.

(b) The licensee or registrant shall retain records of personnel dosimeters required by E.4.15(a) and bioassay results required by E.4.15(c) for inspection until the Agency authorizes disposition of the records.

(c) The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

E.4.16 **Security.** During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized and/or unnecessary entry into a restricted area, as defined in these Regulations.

E.4.17 **Handling Tools.** The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

E.4.18 **Subsurface Tracer Studies.**

(a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

(b) No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the Agency.

E.4.19 **Particle Accelerators.** No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of Sections A.2.3 and A.2.11 of these Regulations, as applicable, are met.

E.4.20 **Radiation Surveys.**

(a) Radiation surveys and/or calculations shall be made and recorded for each area where radioactive materials are stored.

(b) Radiation surveys and/or calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and/or calculations shall include each source of radiation or combination of sources to be transported in the vehicle.

(c) After removal of the sealed source from the logging tool and before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(d) Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operations.

E.4.20(e)

(e) Records required pursuant to Paragraphs E.4.19(a) through (d) shall include the dates, the identification of individual(s) making the survey the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the Agency for 2 years after completion of the survey.

E.4.21 **Documents and Records Required at Field Stations.** Each licensee or registrant shall maintain, for inspection by the Agency, the following documents and records for the specific devices and sources used at the field station:

(a) appropriate license, certificate of registration, or equivalent document;

(b) operating and emergency procedures;

(c) applicable regulations;

(d) records of the latest survey instrument calibrations pursuant to Section E.4.6;

(e) records of the latest leak test results pursuant to Section E.4.7;

(f) records of quarterly inventories required pursuant to Section E.4.8;

(g) utilization records required pursuant to Section E.4.9;

(h) records of inspection and maintenance required pursuant to Section E.4.12; and

(i) survey records required pursuant to Section E.4.19.

(j) training records required pursuant to Section E.4.13.

E.4.22 **Documents and Records Required at Temporary Jobsites.** Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the Agency:

(a) operating and emergency procedures;

(b) survey records required pursuant to E.4.19 for the period of operation at the site;

(c) evidence of current calibration for the radiation survey instruments in use at the site;

(d) when operating in the State under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and

(e) shipping papers for the transportation of radioactive material.

E.4.23 **Notification of Incidents, Abandonment, and Lost Sources.**

(a) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Section A.5.13 of these Regulations.

(b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

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E.4.23(b)(2)

(2) notify the Agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

(c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(1) advise the well-operator of the regulations of the Agency regarding abandonment and an appropriate method of abandonment, which shall include:

(i) the immobilization and sealing in place of the radioactive source with a cement plug,

(ii) a means to prevent inadvertent intrusion on the source (e.g., the setting of a whipstock or other deflection device), unless the source is not accessible to any subsequent drilling operations, and

(iii) the mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by E.4.23(d);

(2) notify the Agency, by telephone, of the circumstances that resulted in the inability to retrieve the source, and:

(i) obtain Agency approval to implement abandonment procedures; or

(ii) that the licensee implemented abandonment before receiving Agency approval because the licensee believed there was an immediate threat to public health and safety; and

(3) file a written report with the Agency within 30 days of the abandonment. The licensee shall send a copy of the report to the state agency(s) that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:

(i) date of occurrence and a brief description of attempts to recover the source,

(ii) a description of the irretrievable radioactive source involved, including radionuclide, quantity, and chemical and physical form,

(iii) surface location and identification of well,

(iv) results of efforts to immobilize and set the source in place,

(v) depth of the radioactive source,

(vi) depth of the top of the cement plug,

(vii) depth of the well,

(viii) The immediate threat to public health and safety justification for implementing abandonment if prior Agency approval was not obtained in accordance with E.4.23 (c)(2)(ii).

(ix) any other information, such as a warning statement, contained on the permanent identification plaque; and

(x) the names of State and Federal agencies receiving a copy of this report.

E.4.23(d)

(d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent identification plaque[75] for mounting at the surface of the well, unless the mounting of the plaque is not practical. This plaque shall:

(1) be at least 17 cm (7 inches) square and 3 mm (1/8 inch) thick and be constructed of long-lasting material, such as stainless steel, brass, bronze, or monel, and

(1) be constructed of long-lasting material, such as stainless steel or monel, and

(2) contain the following engraved on its face:

(i) the word **"CAUTION"**,

(ii) the radiation symbol without the conventional color requirement,

(iii) the date of abandonment,

(iv) the name of the well operator or well owner,

(v) the well name and well identification number(s) or other designation,

(vi) the sealed source(s) by radionuclide and quantity of activity,

(vii) the source depth and the depth to the top of the plug, and

(viii) an appropriate warning, depending on the specific circumstances of each abandonment.[76]

(e) The licensee shall immediately notify the Agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

E.4.24 **Uranium Sinker Bars**. The licensee may use a uranium sinker bar in wireline applications only if it is legibly impressed with the words "**CAUTION-RADIOACTIVE-DEPLETED URANIUM**" and "**NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND**".

E.4.25 **Use of a Sealed Source in a Well Without a Surface Casing.** The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure shall be approved by the Agency.

E.4.26 **Energy Compensation Source.** The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 3.7 MBq (100 microcuries).

(a) For wireline applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of E.4.7, E.4.8 and E.4.9.

(b) For wireline applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of E.4.3, E.4.7, E.4.8, E.4.9, E.4.23 and E.4.25.

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[75] An example of a suggested plaque is shown in Appendix C of this part.

[76] Appropriate warnings may include: (a) "Do not drill below plug back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Rhode Island Radiation Control Agency."

E.4.27 **Tritium Neutron Generator Target Source.**

(a) Use of a tritium neutron generator target source, containing quantities not exceeding 1,110 MBq (30 curies) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this subpart except E.4.3, E.4.10, and E.4.23.

(b) Use of a tritium neutron generator target source, containing quantities exceeding 1,110 MBq (30 curies) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this subpart except E.4.10.

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PART E

APPENDIX A

RADIOGRAPHER CERTIFICATION

I. Requirements for an Independent Certifying Organization

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography.
2. Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability.
3. Have a certification program open to nonmembers, as well as members.
4. Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise.
5. Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board.
6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies.
7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program.
8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions.
9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program.
10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals.
11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees.
12. Exchange information about certified individuals with the U.S. Nuclear Regulatory Commission, other independent certifying organizations and/or Agreement States, and allow periodic review of its certification program and related records.
13. Provide a description to the U.S. Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

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II. Requirements for Certification Programs

All certification programs must:

1. Require applicants for certification to:
   (a) Receive training in the topics set forth in E.2.10(g) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State; and
   (b) Satisfactorily complete a written examination covering these topics.
2. Require applicants for certification to provide documentation that demonstrates that the applicant has:
   (a) Received training in the topics set forth in E.2.10(g) or equivalent Agreement State regulations;
   (b) Satisfactorily completed a minimum period of on-the-job training specified in E.2.10(a); and
   (c) Received verification by a State licensee or registrant or a U.S. Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.
3. Include procedures to ensure that all examination questions are protected from disclosure.
4. Include procedures for denying an application, revoking, suspending, and reinstating a certification.
5. Provide a certification period of not less than 3 years nor more than 5 years.
6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.
7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in E.2.10(g) or equivalent U.S. Nuclear Regulatory Commission and/or State requirements.
2. Written in a multiple-choice format.
3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in E.2.10(g).

PART E

APPENDIX B

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

I. Fundamentals of Radiation Safety

A. Characteristics of radiation

B. Units of radiation dose and quantity of radioactivity

C. Significance of radiation dose

1. Radiation protection standards
2. Biological effects of radiation dose

D. Levels of radiation from sources of radiation

E. Methods of minimizing radiation dose

1. Working time
2. Working distances
3. Shielding

F. Radiation safety practices including prevention of contamination and methods of decontamination

II. Radiation Detection Instrumentation to be Used

A. Use of radiation survey instruments

1. Operation
2. Calibration
3. Limitations

B. Survey techniques

C. Use of personnel monitoring equipment

III. Equipment to be Used

A. Handling equipment

B. Sources of radiation

C. Storage and control of equipment

D. Operation and control of equipment

IV. The Requirements of Pertinent Federal and State Regulations

V. The Licensee's or Registrant's Written Operating and Emergency Procedures

VI. The Licensee's or Registrant's Recordkeeping Procedures

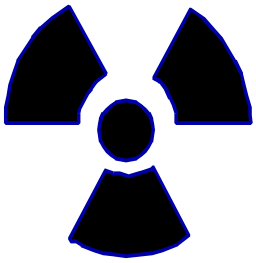
PART E

APPENDIX C

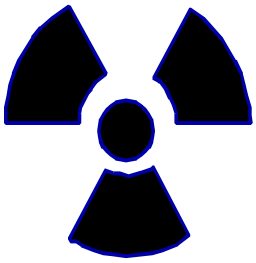
EXAMPLE OF PLAQUE FOR IDENTIFYING WELL CONTAINING SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE

[COMPANY NAME]

[WELL IDENTIFICATION]



CAUTION



ONE 2 CURIE CS-137 RADIOACTIVE

SOURCE ABANDONED 3-3-75 AT

8400 FT. PLUG BACK DEPTH 8200 FT.

DO NOT RE-ENTER THIS WELL

BEFORE CONTACTING

RI RADIATION CONTROL AGENCY

The size of the plaque should be convenient for use on active or inactive wells [e.g. a 7-inch square]. Letter size of the word "CAUTION" should be approximately twice the size of the rest of the information. [e.g. 1/2 inch and 1/4 inch letter size, respectively.]

RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART F

X-RAYS IN THE HEALING ARTS

JUNE 1978

As Amended:

June 1981
October 1984
February 1990
February 1990 (E)
August 1991
February 1994
June 1995
June 1999
September 2004
September 2006
OCTOBER 2013

PART F

DIAGNOSTIC X-RAYS AND ASSOCIATED IMAGING SYSTEMS IN THE HEALING ARTS

F.1 SCOPE

F.1.1 This part establishes requirements, for which a registrant is responsible, for use of diagnostic X-ray equipment and associated imaging systems in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these Regulations.

F.1.2 The use of diagnostic X-ray equipment and associated imaging systems for the intentional exposure of individuals for diagnosis shall be by or under the supervision of a licensed practitioner of the healing arts.

F.1.3 The use of diagnostic X-ray equipment and associated imaging systems in the practice of veterinary medicine shall be by or under the supervision of an individual authorized by and licensed in accordance with RIGL Chapter 5-25 to practice veterinary medicine.

F.2 GENERAL AND ADMINISTRATIVE REQUIREMENTS

F.2.1 **Administrative Controls.** The registrant shall be responsible for directing the operation of the X-ray system(s) under their administrative control. The registrant or the registrant's agent shall assure that the requirements of these Regulations are met in the operation of the X-ray system(s).

F.2.2 An X-ray system which does not meet the provisions of these Regulations shall not be operated for diagnostic purposes.

F.2.3 (a) Individuals who will be operating the X-ray systems for healing arts use shall possess a current license in accordance with the *Rules and Regulations for the Licensure of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants* [*R5-68.1-RAD*] of the Rhode Island Department of Health, unless the individual is specifically exempted from licensure by said regulations. Individuals who will be operating the X-ray systems and who are not subject to licensure under R5-68.1-RAD shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. As a minimum, such instruction shall consist of subjects outlined in Appendix B to Part F of these Regulations.

(b) The names and qualifications of all personnel operating X-ray equipment for healing arts use must be kept on file for Agency inspection at each facility location.

(c) Effective 1 July 2014, all individuals operating fluoroscopic X-ray systems shall have completed at least the following training before using fluoroscopy independently:

(1) Biological effects of X-ray;

(2) Principles of radiation protection;

(3) Factors affecting fluoroscopic outputs;

(4) Dose reduction techniques for fluoroscopic X-ray systems;

(5) Principles and operation of the specific fluoroscopic X-ray system(s) to be used;

(6) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and

F.2.3(c)(7)

(7) Applicable requirements of these Regulations.

(d) Effective 1 July 2014, the registrant shall either provide in-service training for all operators of fluoroscopic x-ray systems used for high dose, high risk procedures, as defined in F.4.15 of these Regulations, at intervals not to exceed twenty-four (24) months or require evidence of continuing medical education, in fluoroscopic radiation safety and patient dose management at intervals not to exceed twenty-four (24) months.

(e) Documentation pertaining to the requirements of F.2.3(c) and (d) of these Regulations shall be maintained for review for three (3) years.

F.2.4 Written technique information shall be provided in the vicinity of the diagnostic X-ray system's control panel, which specifies, for all examinations performed with that system, the following information:

(a) Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

(b) Equivalent manual technique information if AEC is not available;

(c) Type and size of the image receptor combination to be used, if any;

(d) Source to image receptor distance to be used (except for dental intraoral radiography, which shall list cone length to be used);

(e) Type and location of placement of patient shielding (e.g., gonad, thyroid, lap apron, etc.); and

(f) For mammography, indication of kVp/target/filter combination and, if phototimed setting is used, the density setting.

F.2.5 The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

F.2.6 Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material.

(b) 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 material.

(c) 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 or shall be so positioned that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor.

(d) Written safety procedures, as required by F.2.5, shall describe how the requirements of this section will be met when using mobile or portable X-ray systems.

F.2.7 Gonadal shielding of not less than 0.5 millimeter lead equivalent material shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

F.2.8

F.2.8 Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes, and exposure of an individual for the purpose of healing arts screening except as authorized by F.2.12.

F.2.9 **When a Patient or Image Receptor Must be Provided with Auxiliary Support During a Radiation Exposure:**

(a) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by F.2.5, shall list individual projections where holding devices cannot be utilized;

(b) Written safety procedures, as required by F.2.5, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(c) The human holder shall be instructed in personal radiation safety and protected as required by F.2.6;

(d) No individual shall be used routinely to hold image receptor or patients;

(e) In those cases where the patient must hold the image receptor, except during dental examinations covered in Subpart F.6, 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

(f) Each facility shall have protective aprons and gloves available in sufficient numbers to provide protection for all personnel who are involved with X-ray operations and who are otherwise not shielded.

(g) A record shall be made of the examination and shall include the name of the human holder; date of the examination, number of exposures and technique factors utilized for the exposure(s).

F.2.10 Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(a) The fastest imaging system consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

(d) Facilities shall establish and implement a quality assurance program for X-ray film processing, whether processing is manual or automatic.

(e) **X-ray Film Processing Facilities and Practices.** Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions.

(1) **Manual Processing of Films:**

(i) Processing of film: The temperature of solutions in the tanks shall be maintained within the range of 60^{o} F to 80^{o} F (16^{o} C to 27^{o} C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

(ii) Devices shall be utilized which will:

(a) Indicate the actual temperature of the developer; and

F.2.10(e)(1)(ii)(b)

(b) Give an audible or visible signal indicating the termination of a preset time.

(iii) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

(2) **Automatic Processors and Other Closed Processing Systems.**

(i) Films shall be processed in accordance with the time temperature relationships recommended by the film manufacturer; and

(ii) Processing deviations from the requirements of F.2.10(e)(2)(i) shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

(f) **[RESERVED]**

(g) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(1) Be positioned properly (i.e., tube side facing the proper direction) and grid centered to the central ray.

(2) If of the focused type, be of the proper focal distance for the SID being used.

(h) **Other Requirements:**

(1) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(2) The darkroom shall be light-tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.05 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling systems shall preclude fogging of the film.

(3) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(4) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light-tight container.

(5) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to assure radiographs of good diagnostic quality.

(6) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

(7) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(i) The tube housing and the position indicating device (PID) for a permanently mounted intraoral dental system shall not be hand-held during an exposure. Appendix D specifies requirements for the use of intraoral dental radiographic units designed to be hand-held during patient examination.

(j) Dental fluoroscopy without image intensification shall not be used.

F.2.11 All individuals who are associated with the operation of an X-ray system are subject to the applicable

requirements of Part A of these Regulations.

F.2.12

F.2.12 **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 A of this part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

F.2.13 **Information and Maintenance Record and Associated Information.** The registrant shall maintain the following information in a separate file or package in chronological order for each X-ray system, for inspection by the Agency:

(a) Maximum rating of technique factors;

(b) Model and serial numbers of all major components, and user's manuals for those components;

(c) Aluminum equivalent filtration in the useful beam, including any routine variation;

(d) Tube rating charts and cooling curves;

(e) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) after 2 June 1978 with the names of persons who performed such services;

(f) A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimate of the extent of occupancy by an individual in such areas. In addition, the drawing shall include 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 the type and thickness of materials, or lead equivalency, of each protective barrier.

(g) A copy of all correspondence with this Agency regarding that X-ray system.

F.2.14 **X-Ray Utilization Log.**

(a) Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. The record shall also include the following information:

(1) Name of the licensed practitioner of the healing arts ordering the examination.

(2) Name(s) of individuals who performed the examination.

(3) Any deviation from the standard procedure as specified on the technique chart, including all repeat exposures.

(4) When applicable, the fluoro recordkeeping requirements of F.4.3(e).

(5) When applicable, the X-ray system used.

(6) When the patient or image receptor must be provided with human auxiliary support, the name of the human holder.

(b) X-ray utilization logs shall be maintained for a minimum of five (5) years following the examination or treatment of adult patients. Records of examination or treatment of minors shall be maintained for a minimum of five (5) years beyond the age of majority.

(c) If X-ray utilization logs are stored electronically, records shall be maintained in a manner that will allow retrieval of records for any specified time period.

F.2.15 **Report and Notification of a Dose to an Embryo/Fetus.**

(a) A registrant 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 radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring physician.

(b) The registrant shall notify the Agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report in F.2.15(a).

(c) The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of a dose to the embryo/fetus that requires a report in F.2.15(a).

(1) The written report shall include:

(i) The registrant's name and registration number;

(ii) The name of the referring physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the registrant notified the pregnant individual (or the pregnant individual's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's name or any other information that could lead to identification of the individual.

(d) The registrant shall provide notification of the event to the referring physician and also notify the pregnant individual, no later than twenty-four (24) hours after discovery of an event that would require reporting under F.2.15(a), unless the referring physician personally informs the registrant either that he or she will inform the pregnant individual or that, based on medical judgment, telling the pregnant individual would be harmful. The registrant is not required to notify the pregnant individual without first consulting with the referring physician. If the referring physician or pregnant individual cannot be reached within twenty-four (24) hours, the registrant shall make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the pregnant individual's responsible relative or guardian instead of the pregnant individual. If a verbal notification is made, the registrant shall inform the pregnant individual, or the pregnant individual's responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(e) A registrant shall:

(1) Annotate a copy of the report provided to the Agency with the:

(i) Name of the pregnant individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the pregnant 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 registrant, no later than fifteen (15) days after the discovery of the event.

F.3 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS

F.3.1 In addition to other requirement of Part F, all diagnostic X-ray systems shall meet the requirements of Subpart F.3.

F.3.2 **Maintaining Compliance.** Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

F.3.3 **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 and maintenance schedules are observed"**.

F.3.4 **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.

F.3.5 **Leakage Radiation from the Diagnostic Source Assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma [100 milliroentgen (mR) exposure] in one (1) hour when the X-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) centimeters.

F.3.6 **Radiation from Components Other Than the Diagnostic Source Assembly.** The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of eighteen (18) μgray (two (2) milliroentgens exposure) in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20).

F.3.7 **Beam Quality.**

(a) **Half-Value Layer (HVL)**

(1) The HVL of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table 1 of F.3.7 under the heading "Specified Dental Systems," for any dental X-ray system designed for use with intraoral image receptors and manufactured after 1 December 1980; under the heading," Other X-Ray Systems2" for any dental X-ray system designed for use with intraoral image receptors and manufactured before or on 1 December 1980, and all other X-ray systems subject to this section and manufactured before 10 June 2006; and under the heading, "Other X-Ray Systems3" for all X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after 10 June 2006. 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. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent X-ray emissions if the minimum required filtration is not in place.

F.3.7(a)(2)

(2) Optional Filtration. Fluoroscopic systems manufactured on or after 10 June 2006, incorporating an X-ray tube(s) with a continuous output of one (1) kilowatt or more and an anode heat storage capacity of one-million (1,000,000) heat units or more shall provide the option of adding X-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of F.3.7(a)(1). The selection of this additional X-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the X-ray beam shall be provided.

(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(c) **Measuring Compliance**. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

TABLE 1
X-Ray Tube Voltage (kilovolt peak)

Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems[1]	Other X-Ray Systems[2]	Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental X-ray systems designed for use with intraoral image receptors and manufactured after 1 December 1980

[2] Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on 1 December 1980, and all other X-ray systems subject to this section and manufactured before 10 June 2006

[3] All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after 10 June 2006.

F.3.7(d)

(d) **Aluminum Equivalent of Material Between Patient and Image Receptor.** Except when used in a CT X-ray system, the aluminum equivalent of each of the items listed in Table 2 of F.3.7, which are used between the patient and the image receptor, shall not exceed the indicated limits. Compliance shall be determined by X-ray measurements made at a potential of one-hundred (100) kilovolts peak and with an X-ray beam that has an HVL specified in Table 1 of F.3.7 for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE 2

ITEM	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Film panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

(e) **Modification of Certified Diagnostic X-ray Components and Systems.**

(1) Diagnostic X-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of Part F of these Regulations unless a variance in accordance with 21 CFR 1010.4 or an exemption under §534(a)(5) or §538(b) of the Federal Food, Drug, and Cosmetic Act has been granted..

(2) The owner of a diagnostic X-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of Part F of these Regulations. The owner who causes such modification need not submit the reports required by these Regulations, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the X-ray system does not result in a failure to comply with these Regulations.

(f) **kVp Limitations**. Dental X-ray machines with a nominal fixed kVp of less than fifty (50) kVp shall not be used to make diagnostic dental radiographs of humans.

F.3.8 **Multiple Tubes.** Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

F.3.9

F.3.9 **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.

F.3.10 **Technique Indicators.**

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic EXPOSURE controls are used, the technique factors which are set prior to the exposure shall be indicated.

(b) The requirement of F.3.10(a) 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.

F.3.11 **Structural Shielding.** Structural shielding shall be provided whenever necessary to meet the requirements of A.2.3 and A.2.11, in addition to specific requirements contained in other parts of these Regulations.

F.3.12 **Locks.** All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

F.3.13 **Use of Calibrated Dosimetry System.** The measurement of the radiation output of an X-ray system shall be performed with a calibrated dosimetry system. The calibration of such a system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two (2) years.

F.3.14 **Reports and Notifications of Radiation Medical Events.**

(a) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of ionizing radiation from a diagnostic radiation machine:

(1) Results in a patient or human research subject receiving an unintended dose to the skin greater than two (2) Gy [two-hundred (200) rads] to the same area for a procedure or series; or

(2) Results in a patient or human research subject receiving an unintended dose greater than five-hundred (500) mGy [fifty (50) rads] to an organ/tissue; or

(3) Results in a patient or human research subject receiving an unintended dose greater than fifty (50) mSv [five (5) rem] total effective dose; or

(4) Involves the wrong patient or wrong site for the entire diagnostic exam (procedure or service)[77] and exceeds five-hundred (500) mGy [fifty (50) rads] to an organ/tissue or fifty (50) mSv [five (5) rem] total effective dose; or

(5) Involves equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds fifty (50) mGy [five (5) rads] total effective dose.

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[77] Any wrong patient or wrong site imaged regardless of dose received should be reported, documented and addressed internally within the facility.

F.3.14(b)

(b) The registrant shall notify the Agency by telephone[78] no later than the next calendar day after discovery of the radiation medical event.

(c) The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of the radiation medical event. The written report shall include:

(1) The registrant's name;

(2) Date of event and date discovered;

(3) The total estimated dose received;

(4) The imaging procedure(s) performed;

(5) The type of equipment in use (e.g., CT, fluoroscopy, radiographic, other);

(6) The manufacturer and model of the unit used:

(7) Why the event occurred;

(8) How the event was discovered;

(9) The effect, if any, on the individuals(s) who is the subject of the radiation medical event;

(10) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(11) Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

(12) If there was notification, what information was provided to the individual.

(d) The report shall not contain the individual's name or any other information that could lead to the identification of the individual. To meet the requirements of F.3.14, the notification of the individual who is the subject of the radiation medical event may be made instead to that individual's responsible relative or guardian, when appropriate.

(e) (1) The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the radiation medical event no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four (24) hours, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the radiation medical event, because of any delay in notification.

(2) To meet the requirements of F.3.14(a)(1), the notification of the individual who is the subject of the radiation medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that either a copy of the report that was submitted to the Agency, or a written description of both the event and the consequences as they may effect the can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

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[78] During normal business hours, the Agency may be contacted at (401) 222-2566. At other times, this number will allow you to leave a message on the answering machine. In case of an emergency when it is necessary to immediately contact the Agency, utilize the RI Department of Health 24 hour number [(401) 272-5952] and indicate the nature of your emergency. FAX communication may be sent 24 hours a day to (401) 222-5901.

F.3.14(f)

(f) Aside from the notification requirement, nothing in F.3.14 affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the radiation medical event, or to that individual's responsible relatives or guardians.

(g). The registrant shall retain a record of a radiation medical event in accordance with F.3.15. A copy of the record required shall be provided to the referring physician if other than the registrant within fifteen (15) days after discovery of the radiation medical event.

F.3.15 **Records of Radiation Medical Events.** A registrant shall retain a record of radiation medical events reported in accordance with F.3.14 for three (3) years. The record shall contain the following:

(a) The registrant's name and the names of the individuals involved (including allied health personnel, the individual who is the subject of the radiation medical event, and the individual's referring physician, if applicable);

(b) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the radiation medical event;

(c) A brief description of the event; why it occurred; the effect, if any, on the individual;

(d) The actions, if any, taken or planned to prevent recurrence; and

(e) Whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

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F.4 FLUOROSCOPIC EQUIPMENT

F.4.1 The provisions of Subpart F.4 apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography X-ray systems manufactured on or after 29 November 1984.

F.4.2 **Primary Protective Barrier.**

(a) **Limitation of Useful Beam.** The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam. The air kerma (exposure) rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34x10-3 percent of the entrance air kerma (exposure) rate, at a distance of ten (10) cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

(b) **Measuring Compliance.** The air kerma (exposure) rate shall be measured in accordance with F.4.6. The air kerma (exposure) rate due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm2) with no linear dimension greater than twenty (20) cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than thirty (30) cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam ten (10) cm from the point of measurement of entrance air kerma (exposure) rate and between this point and the input surface of the fluoroscopic imaging assembly.

F.4.3 **Equipment Operation.**

(a) All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

(b) The operation of mobile or portable fluoroscopic x-ray systems, for positioning purposes only, by radiologic technologists shall be performed under the direct supervision of a licensed practitioner of the healing arts who meets the requirements of F.2.3(c) of these Regulations.

(c) Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless in the physical presence of a licensed practitioner of the healing arts and a radiologic technologist, as specified in F.2.3(c) of these Regulations.

(d) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(e) Each registrant that uses fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of images recorded from the fluoroscopic image receptor for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name. The record shall be maintained for five (5) years.

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F.4.4

F.4.4 **Field Limitation**.

(a) **Angulation.** For fluoroscopic equipment manufactured after 25 February 1978, when the angle between the image receptor and the beam axis of the X-ray beam 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. Compliance with F.4.4(d) and (e) shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(b) **Further Means for Limitation.** Means shall be provided to permit further limitation of the X-ray field to sizes smaller than the limits of F.4.4(d) and (e). Beam-limiting devices manufactured after 22 May 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than three-hundred square cm (300 cm2), shall be provided with means for stepless adjustment of the X-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than three-hundred square cm (300 cm2) shall be provided with either stepless adjustment of the X-ray field or with a means to further limit the X-ray field size at the plane of the image receptor to one-hundred twenty five square cm (125 cm2) or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five (5) cm by five (5) cm. This paragraph does not apply to non-image-intensified fluoroscopy.

(c) **Non-Image-Intensified Fluoroscopy.** The X-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.

(d) **Fluoroscopy and Radiography Using the Fluoroscopic Imaging Assembly With Inherently Circular Image Receptors.**

(1) For fluoroscopic equipment manufactured before 10 June 2006, other than radiation therapy simulation systems, the following applies:

(i) Neither the length nor 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 three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

(ii) For rectangular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(2) For fluoroscopic equipment manufactured on or after 10 June 2006, other than radiation therapy simulation systems, the maximum area of the X-ray field in the plane of the image receptor shall conform with one of the following requirements:

(i) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to thirty-four (34) cm in any direction, at least eighty percent (80%) of the area of the X-ray field overlaps the visible area of the image receptor, or

(ii) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than thirty-four (34) cm in any direction, the X-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two (2) cm.

F.4.4(e)

(e) **Fluoroscopy and Radiography Using Fluoroscopic Imaging Assembly With Inherently Rectangular Image Receptors.** For X-ray systems manufactured on or after 10 June 2006, the following applies:

(1) Neither the length nor 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 three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

(2) 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.

(f) **Override Capability.** If the fluoroscopic X-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

F.4.5 **Activation of the Tube.** X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images from the fluoroscopic image receptor, the operator shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

F.4.6 **Air Kerma (Exposure) Rates**. For fluoroscopic equipment, the following requirements apply:

(a) Fluoroscopic equipment manufactured before 19 May 1995.

(1) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in F.4.6(c), except as specified in F.4.6(a)(5).

(2) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in F.4.6(c), except as specified in F.4.6(a)(5)..

(3) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in F.4.6(c), except as specified in F.4.6(a)(5).

(4) Equipment may be modified in accordance with F.3.7(e)(1) to comply with F.4.6(b). When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

(5) Exceptions:

(i) During recording of fluoroscopic images, or

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F.4.6(a)(5)(ii)

(ii) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of the rates specified in F.4.6(a)(1), (2) and (3) at the measurement point specified in F.4.6(c), unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is being employed.

(b) Fluoroscopic equipment manufactured on or after 19 May 1995.

(1) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an air kerma (exposure) rate greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in F.4.6(c). Provision for manual selection of technique factors may be provided.

(2) Shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in F.4.6(c), except as specified in F.4.6(b)(3).

(3) Exceptions:

(i) For equipment manufactured prior to 10 June 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the X-ray source is operated in a pulsed mode.

(ii) For equipment manufactured on or after 10 June 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(iii) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in F.4.6(c). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is employed.

F.4.7 **Measurement of Entrance Air Kerma (Exposure) Rate.** Measurement of entrance air kerma (exposure) rate shall be performed for both maximum and typical values and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the air kerma (exposure) rate. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results during the fluoroscopic procedure and in the record required in F.2.13(e). Results of the measurements shall include the mGy per minute (R/min exposure rate), as well as the technique factors used to determine such results. The name of the Qualified Medical Physicist performing the measurements and the date the measurements were performed shall be included in the results.

(a) Conditions of measurement of maximum entrance air kerma (exposure) rate are as follows:

(1) The measurements shall be made under conditions that satisfy the requirements of F.4.6(a) & (b);

(2) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum air kerma (exposure) rate; and

F.4.7(a)(3)

(3) An X-ray system that incorporates automatic exposure rate control (AERC) shall have sufficient material placed in the useful beam to produce the maximum output of that system.

(b) Conditions of measurement of typical air kerma (exposure) rate are as follows:

(1) The measurements shall be made under conditions that satisfy the requirements of F.4.7(c) and are typical of clinical use of the X-ray system;

(2) The kVp shall be that typical of clinical use of the X-ray system;

(3) An X-ray system(s) that incorporates AERC shall have sufficient material placed in the useful beam to produce operating parameters typical of the use of the X-ray system; and

(4) An X-ray system(s) that does not incorporate an AERC shall utilize a milliamperage typical of the clinical use of the X-ray system.[79]

(c) **Measuring Compliance.** Compliance with this subsection shall be determined as follows:

(1) If the source is below the X-ray table, the air kerma (exposure) rate shall be measured at one (1) cm above the tabletop or cradle.

(2) If the source is above the X-ray table, the air kerma (exposure) rate shall be measured at thirty (30) cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(3) In a C-arm type of fluoroscope, the air kerma (exposure) rate shall be measured at thirty (30) cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than thirty (30) cm from the input surface of the fluoroscopic imaging assembly.

(4) In a C-arm type of fluoroscope having an SID less than forty-five (45) cm, the air kerma (exposure) rate shall be measured at the minimum SSD.

(5) In a lateral type of fluoroscope, the air kerma (exposure) rate shall be measured at a point fifteen (15) cm from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it 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 fifteen (15) cm to the centerline of the X-ray table.

F.4.8 **[DELETED]**

F.4.9 **[RESERVED]**

F.4.10 **Indication of Potential and Current.** During fluoroscopy and cinefluorography, the X-ray tube potential and current shall be continuously indicated. Deviation of X-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer. shall be continuously indicated.

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[79] Material should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

F.4.11

F.4.11 **Source-Skin Distance.**

(a) Means shall be provided to limit the source-skin distance to not less than thirty-eight (38) cm on stationary fluoroscopes and to not less than thirty (30) cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operating at shorter source-skin distances but in no case less than twenty (20) cm.

(b) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after 10 June 2006, having a maximum source-image receptor distance of less than forty-five (45) cm, means shall be provided to limit the source-skin distance to not less than nineteen (19) cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than ten (10) cm.

F.4.12 **Fluoroscopic Irradiation Time, Display and Signal.**

(a) Fluoroscopic equipment manufactured before 10 June 2006

(1) Shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the operator shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of F.4.12. When the equipment is modified, it shall bear a label indicating the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

(b) For X-ray controls manufactured on or after 10 June 2006, there shall be provided for each fluoroscopic tube:

(1) A display of the fluoroscopic irradiation time at the operator's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply:

(i) When the X-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six (6) seconds.

(ii) The fluoroscopic irradiation time shall also be displayed within six (6) seconds of termination of an exposure and remain displayed until reset.

(iii) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

(2) A signal audible to the operator shall sound for each passage of five (5) minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two (2) seconds.

F.4.13 **Mobile and Portable Fluoroscopes.** In addition to the other requirements of Subpart F.4, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

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F.4.14 **Control of Scattered Radiation**.

(a) 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.

(b) 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:

(1) Is at least one-hundred twenty (120) centimeters from the center of the useful beam, or

(2) The radiation has passed through not less than 0.25 millimeter lead equivalent material (e.g., drapes, Bucky-slot cover-sliding or folding panel, or self supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in F.2.6.

(c) The Agency may grant exemptions to F.4.14(b) 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.

F.4.15 **Patient Dose Evaluation.**

(a) Each registrant performing fluoroscopically-guided interventional procedures shall develop written policies and procedures to:

(1) Identify those procedures which have a potential to result in patient doses exceeding the threshold for injury;

(2) Reduce the probability of such exposures; and

(3) Ensure that appropriate action occurs for patients receiving doses that warrant follow-up.

(b) The registrant shall have a patient dose monitoring procedures in place and shall document (in the patient's medical record) an estimate of the absorbed dose to the skin. When the fluoroscopy unit is equipped with an Air-Kerma dose readout, the recording of this value shall suffice as a patient dose record.

(c) The registrant shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury (i.e., a cumulative absorbed dose to the skin equal to or greater than 1 Gy (100 rads)). This evaluation shall be noted in the patients medical record and reviewed by the Radiation Safety Committee[80].

F.4.16 **Radiation Therapy Simulation Systems.**

(a) Radiation therapy simulation systems shall be exempt from the requirements of F.4.2(a), provided such systems are intended only for remote control operation.

(b) Radiation therapy simulation systems shall be exempt from all the requirements of F.4.4(d), F.4.6 and F.5.12(b)(2) when used for therapy simulation purposes.

(c) As an alternative to the requirements of F.4.12, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which X-rays were produced, and which is capable of being reset between X-ray examinations.

[80] If the registrant does not have a Radiation Safety Committee, the review shall be conducted by the Radiation Safety Officer and the registrant's medical physicist.

F.4.17

F.4.17 **Display of Last-Image-Hold (LIH).** Fluoroscopic equipment manufactured on or after 10 June 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

(a) For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

(b) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

(c) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

F.4.18 **Displays of Values of Air Kerma (Exposure) Rate and Cumulative Air Kerma.** Fluoroscopic equipment manufactured on or after 10 June 2006, shall display at the operator's working position the air kerma (exposure) rate and cumulative air kerma. The following requirements apply for each X-ray tube used during an examination or procedure:

(a) When the X-ray tube is activated and the number of images produced per unit time is greater than six (6) images per second, the air kerma (exposure) rate in mGy/min shall be continuously displayed and updated at least once every second.

(b) The cumulative air kerma in units of mGy shall be displayed either within five (5) seconds of termination of an exposure or displayed continuously and updated at least once every five (5) seconds.

(c) The display of the air kerma (exposure) rate shall be clearly distinguishable from the display of the cumulative air kerma.

(d) The air kerma (exposure) rate and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

(1) For fluoroscopes with X-ray source below the X-ray table, X-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in F.4.7(c)(1), (c)(2) or (c)(5).

(2) For C-arm fluoroscopes, the reference location shall be fifteen (15) cm from the isocenter toward the X-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the X-ray beam with the patient's skin.

(e) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(f) The displayed air kerma (exposure) rate and cumulative air kerma shall not deviate from the actual values by more than ± thirty-five percent (± 35%) over the range of 6 mGy/min and 100 mGy to the maximum indication of air kerma (exposure) rate and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three (3) seconds.

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F.5 RADIOGRAPHIC EQUIPMENT[81]

F.5.1 **Beam Limitation, Except Mammographic Systems.** The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of F.3.2 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

F.5.2 **Radiation Exposure Control.**

(a) **Exposure Initiation.** Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(b) **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.

(c) **Operator Protection, Except Veterinary Systems.**

(1) **Stationary Systems.** Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(2) **Mobile and Portable Systems.** Mobile and portable X-ray systems which are:

(i) Used continuously for greater than one (1) week in the same location (i.e., a room or suite) shall meet the requirements of F.5.2(c)(1);

(ii) Used for less than one (1) week at the same location shall be provided with either a protective barrier at least two (2) meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

(d) **Operator Protection for Veterinary Systems**.

(1) All stationary, mobile or portable X-ray systems used for veterinary work shall be provided with either a two (2) meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures. 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. Refer to Appendix D for hand-held intraoral dental radiographic units used in veterinary practice.

(2) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If necessary, general anesthesia, sedation or tranquilization 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 shall be so positioned that no part of their body will be struck by the useful beam. No individual shall be used routinely to hold animals or film during radiation exposures. The exposure of any individual used for this purpose shall be monitored, and a record shall be made of the examination, including the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).

[81] Dental intra-oral radiographic equipment previously regulated pursuant to Subpart F.6 of these Regulations is now being regulated pursuant to Subpart F.5. Subpart F.6 has been deleted in its entirety.

F.5.3 **Control and Indication of Technique Factors.**

(a) **Visual Indication**. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the operator.

(b) **Timers.** Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(1) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half (0.5) second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(2) During serial radiography, the operator shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(c) **Automatic Exposure Controls.** When an automatic exposure control is provided:

(1) Indication shall be made on the control panel when this mode of operation is selected;

(2) When the X-ray tube potential is equal to or greater than fifty-one (51) kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver five (5) milliampere-seconds (mAs), whichever is greater;

(3) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than sixty (60) kilowatt-seconds (kWs) per exposure or the product of X-ray tube current and exposure time shall be limited to not more than six-hundred (600) mAs per exposure, except when the X-ray tube potential is less than fifty-one (51) kVp, in which case the product of X-ray tube current and exposure time shall be limited to not more than two-thousand (2,000) mAs per exposure; and

(4) A visible signal shall indicate when an exposure has been terminated at the limits described in F.5.3(c)(3), and manual resetting shall be required before further automatically timed exposures can be made.

(d) **Accuracy.** Deviation of technique factors from indicated values shall not exceed the limits given by the manufacturer.

F.5.4 **Positive Beam Limitation (PBL).** The requirements of F.5.4 shall apply to radiographic systems which contain PBL.

(a) **Field Size.** When a PBL system is provided, it shall prevent X-ray production when:

(1) Either the length or width of the X-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three percent (3%) of the SID; or

(2) The sum of the length and width differences stated in F.5.4(a)(1) without regard to sign exceeds four percent (4%) of the SID.

(3) The beam-limiting device is at an SID for which PBL is not designed for sizing.

F.5.4(b)

(b) **Conditions For PBL**. When provided, the PBL system shall function as described in §F.5.4(a) whenever all the following conditions are met:

(1) The image receptor is inserted into a permanently mounted cassette holder;

(2) The image receptor length and width are less than fifty (50) cm;

(3) The X-ray beam axis is within ± three degrees (±3°) of vertical and the SID is ninety (90) cm to one-hundred thirty (130) cm inclusive; or the X-ray beam axis is within ± three degrees (±3°)of horizontal and the SID is ninety (90) cm to two-hundred five (205) cm inclusive;

(4) The X-ray beam axis is perpendicular to the plane of the image receptor to within ± three degrees (±3°); and

(5) Neither tomographic nor stereoscopic radiography is being performed.

(c) **Measuring Compliance**. Compliance with the requirements of §F.5.4(a) 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.5.4(b) are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

(d) **Operator Initiated Undersizing**. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of one-hundred (100) cm shall be equal to or less than five (5) cm. Return to PBL function as described in §F.5.4(a) shall occur automatically upon any change of image receptor size or SID.

(e) **Override of PBL**. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

F.5.5 **Source-to-Skin Distance.**

(a) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(1) Eighteen (18) cm if operable above fifty (50) kVp; or

(2) Ten (10) cm if not operable above fifty (50) kVp.

(b) Mobile and portable X-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than thirty (30) cm.

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F.5.6

F.5.6 **Air Kerma (Exposure) Reproducibility.** The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

(a) For any specific combination of selected technique factors, the coefficient of variation of the air kerma (exposure) shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four **EXPOSURES** are made at identical technique factors, the value of the average **EXPOSURE** (E) is greater than or equal to 5 times the maximum **EXPOSURE** (E_{max}) minus the minimum **EXPOSURE** (E_{min});

$$\text{i.e., } E \geq 5\ (E_{max} - E_{min}).$$

(b) For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of twelve (12) pulses on field emission equipment rated for pulsed operation or no less than one-tenth (0.1) second per exposure on all other equipment.

F.5.7 **Radiation from Capacitor Energy Storage Equipment.** Radiation emitted from the X-ray tube shall not exceed:

(a) An air kerma of 0.26 μGy (0.03 mR exposure) in one (1) minute at five (5) cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of one-hundred square cm (100 cm^2), with no linear dimensions greater than twenty (20) cm: and

(b) An air kerma of 0.88 mGy (100 mR exposure) in one (1) hour at one-hundred (100) cm from the X-ray source, with beam-limiting device fully open, when the system is discharged through the X-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total projected number of discharges in one (1) hour. The measurements shall be averaged over an area of one-hundred square cm (100 cm^2)with no linear dimension greater than twenty (20) cm.

F.5.8 **Tube Stands for Portable X-Ray Systems.** A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be hand-held during exposures.

F.5.9 **Measurement of Radiation Output.**

(a) Measurement of the radiation output shall be performed at a specified distance and over a range of clinical kVp values, and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the radiation output. These measurements shall be performed in-air with minimum scatter conditions. Results of the measurements shall include the μGy/mAs (mR/mAs), as well as the technique factors used to determine such results.

(b) The name and signature of the Qualified Medical Physicist performing the measurements, and the date the measurements were performed, shall be included in the results.

(c) These measurements may be used to estimate entrance skin exposure (ESE) for the average adult patient for selected routine radiographic procedures. These values should be compared with available national reference values.

F.5.10 **Beam-on Indicators.** The X-ray control shall provide visual indication whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

F.5.11 **Primary Protective Barrier For Mammography X-ray Systems.**

(a) For X-ray systems manufactured after 5 September 1978, and before 30 September 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 μGy (0.1 mR exposure) for each activation of the tube.

(b). For mammographic X-ray systems manufactured on or after 30 September 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(2) The X-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in F.5.11(b)(1).

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 μGy (0.1 mR exposure) for each activation of the tube.

(c) Compliance with the requirements of F.5.11(a) and (b)(3) for transmission shall be determined with the X-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of X-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of one-hundred square cm (100 cm^2) with no linear dimension greater than twenty (20) cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

F.5.12 **Field Limitation and Alignment for Mobile, Portable and Stationary General Purpose X-ray Systems.** Except when spot-film devices are in service, mobile, portable and stationary general purpose radiographic X-ray systems shall meet the following requirements:

(a) **Variable X-ray Field Limitation.** A means for stepless adjustment of the size of the X-ray field shall be provided. Each dimension of the minimum field size at an SID of one-hundred (100) cm shall be equal to or less than five (5) cm.

(b) **Visual Definition**.

(1) Means for visually defining the perimeter of the X-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

(2) When a light localizer is used to define the X-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at one-hundred (100) cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field.

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F.5.12(c)(3)

(3) The edge of the light field at one-hundred (100) cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance three (3) mm from the edge of the light field toward the center of the field; and I_2 is the illuminance three (3) mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one (1) mm.

(c) (1) Portable X-ray systems shall have an evaluation of light field vs. X-ray field alignment performed at least every six (6) months to determine compliance with both F.5.12(b)(1) and F.5.13(c).

(2) Portable X-ray systems shall have an evaluation of centering alignment performed at least every six (6) months to determine compliance with F.5.13(a).

F.5.13 **Field Indication and Alignment on Stationary General Purpose X-ray Equipment.** Except when spot-film devices are in service, stationary general purpose X-ray systems shall meet the following requirements in addition to those prescribed in F.5.12:

(a) Means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);

(b) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(c) Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(d) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic X-ray system is uniquely designed to operate.

F.5.14 **Linearity**. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed X-ray tube potential within the range of forty percent (40%) to one-hundred percent (100%) of the maximum rated:

(a) **Equipment Having Independent Selection of X-Ray Tube Current (mA)**. The average ratios (X_i) of air kerma (exposure) to the indicated milliampere-seconds product (mGy/mAs or mR/mAs) obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs (mR/mAs) values obtained at each of two (2) consecutive tube current settings, or at two (2) settings differing by no more than a factor of two (2) where the mA selector provides continuous selection.

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F.5.14(b)

(b) **Equipment Having Selection of X-Ray Tube Current-Exposure Time Product (mAs)**. For equipment manufactured after 3 May 1994, the average ratios of air kerma (exposure) to the indicated milliampere-seconds product (mGy/mAs or mR/mAs) obtained at any two (2) consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1\text{-}X_2 \leq 0.10\,(X_1 + X_2)$$

where X1 and X2 are the average mGy/mAs values obtained at any two (2) consecutive mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

(c) **Measuring Compliance.** Determination of compliance will be based on consecutive exposures, made within one (1) hour. These settings may include any two (2) focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the X-ray tube manufacturer.

F.5.15 **Field Limitation on Radiographic X-ray Equipment Other Than General Purpose Radiographic Systems**

(a) Equipment for Use With Intraoral Image Receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is eighteen (18) cm or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven (7) cm; and

(2) If the minimum SSD is less than eighteen (18) cm, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six (6) cm.

(b) **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 image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

(c) **Systems Designed for Mammography.**

(1) Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after 1 November 1977, and before 30 September 1999, shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in F.5.15(d)(1), (2) and (3). When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in F.5.15(d)(2) and (3) shall be the maximum SID for which the beam-limiting device or aperture is designed.

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F.5.15(c)(2)

(2) Mammographic beam-limiting devices manufactured on or after 30 September 1999, shall be provided with a means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in F.5.15(d)(1), (2) and (3). For systems that allow changes in SID, the SID indication specified in F.5.15(d) (2) and (3 shall be the maximum SID for which the beam-limiting device or aperture is designed.

(3) Each image receptor support device manufactured on or after 1 November 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(d) **Other X-ray Systems**. Radiographic systems not specifically covered in F.5.12, F.5.13, F.5.15(b), F.5.15(c), F.5.16, and systems covered in F.5.15(a), which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and alignment the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(1) A system which performs in accordance with F.5.12 and F.5.13; or when alignment means are also provided, may be met with either;

(2) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(3) 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.

F.5.16 **Field Limitation and Alignment for Spot-Film Devices**. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(a) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the X-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the X-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(b) Neither the length nor width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID. On spot film devices manufactured after 25 February 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.

F.5.16(c)

(c) The center of the X-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent (2%) of the SID.

(d) Means shall be provided to reduce the X-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(1) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the X-ray field, the minimum field size, at the greatest SID, does not exceed one-hundred twenty-five square cm (125 cm^2); or

(2) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.

(e) A capability may be provided for overriding the automatic X-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic X-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

F.6 [RESERVED]

F.7 [RESERVED]

F.8 [RESERVED]

F.9 [RESERVED]

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

F.10 COMPUTED TOMOGRAPHY SYSTEMS

F.10.1 **Requirements for Equipment.**

(a) **Applicability.** Unless otherwise specified, the requirements for equipment contained in F.10.1 are applicable to CT X-ray systems manufactured or remanufactured on or after 3 September 1985.

(b) **Termination of Exposure.**

(1) Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than one hundred ten percent (110%) of its preset value through the use of either a backup timer or devices which monitor equipment function.

(2) A visible signal shall indicate when the X-ray exposure has been terminated through the means required by F.10.1(b)(1).

(3) The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half (0.5) second duration.

(c) **Tomographic Plane Indication and Alignment.**

(1) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

(3) If a device using a light source is used to satisfy F.10.1(c)(1) or (2), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to five hundred (500) lux.

(d) **Beam-On and Shutter Status Indicators and Control Switches.**

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) Each emergency button or switch shall be clearly labeled as to its function.

(e) **Indication of CT Conditions of Operation.** The CT system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(f) **Extraneous Radiation.** When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by F.3.5.

(g) **Maximum Surface CTDI Identification.** The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(h) **Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry.**

(1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five (5) millimeters.

F.10.1(h)(2)

(2) If the X-ray production period is less than one-half (0.5) second, the indication of X-ray production shall be actuated for at least one-half (0.5) second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from zero (0) to one hundred (100) kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(4) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

F.10.2 **Facility Design Requirements.**

(a) **Aural Communication.** Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(b) **Viewing Systems.**

(1) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(2) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

F.10.3 **Radiation Output Measurements, Spot Checks, and Operating Procedures.**

(a) **[DELETED]**

(b) **Output Measurements.**

(1) The measurement of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a Qualified Medical Physicist.

(2) The measurement of the radiation output of a CT X-ray system shall be performed:

(i) Before the first medical use following installation or reinstallation of the CT X-ray system; and

(ii) At intervals not to exceed twelve (12) months; and

(iii) After any change or replacement of components which, in the opinion of the Qualified Medical Physicist, could cause a change in the radiation output.

(3) **[DELETED]**

(4) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

F.10.3(b)(4)(i)

(i) CT dosimetry phantoms shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter (g/cm^3). The phantoms shall be at least fourteen (14) centimeters in length and shall have diameters of thirty-two (32.0) centimeters for testing CT X-ray systems designed to image any section of the body and sixteen (16.0) centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

(ii) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(iv) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(5) These radiation output measurements shall be required for a representative type of head and body scans performed at the facility.

(6) The CTDI[82] along the two (2) axes specified in F.10.3(b)(4)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

(7) Procedures for measurement of radiation output shall be in writing. Records of radiation measurements performed shall be maintained for inspection by the Agency.

(8) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be readily available.

(c) **Spot-checks.**

(1) The spot-check procedures shall be in writing and shall have been developed by a Qualified Medical Physicist.

(2) The spot-check procedures shall incorporate the use of a CT imaging phantom which has the capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

(3) Spot-checks shall be evaluated for compliance with tolerance limits specified pursuant to F.10.3(c)(1) at the time the radiation measurements required by F.10.3(b) are performed.

[82] For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

F.10.3(c)(4)

(4) Spot-checks shall include acquisition of images obtained with the CT imaging phantoms. The images shall be retained, until a new set of radiation measurements is performed as follows:

(i) If applicable, photographic copies of the images obtained from the image display device;

(ii) Images stored in digital form on a storage medium compatible with the CT X-ray system; and

(iii) Acceptance criteria for image validation shall be documented.

(5) The registrant shall maintain a record of each spot check required by F.10.3(c) for three (3) years.

(d) **Operating Procedures.**

(1) The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation.

(2) Information shall be readily available regarding the operation of the system. Such information shall include the following:

(i) The latest set of radiation measurements and spot-checks;

(ii) Instructions on the use of the CT imaging phantom, including a schedule of spot-checks appropriate for the system, and allowable variations for the indicated parameters;

(iii) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(iv) Current imaging protocols shall be available at the control panel which specify the CT conditions of operation and the number of scans for each routine examination.

(3) If the measurement of radiation output or spot-check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by a Qualified Medical Physicist, report the problem to the service engineer and notify the Qualified Medical Physicist. The registrant shall maintain a record of all such notifications for three (3) years.

F.10.4 **CT X-ray System Used for Radiation Therapy Simulation.**

(a) A CT X-ray system used solely for radiation therapy simulation is exempt from the specific requirements of Sections F.10.1, F.10.2 and F.10.3, and is only subject to the requirements of Subpart H.10.

(b) A CT X-ray system used for both diagnostic X-ray and radiation therapy simulation is subject to the requirements of both Subpart F.10 and Subpart H.10.

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F.11 MAMMOGRAPHY

F.11.1 **Applicability.**

(a) The provisions of this subpart are in addition to, and not in substitution for, other applicable provisions of these Regulations.

F.11.2 **Certification Requirements**.

(a) Only X-ray systems in compliance with the requirements of the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900 shall be used for screening and diagnostic mammography.

(b) A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

(c) A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

F.11.3 **Retention of Mammography X-rays.** Pursuant to RIGL §23-4.9-1, each mammographic imaging facility that takes a mammography x-ray of any individual within Rhode Island shall keep and maintain that mammography x-ray for the life of the individual. However, any mammography x-ray may be destroyed if the individual has had no contact with the mammographic imaging facility for a period exceeding fifteen (15) years.

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F.12 BONE DENSITOMETRY

F.12.1 Bone densitometry systems shall be:

(a) Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C - Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act.;

(b) Registered in accordance with Part B of these Regulations; and

(c) Maintained and operated in accordance with the manufacturer's specification and recommendations.

F.12.2 **Equipment Requirements.** Systems with stepless collimators shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond two percent (2%) of the SID.

F.12.3 Operators of bone densitometry systems shall be:

(a) Licensed as a practitioner of the healing arts; or

(b) Individuals who possess a current license in accordance with the *Rules and Regulations for the Licensure of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants* [*R5-68.1-RAD*] of the Rhode Island Department of Health, unless the individual is specifically exempted from licensure by Section 2.0 of said regulations; or

(c) Individuals who are not subject to licensure under R5-68.1-RAD and have been instructed in the proper use of the bone densitometry system. As a minimum, such instruction shall include:

(1) Basic radiation protection;

(2) Operating procedures for bone densitometry systems, to include use of various system functions, safety, and maintenance; and

(3) Patient positioning for the types of examinations performed.

F.12.4 During the operation of any bone densitometry system:

(a) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination

(b) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

F.12.5 The registrant shall keep maintenance records for bone densitometry systems as prescribed by F.12.1(c). These records shall be maintained for inspection by the Agency for five (5) years from the date the maintenance action was completed.

F.12.6 Bone densitometry on human patients shall be conducted only:

(a) Under a prescription of a licensed practitioner of the healing arts; or

(b) Under a screening program approved by the Agency.

F.12.7 Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in Appendix A to this Part, and include the name and address of the licensed practitioner of the healing arts who will interpret the screening results.

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F.13 QUALITY ASSURANCE PROGRAM.

F.13.1 Effective 1 July 2014, all registrants[83, 84] of diagnostic X-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

(a) **Administration**:

(1) Written standard operating procedures on radiation protection are reviewed and updated annually by management;

(2) Employee review and written acknowledgement of standard operating procedures and policies on radiation protection;

(3) Credentialing of practitioners, medical physicists, and X-ray equipment operators; and

(4) Record retention in accordance with applicable Rhode Island statutes and regulations, but in no case less than three (3) years.

(b) **Image Processing Equipment**: Compliance with Section F.2.10;

(c) **Radiographic Equipment:**

(1) Compliance with performance standards in Sections F.3 and F.5, as specified by a Qualified Medical Physicist;

(2) Estimated entrance skin exposures for selected patient examinations;

(3) Image printing and viewing equipment;

(4) Evaluation of image quality; and

(5) Radiation protection.

(d) **Fluoroscopic Equipment:**

(1) Compliance with performance standards in Sections F.3 and F.4, as specified by a Qualified Medical Physicist;

(2) Low and high contrast resolution; and

(3) Radiation protection.

(e) **Computerized Tomography Equipment:**

(1) Compliance with performance standards in Section F.10, as specified by a Qualified Medical Physicist;

(2) CT number;

(3) Low and high contrast resolution;

(4) Dosimetry of selected patient examinations to include pediatric patients if applicable;

(5) Image printing and viewing equipment; and

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[83] The requirements of Subpart F.13 do not pertain to diagnostic X-ray imaging equipment subject to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

[84] Registrants performing diagnostic radiography limited to intra-oral dental procedures and/or panoramic procedures and cephalometric procedures which do not utilize an open beam configuration are only required to comply with Sections F.13.1(a)(1), (a)(2), (a)(4) and (b) of Subpart F.13.

F.13.1(e)(6)

(6) Radiation protection.

(f) **Bone Densitometry Equipment: C**ompliance with requirements in Section F.12.

F.13.2 The quality assurance program shall be in written form and available for review by the Agency.

F.13.3 **Implementation of Quality Assurance Program**

(a) The registrant shall assign qualified personnel to fully implement the quality assurance program. Quality control assessments for F.13.1(b), (c), (d) and (e) shall be conducted by, or under the direction of, a Qualified Medical Physicist.

(b) A Qualified Medical Physicist shall determine the frequency and nature of quality control tests, except when the frequency for a specific quality control test is defined by these Regulations.

(c) A Qualified Medical Physicist shall perform a review of the Quality Assurance Program at an interval not to exceed twelve (12) months, and shall provide a written report which documents the results of this review.

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PART F

APPENDIX A

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 Rhode Island.
2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.
3. A description of the X-ray examinations proposed in the screening program (i.e., type and number of views).
4. Description of the population to be examined in the screening program, i.e., age range, gender, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation that 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 conducted by a Qualified Medical Physicist, of the X-ray system(s) to be used in the screening program. The evaluation shall include the following:

   (i) Documentation that such system(s) satisfy all requirements of these Regulations; and

   (ii) Estimation of patient entrance skin exposures from the X-ray examinations to be performed;
7. A description of the diagnostic X-ray quality control program.
8. Documentation of the techniques for the X-ray examination procedures to be used.
9. The name and RI license number of each radiologic technologist who will be operating the X-ray system(s).
10. The name and RI license number of each health care provider 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 Rhode Island-licensed practitioner of the healing arts who will interpret the images.
12. Procedures to be used in advising the individuals screened and their health care provider(s) of the results of the screening procedure and any further medical needs indicated.
13. Procedures for the retention or disposition of the images and other records pertaining to the X-ray examinations.
14. Frequency of screening of individuals.
15. The duration of the screening program.

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PART F

APPENDIX B

INSTRUCTION OF USERS OF X-RAY EQUIPMENT IN THE HEALING ARTS

I. **Fundamentals of Radiation Safety**

- A. Characteristics of x-radiation
- B. Units of radiation dose
- C. Hazards of excessive exposure to radiation
- D. Levels of radiation from sources of radiation
- E. Methods of controlling radiation dose
  1. Working time
  2. Working distances
  3. Shielding

II. **Radiation Detection Instrumentation to be Used**

- A. Radiation survey instruments
  1. Operation
  2. Calibration
  3. Limitations
- B. Survey, monitoring and spot-check techniques
- C. Personnel monitoring devices
- D. Interpretation of personnel monitoring reports

III. **Operation and Control of X-ray Equipment**

- A. Collimation and Filtration
- B. Exposure techniques for the equipment used
- C. Image processing techniques
- D. Anatomy and positioning
  1. Relevant human anatomy
  2. Relevant human physiology
  3. Radiographic positioning

IV. **The requirements of pertinent federal and state regulations**

V. **The licensee's or registrant's written operating and emergency procedures**

PART F

APPENDIX C – [REMOVED]

PART F

APPENDIX D

HAND-HELD INTRAORAL DENTAL RADIOGRAPHIC UNIT REQUIREMENTS FOR USE

The following requirements are applicable to intraoral dental radiographic units designed to be operated as a hand-held unit:

1. **For All Uses**:

(a) Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.

(b) When operating a hand-held intraoral dental radiographic unit, operators shall wear a protective apron and thyroid collar, unless otherwise authorized by the Agency or recommended by a Qualified Medical Physicist.

(c) A hand-held intraoral dental radiographic unit shall be held with minimal motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.

(d) Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall be used with a secondary radiation block to shield the operator.

(e) The operator shall ensure there are no bystanders within a radius of six (6) feet from the patient being examined with a hand-held intraoral radiographic unit.

(f) Hand-held intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

(g) The registrant shall comply with any facility-specific requirements established by the Agency

2. **Additional Requirements for Operatories in Permanent Facilities:** When hand-held intraoral dental radiographic units are used for patient examinations in dental operatories, that facility shall meet the structural shielding requirements specified by the Agency or by a health physicist or Qualified Medical Physicist.

RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART G

RADIATION SAFETY REQUIREMENTS FOR MICROWAVE OVENS

JUNE 1978

PART G

RADIATION SAFETY REQUIREMENTS FOR MICROWAVE OVENS

G.1 PURPOSE AND SCOPE

The regulations in this part establish radiation safety requirements for microwave ovens which are designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz.

G.2 PERFORMANCE STANDARDS

Microwave ovens manufactured after October 6, 1971, shall be maintained in compliance with the applicable federal performance standards for microwave ovens in Title 21, Code of Federal Regulations, Chapter I, Subchapter J.

G.3 POWER DENSITY LIMITS

G.3.1 (a)The power density of the microwave radiation emitted by any microwave oven manufactured after October 6, 1971, shall not exceed one (1) milliwatt per square centimeter at any point 5 centimeters or more from the external surface of the oven, measured prior to acquisition by a purchaser, and thereafter, 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven.

(b) For ovens manufactured on or before October 6, 1971, the power density of the emitted microwave radiation shall not exceed 10 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven.

G.4 NON-COMPLIANCE

Any microwave oven which fails to meet the requirements of this part shall be removed from service until the repairs or modifications necessary to meet the applicable standard(s) have been made.

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RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART H

THERAPEUTIC RADIATION MACHINES

June 1999

As Amended:

September 2004
September 2006
OCTOBER 2013

PART H

THERAPEUTIC RADIATION MACHINES

H.1 SCOPE AND APPLICABILITY

H.1.1 **Purpose, Scope, Provisions for Research Involving Human Subjects and FDA, Other Federal and State Requirements.**

(a) **Scope.** This Part establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these Regulations.

(b) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by H.3.3.

(c) **Provisions for Research Involving Human Subjects.** A registrant may conduct research involving human subjects using therapeutic radiation machines provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a registrant shall apply for and receive approval of a specific amendment to its Agency registration before conducting such research. Both types of registrants shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

(d) **FDA, Other Federal and State Requirements.** Nothing in this Part relieves the registrant from complying with applicable FDA, other federal, and State requirements governing therapeutic radiation machines or auxiliary devices.

H.2 DEFINITIONS

Whenever used in this Part, the following terms shall be construed as follows:

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

Absorbed dose rate means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible surface means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

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

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 name for the unit of kerma is the gray (Gy).

Barrier (See "Protective barrier").

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

Beam-limiting device means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

H.2

Beam monitoring system means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Beam scattering foil means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Bent beam linear accelerator means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

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

Contact therapy system means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than 5 centimeters.

Conventional Simulator means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment

Detector (See "Radiation detector").

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

Dose monitor unit (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

Electronic Brachytherapy means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver a therapeutic radiation dose.

Electronic brachytherapy device means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

Electronic brachytherapy source means the x-ray tube component used in an electronic brachytherapy device.

External beam radiation therapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening filter means a filter used to homogenize the absorbed dose rate over the radiation field.

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to Subpart H.6.

Gantry means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

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

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

Intensity Modulated Radiation Therapy (IMRT) means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

Interlock means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

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Interruption of irradiation means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

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

Isocenter means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

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.

Leakage radiation means radiation emanating from the radiation therapy system except for the useful beam.

Light field means the area illuminated by light, simulating the radiation field.

mA means milliampere.

Mega electron volt (MeV) means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note: current convention is to use MV for photons and MeV for electrons.]

Misadministration means an event that meets the criteria in H.5.2.

Mobile Electronic Brachytherapy Service means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

Monitor unit (MU) (See "Dose monitor unit").

Moving beam radiation therapy means radiation therapy with any planned displacement of radiation field or patient/human research subject 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:

(1) 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.

(2) 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.

Patient means an individual subjected to machine produced radiation for the purpose(s) of medical therapy.

Peak tube potential means the maximum value of the potential difference across the X-ray tube during an exposure.

Periodic quality assurance check means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.

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

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H.2

Practical range of electrons corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" [Medical Physics 18(1): 73-109, Jan/Feb 1991] and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

Prescribed dose means the total dose and dose per fraction as documented in the written directive. The prescribed dose is 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.

Primary dose monitoring system means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

Primary protective barrier (See "Protective barrier").

Radiation field (See useful beam)

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

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

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

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 properties or quantities of incident radiation.

Radiation head means the structure from which the useful beam emerges.

Recordable event means the administration of a therapeutic radiation machine dose when the calculated weekly administered dose differs by fifteen percent (15%) or more from the weekly prescribed dose.

Redundant beam monitoring system means a combination of two (2) independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

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

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

Secondary protective barrier (See "Protective barrier").

Shadow tray means a device attached to the radiation head to support auxiliary beam blocking material.

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Sievert (Sv) means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous special unit of dose equivalent (rem) is being replaced by the sievert. [1 Sv=100 rem].

Simulator (radiation therapy simulation system) means any X-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. [See: Conventional Simulator and Virtual Simulator.]

H.2

Source means the region and/or material from which the radiation emanates.

Source-skin distance (SSD) [See Target-skin distance]

Stationary beam radiation therapy means radiation therapy without displacement of one or more mechanical axes relative to the patient/human research subject during irradiation.

Stray radiation means the sum of leakage and scattered radiation.

Target means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

Target-skin distance (TSD) means the distance measured along the beam axis from the center of the front surface of the X-ray target and/or electron virtual source to the surface of the irradiated object or patient/ human research subject.

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

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

Therapeutic radiation machine means X-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these Regulations, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

Tube means an X-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

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

Virtual Simulator means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

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

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

Written directive means an order in writing for the administration of radiation to a specific patient or human research subject, as specified in H.5.1.

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

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H.3 GENERAL ADMINISTRATIVE REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

H.3.1 **Administrative Controls.** The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of Part H are met in the operation of the therapeutic radiation machine(s).

H.3.2 A therapeutic radiation machine which does not meet the provisions of these Regulations shall not be used for irradiation of patients/human research subjects.

H.3.3 **Training for Therapeutic Radiation Machine Authorized Users.** The registrant for any therapeutic radiation machine subject to H.6 or H.7 shall require the Authorized User to be a physician who:

(a) Is certified in:

(1) Radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has completed two hundred (200) hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of ionization radiation; and

(iv) Radiation biology.

(2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an Authorized User and shall include:

(i) Review of the full calibration measurements and periodic quality assurance checks;

(ii) Evaluation of prepared treatment plans and calculation of treatment times and patient/human research subject treatment settings;

(iii) Using administrative controls to prevent misadministrations;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(v) Checking and using radiation survey meters.

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H.3.3(b)(3)

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an Authorized User. The supervised clinical experience shall include:

(i) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(ii) Selecting proper dose and how it is to be administered;

(iii) Calculating the therapeutic radiation machine doses and collaborating with the Authorized User in the review of patients'/human research subjects' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients'/human research subjects' reaction to radiation; and

(iv) Post-administration follow-up & review of case histories.

(c) Notwithstanding the requirements of H.3.3(a) and H.3.3(b), the registrant for any therapeutic radiation machine subject to H.6 may also submit the training of the prospective Authorized User physician for Agency review on a case-by-case basis.

(d) A physician shall not act as an Authorized User for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.

H.3.4 **Training for Qualified Medical Physicist.** The registrant for any therapeutic radiation machine subject to H.6 or H.7 shall require the Qualified Medical Physicist to:

(a) Be registered with the Agency, under the provisions of Part B of these Regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units. and

(b) Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

(5) Therapeutic medical physics; or

(c) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(d) Be certified by the Canadian College of Physicists in Medicine (CCPM) in Radiation Oncology Physics.

H.3.5 **Qualifications of Operators.**

(a) Individuals who will be operating a therapeutic radiation machine for medical use shall possess a current license as a Radiation Therapist in accordance with the *Rules and Regulations for the Licensure of Radiographers, Nuclear Medicine Technologists*, *Radiation Therapists and Radiologist Assistants* [*R5-68.1-RAD*] of the Rhode Island Department of Health, unless the individual is specifically exempted from licensure by Section 2.0 of said regulations.

H.3.5(b)

(b) The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two (2) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

H.3.6 Written safety procedures and rules shall be developed by a Qualified Medical Physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

H.3.7 Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine Authorized User. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

H.3.8 **Visiting Authorized User.** Notwithstanding the provisions of H.3.7, a registrant may permit any physician to act as a Visiting Authorized User under the term of the registrant's Certificate of Registration for up to sixty (60) days per calendar year under the following conditions:

(a) The Visiting Authorized User has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee (where applicable); and

(b) The Visiting Authorized User meets the requirements established for Authorized User(s) in H.3.3(a) and H.3.3(b); and

(c) The registrant shall maintain copies of the written permission required in H.3.8(a) and documentation that the Visiting Authorized User met the requirements of H.3.8(b) for five (5) years from the date of the last visit.

H.3.9 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. In addition to the requirements of Part H, these individuals are also subject to the requirements of A.2.3, A.2.7 and A.3.3.

H.3.10 **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 H, 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 1 August 1978 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.

H.3.11 **Records Retention.** All records required by Part H shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in Part H. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

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H.3.12 **Report and Notification of a Dose to an Embryo/Fetus.**

(a) A registrant 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 radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring physician.

(b) The registrant shall notify the Agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report H.3.12(a).

(c) The registrant shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus that requires a report in H.3.12(a).

(1) The written report shall include:

(i) The registrant's name and registration number;

(ii) The name of the referring physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the registrant notified the pregnant individual (or the pregnant individual's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's name or any other information that could lead to identification of the individual.

(d) The registrant shall provide notification of the event to the referring physician and also notify the pregnant individual, no later than 24 hours after discovery of an event that would require reporting under H.3.12(a), unless the referring physician personally informs the registrant either that he or she will inform the pregnant individual or that, based on medical judgment, telling the pregnant individual would be harmful. The registrant is not required to notify the pregnant individual without first consulting with the referring physician. If the referring physician or pregnant individual cannot be reached within 24 hours, the registrant shall make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the pregnant individual's responsible relative or guardian instead of the pregnant individual. If a verbal notification is made, the registrant shall inform the pregnant individual, or the pregnant individual's responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(e) A registrant shall:

(1) Annotate a copy of the report provided to the Agency with the:

(i) Name of the pregnant individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the pregnant individual who is the subject of the event; and

(iii) Provide a copy of the annotated report to the referring physician, if other than the registrant, no later than 15 days after the discovery of the event.

H.4 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

H.4.1 **Protection Surveys.**

(a) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with H.8. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in A.2.3(a); and

(2) Radiation levels in unrestricted areas do not exceed the limits specified in A.2.11(a) and A.2.11(b).

(b) In addition to the requirements of H.4.1(a), a radiation protection survey shall also be performed prior to any subsequent medical use and:

(1) After making any change in the treatment room shielding;

(2) After making any change in the location of the therapeutic radiation machine within the treatment room;

(3) After relocating the therapeutic radiation machine; or

(4) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(c) The survey record shall indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or a Certified Health Physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(d) If the results of the surveys required by H.4.1(a) or H.4.1(b) indicate any radiation levels in excess of the respective limit specified in H.4.1(a), the registrant shall lock the control in the "OFF" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(2) Until the registrant has received a specific exemption from the Agency.

H.4.2 **Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program.** If the survey required by H.4.1 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by A.2.11(a) and A.2.11(b), 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 A.2.11(a) and A.2.11(b);

H.4.2(b)

(b) Perform the survey required by H.4.1 again; and

(c) Include in the report required by H.4.4 the results of the initial survey, a description of the modification made to comply with H.4.2(a) and the results of the second survey; or

(d) Request and receive a registration amendment under A.2.11(c) that authorizes radiation levels in unrestricted areas greater than those permitted by A.2.11(a) and A.2.11(b).

H.4.3 **Dosimetry Equipment.**

(a) 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 twenty-four (24) months and after any servicing that may have affected system calibration.

(1) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(2) 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;

(b) 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 H.4.3(a). This comparison shall have been performed within the previous twelve (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 H.4.3(a).

(c) 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 H.4.3(a) and H.4.3(b), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Qualified Medical Physicist.

H.4.4 **Reports of External Beam Radiation Therapy Surveys and Measurements.** The registrant for any therapeutic radiation machine subject to H.6 or H.7 shall furnish a copy of the records required in H.4.1 and H.4.2 to the Agency within thirty (30) days following completion of the action that initiated the record requirement.

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H.5 QUALITY MANAGEMENT PROGRAM

H.5.1 **Scope and Applicability.** Each applicant or registrant subject to H.6, H.7 or H.11 shall develop, implement 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 address, as a minimum, the following specific objectives:

(a) **Written Directive**

(1) A written directive must be dated and signed by an Authorized User prior to the administration of radiation;

(2) Notwithstanding H.5.1(a)(1), if, because of the patient's/human research subject's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's/human research subject's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in writing in the patient's/human research subject's record and a revised written directive is signed by an Authorized User within forty-eight (48) hours of the oral revision;

(3) The written directive shall contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(4) A written revision to an existing written directive may be made provided that the revision is dated and signed by an Authorized User prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

(5) The registrant shall retain a copy of each written directive, in an auditable form, for three (3) years after the date of administration.

(b) **Procedures for Administrations.** The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

(1) Prior to the administration of each course of radiation treatments, the patient's/human research subject's identity is verified, by more than one method, as the individual named in the written directive.

(2) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:

(i) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and

(ii) Verifying that any manual and computer-generated calculations are correctly transferred into the consoles of therapeutic radiation machines;

(3) Each administration is in accordance with the written directive. and

(4) Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(5) A registrant shall retain a copy of the procedures required by H.5.1(b) for the duration of the registration.

H.5.2 **Reports and Notifications of Misadministrations.**

(a) A registrant shall report any event resulting from intervention by a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

H.5.2(b)

(b) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:

(1) Involves the wrong patient, wrong treatment modality, or wrong treatment site; or

(2) The calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent (30%); or

(3) The calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose;

(c) The registrant shall notify the Agency by telephone[85] no later than the next calendar day after discovery of the misadministration.

(d) The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of the misadministration. The written report shall include:

(1) The registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individuals(s) who received the misadministration;

(6) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(7) Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

(8) If there was notification, what information was provided to the individual.

(e) The report shall not contain the individual's name or any other information that could lead to the identification of the individual. To meet the requirements of this Section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(f) (1) The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four (24) hours, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

[85] During normal business hours, the Agency may be contacted at (401) 222-2566. At other times, this number will allow you to leave a message on the answering machine. In case of an emergency when it is necessary to immediately contact the Agency, utilize the RI Department of Health 24 hour number [(401) 272-5952] and indicate the nature of your emergency. FAX communication may be sent 24 hours a day to (401) 222-5901.

H.5.2(h)(2)

(2) To meet the requirements of H.5.2(b)(1), the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that either a copy of the report that was submitted to the Agency, or a written description of both the event and the consequences as they may effect the can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(g) Aside from the notification requirement, nothing in H.5.2 affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

(h). The registrant shall retain a record of a misadministration in accordance with H.5.3. A copy of the record required shall be provided to the referring physician if other than the registrant within fifteen (15) days after discovery of the misadministration.

H.5.3 **Records of Misadministrations.** A registrant shall retain a record of misadministrations reported in accordance with H.5.2 for three (3) years. The record shall contain the following:

(a) The registrant's name and the names of the individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and the individual's referring physician, if applicable);

(b) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

(c) A brief description of the event; why it occurred; the effect, if any, on the individual;

(d) The actions, if any, taken or planned to prevent recurrence; and

(e) Whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

H.5.4 **Implementation of Quality Management Program.** 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/human research subject administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program.

(b) Conduct these reviews at intervals not to exceed twelve (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 of H.5.1; and

(d) Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for three (3) years.

H.5.5 The registrant shall evaluate and respond, within thirty (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

H.5.5(c)

(c) Retaining a record, in an auditable form, for three (3) years, of the relevant facts and what corrective action, if any, was taken.

H.5.6 The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

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H.6 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 kV[86]

H.6.1 **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:

(a) **5-50 kV Systems.** The leakage air kerma rate measured at any position five (5) centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in any one (1) hour.

(b) **>50 and <500 kV Systems.** The leakage air kerma rate measured at a distance of one (1) meter from the target in any direction shall not exceed 1 cGy (1 rad) in any one (1) hour. This air kerma rate measurement may be averaged over areas no larger than one-hundred square centimeters (100 cm^2). In addition, the air kerma rate at a distance of five (5) centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

(c) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in H.6.1(a) and H.6.1(b) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

H.6.2 **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.

H.6.3 **Adjustable or Removable Beam Limiting Devices.**

(a) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used.

(b) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

H.6.4 **Filter System.** The filter system shall be so designed that:

(a) Filters can not be accidentally displaced at any possible tube orientation;

(b) For equipment installed after 1 August 1978, an interlock system prevents irradiation if the proper filter is not in place;

(c) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one (1) meter under any operating conditions; and

(d) Each filter shall be marked as to its material of construction and its thickness.

H.6.5 **Tube Immobilization.**

(a) The X-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

(b) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

H.6.6 **Source Marking.** The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five (5) millimeters, and such marking shall be readily accessible for use during calibration procedures.

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[86] Electronic brachytherapy devices are subject to the requirements of H.11, and are exempt for the requirements of H.6.

H.6.7 **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.6.8 **Timer.** A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(a) A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator.

(b) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.

(c) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

(d) The timer shall permit accurate pre-setting and determination of exposure times as short as one (1) second.

(e) The timer shall not permit an exposure if set at zero.

(f) 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

(g) Timer shall be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

H.6.9 **Control Panel Functions.** The control panel, in addition to the displays required by other provisions in H.6, shall have:

(a) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible.

(b) An indication of whether X-rays are being produced.

(c) Means for indicating X-ray tube potential and current.

(d) The means for terminating an exposure at any time.

(e) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

(f) For therapeutic radiation machines manufactured after 1 August 1978, a positive display of specific filter(s) in the beam.

H.6.10 **Multiple Tubes.** When a control panel may energize more than one X-ray tube:

(a) It shall be possible to activate only one X-ray tube at any time;

(b) There shall be an indication at the control panel identifying which X-ray tube is activated; and

(c) There shall be an indication at the tube housing assembly when that tube is energized.

H.6.11 **Target-to-Skin Distance (TSD).** There shall be a means of determining the central axis TSD to within one (1) centimeter and of reproducing this measurement to within two (2) millimeters thereafter.

H.6.12

H.6.12 **Shutters.** Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five (5) 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.

H.6.13 **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.

H.6.14 **Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV.** In addition to shielding adequate to meet requirements of H.9, the treatment room shall meet the following design requirements:

(a) Aural Communication. Provision shall be made for continuous two-way aural communication between the patient/human research subject and the operator at the control panel.

(b) Viewing Systems. Provision shall be made to permit continuous observation of the patient/human research subject during irradiation and the viewing system shall be so located that the operator can observe the patient/human research subject from the control panel. The therapeutic radiation machine shall not be used for patient/human research subject irradiation unless at least one viewing system is operational.

H.6.15 **Additional Requirements.** Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(a) All protective barriers shall be fixed except for entrance doors or beam interceptors.

(b) The control panel shall be located outside the treatment room.

(c) 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

(d) When any door referred to in H.6.15(c) is opened while the X-ray tube is activated, the air kerma rate at a distance of one (1) meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

H.6.16 **Full Calibration Measurements.**

(a) Full calibration of a therapeutic radiation machine subject to H.6 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist:

(1) Before the first medical use following installation or reinstallation of the therapeutic radiation machine; and

(2) At intervals not exceeding twelve (12) calendar months; and

(3) Before medical use under the following conditions:

(i) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled; and

H.6.16(a)(3)(ii)

(ii) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(4) Notwithstanding the requirements of H.6.16(a)(3):

(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 H.6.16(a)(3)(i).

(b) To satisfy the requirement of H.6.16(a), full calibration shall include all measurements recommended for annual calibration by "AAPM Protocol for 40-300 kV X-ray Beam Dosimetry in Radiotherapy and Radiobiology": AAPM Report No. 76, prepared by AAPM Radiation Therapy Committee Task Group #61.

(c) 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 both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Qualified Medical Physicist responsible for performing the calibration.

H.6.17 **Periodic Quality Assurance Checks.**

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to H.6, which are capable of operation at greater than or equal to 50 kV.

(b) To satisfy the requirement of H.6.17(a), quality assurance checks shall meet the following requirements:

(1) The registrant shall perform quality assurance checks in accordance with written procedures established by the Qualified Medical Physicist; and

(2) 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 H.6.16(a). 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 H.6.16(a), shall be stated.

(c) The cause for a parameter exceeding a tolerance set by the Qualified Medical Physicist shall be investigated and corrected before the system is used for patient/human research subject irradiation.

(d) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's quality assurance check procedures, those elements of a full calibration shall be performed, as required in H.6.16(a), that are necessary to determine that all affected parameters are within acceptable limits. Other quality assurance check procedures should be repeated, as necessary, to ensure that all system parameters are within acceptable limits.

(e) The registrant shall use the dosimetry system described in H.4.3(b) to make the quality assurance check required in H.6.17(b).

(f) The registrant shall have the Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within thirty (30) days of the date that the check was performed.

H.6.17(g)

(g) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to H.6 are performed at intervals not to exceed thirty (30) days.

(h) Notwithstanding the requirements of H.6.17(f) and H.6.17(g), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by H.6.17(f) and H.6.17(g) have been performed within the thirty (30) day period immediately prior to said administration.

(i) To satisfy the requirement of H.6.17(g), safety quality assurance checks shall ensure proper operation of:

(1) Electrical interlocks at each external beam radiation therapy room entrance;

(2) Proper operation of the "BEAM-ON" and termination switches;

(3) Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

(4) Viewing systems;

(5) If applicable, electrically operated treatment room doors from inside and outside the treatment room;

(j) The registrant shall maintain a record of each quality assurance check required by H.6.17(a) and H.6.17(g) for three (3) years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

H.6.18 **Operating Procedures.**

(a) The therapeutic radiation machine shall not be used for irradiation of patients/human research subjects unless the requirements of H.6.16 and H.6.17 have been met.

(b) Therapeutic radiation machines shall not be left unattended unless secured pursuant to H.6.9(e).

(c) When a patient/human research subject must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(d) 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.

(e) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(f) No individual other than the patient/human research subject 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/human research subject, in the treatment room shall be protected by a barrier sufficient to meet the requirements of A.2.3 of these Regulations.

H.6.19

H.6.19 **Possession of Survey Instrument(s).** Each facility location authorized to use a therapeutic radiation machine in accordance with H.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 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with H.8.

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H.7 THERAPEUTIC RADIATION MACHINES - PHOTON THERAPY SYSTEMS (500 kV AND ABOVE) AND ELECTRON THERAPY SYSTEMS (500 keV AND ABOVE)

H.7.1 **Possession of Survey Instrument(s).** Each facility location authorized to use a therapeutic radiation machine in accordance with H.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 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with H.8.

H.7.2 **Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.**

(a) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two (2) meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient/human research subject 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 one hundred square centimeters (100 cm^2) at a minimum of sixteen (16) points uniformly distributed in the plane.

(b) Except for the area defined in H.7.2(a), the absorbed dose due to leakage radiation (excluding neutrons) at one (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 one hundred square centimeters (100 cm^2).

(c) For equipment manufactured after 1 July 1999, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

(d) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in H.7.2(a) through H.7.2(c) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

H.7.3 **Leakage Radiation Through Beam Limiting Devices.**

(a) **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 (2%) of the maximum absorbed dose on the central axis of the useful beam measured in a one hundred square centimeter (100 cm^2) radiation field, or maximum available field size if less than one hundred square centimeters (100 cm^2).

(b) **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:

(1) A maximum of two percent (2%) 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 seven (7) centimeters outside the periphery of the useful beam; and

(2) A maximum of ten percent (10%) of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two (2) centimeters outside the periphery of the useful beam.

H.7.3(c)

(c) **Measurement of Leakage Radiation.**

(1) **Photon Radiation.** Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two (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 ten square centimeters (10 cm^2);

(2) **Electron Radiation.** Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter (1 cm^2) suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

H.7.4 **Filters/Wedges.**

(a) Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.

(b) If the absorbed dose rate information required by H.7.1 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.

(c) For equipment manufactured after 1 January 1985 which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

(1) 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;

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(3) 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

(4) 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.

H.7.5 **Stray Radiation in the Useful Beam.** For equipment manufactured after 1 July 1999, 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).

H.7.6 **Beam Monitors.** All therapeutic radiation machines subject to H.7 shall be provided with redundant beam monitoring systems. The detectors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(a) Equipment manufactured after 1 January 1985 shall be provided with at least two (2) independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

H.7.6(b)

(b) Equipment manufactured on or before 1 January 1985 shall be provided with at least one (1) radiation detector. This detector shall be incorporated into a useful beam monitoring system.

(c) The detector and the system into which that detector is incorporated shall meet the following requirements:

(1) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

(2) 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;

(3) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(4) For equipment manufactured after 1 January 1985, 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.

(5) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after 1 January 1985, each display shall:

(i) Maintain a reading until intentionally reset;

(ii) Have only one (1) 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 H.7.6(c)(5)(iii) displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty (20) minute period of time.

H.7.7 **Beam Symmetry.**

(a) A bent-beam linear accelerator with beam flattening filter(s) subject to H.7 shall be provided with auxiliary device(s) to monitor beam symmetry.

(b) The device(s) referenced in H.7.7(a) shall be able to detect field asymmetry greater than ten percent (10%). and

(c) The device(s) referenced in H.7.7(a) shall be configured to terminate irradiation if the specifications in H.7.7(b) can not be maintained.

H.7.8 **Selection and Display of Dose Monitor Units.**

(a) Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

(b) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(c) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated. and

H.7.8(d)

(d) For equipment manufactured after 1 January 1985, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

H.7.9 **Air Kerma Rate/Absorbed Dose Rate.** For equipment manufactured after 1 January 1985, 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 H.7.6 may form part of this system.] In addition:

(a) The dose monitor unit rate shall be displayed at the treatment control panel;

(b) 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;

(c) 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 (10) 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

(d) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in H.7.9(b) and H.7.9(c) for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Agency.

H.7.10 **Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.**

(a) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

(b) 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 fifteen percent (15%) or forty (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

(c) For equipment manufactured after 1 January 1985, an indicator on the control panel shall show which monitoring system has terminated irradiation.

H.7.11 **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.

H.7.12 **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.

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H.7.13 **Timer.** A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(a) 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.

(b) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.

(c) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

H.7.14 **Selection of Radiation Type.** Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(a) Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

(b) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(c) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

(d) An interlock system shall be provided to prevent irradiation with X-rays, except to obtain an image, when electron applicators are fitted;

(e) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

(f) 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.

H.7.15 **Selection of Energy.** Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(b) 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;

(c) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

(d) For equipment manufactured after 1 July 1999, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

H.7.16 **Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy.** Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(a) 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.

H.7.16(b)

(b) The mode of operation shall be displayed at the treatment control panel.

(c) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

(d) 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.

(e) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement.

(1) For equipment manufactured after 1 January 1985:

(i) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent (5%) from the dose monitor unit value selected;

(ii) An interlock shall be provided to prevent motion of more than five (5) degrees or one (1) cm beyond the selected limits during moving beam radiation therapy;

(iii) 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.

(2) For equipment manufactured after 1 July 1999:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten (10) degrees of rotation or one (1) cm of linear motion differs by more than twenty percent (20%) from the selected value;

(ii) 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.

(f) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by H.7.10. and

(g) For equipment manufactured after1 January 1985, an interlock system shall be provided to terminate irradiation if movement:

(1) Occurs during stationary beam radiation therapy; or

(2) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

H.7.17 **Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV.** In addition to shielding adequate to meet requirements of H.9, the following design requirements are made:

(a) **Protective Barriers.** All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(b) **Control Panel.** In addition to other requirements specified in this Part, the control panel shall also:

(1) Be located outside the treatment room;

(2) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

H.7.17(b)(3)

(3) Provide an indication of whether radiation is being produced; and

(4) Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine;

(c) **Viewing Systems.** Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient/human research subject following positioning and during irradiation and shall be so located that the operator may observe the patient/human research subject from the treatment control panel. The therapeutic radiation machine shall not be used for patient/human research subject irradiation unless at least one viewing system is operational.

(d) **Aural Communications.** Provision shall be made for continuous two-way aural communication between the patient/human research subject and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients/human research subjects unless continuous two-way aural communication is possible.

(e) **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".

(f) **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.

(g) **Beam Interceptor Interlocks.** If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with A.2.11(a) and A.2.11(b), interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(h) **Emergency Cutoff Switches.** At least 1 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 H.7.11. 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.

(i) **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

(j) **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.

H.7.18 **Qualified Medical Physicist Support.**

(a) The services of a Qualified Medical Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Qualified Medical Physicist shall be responsible for:

(1) Full calibration(s) required by H.7.20 and protection surveys required by H.4.1;

(2) Supervision and review of dosimetry;

(3) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

H.7.18(a)(4)

(4) Quality assurance, including quality assurance check review required by H.7.21(e) of these Regulations;

(5) Consultation with the Authorized User in treatment planning, as needed; and

(6) Performing calculations/assessments regarding misadministrations.

(b) If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by H.7.19 shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

H.7.19 **Operating Procedures.**

(a) No individual, other than the patient/human research subject, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

(b) Therapeutic radiation machines shall not be made available for medical use unless the requirements of H.4.1, H.7.20 and H.7.21 have been met.

(c) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use.

(d) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

(e) If a patient/human research subject must be held in position during treatment, mechanical supporting or restraining devices shall be used. and

(f) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

H.7.20 **Acceptance Testing, Commissioning and Full Calibration Measurements.**

(a) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to H.7 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist.

(b) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by AAPM Radiation Therapy Task Group 45, and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

(c) Full calibration shall include measurement of all applicable parameters required by "Quality Assurance of Medical Accelerators: AAPM Report No. 142"[87], and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by 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 applicable parameters (for all energies) shall be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in AAPM Report No. 142.

(d) The Qualified Medical Physicist shall perform or directly supervise all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

[87] AAPM Report 142 supersedes Table II of "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Task Group 40.

H.7.20(d)(1)

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and

(2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the affected 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 H.7.20(d)(1).

(e) The registrant shall use the dosimetry system described in Section H.4.3(a) to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in H.7.20(b), (c) and (d) may then be made using a dosimetry system that indicates relative dose rates. and

(f) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Qualified Medical Physicist responsible for performance of the calibration.

(g) **Therapy-Related Computer Systems.** The registrant shall perform acceptance testing on the treatment planning system of therapeutic radiation machine -related computer systems in accordance with current published recommendations from a recognized national professional association (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

(1) Acceptance testing shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

(i) The source-specific input parameters required by the dose calculation algorithm;

(ii) The accuracy of dose calculations at representative points;

(iii) The accuracy of isodose plots and graphic displays;

(iv) The accuracy of the software used to determine radiation source positions from radiographic images; and

(v) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(2) Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Authorized User and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

H.7.21 **Periodic Quality Assurance Checks.**

(a) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to H.7 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46, prepared by AAPM Radiation Therapy Committee Task Group 40. All periodic quality assurance checks with an annual frequency do not have to be performed at the same time, but shall be completed during

an interval not to exceed twelve (12) consecutive calendar months.

H.7.21(b)

(b) The registrant shall use a dosimetry system which has been inter-compared within the previous twelve (12) months with the dosimetry system described in H.4.3(a) to make the periodic quality assurance checks required in H.7.21(a).

(c) The registrant shall perform periodic quality assurance checks required by H.7.21(a) in accordance with procedures established by the Qualified Medical Physicist.

(d) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(1) The Authorized User or Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

(2) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within three (3) treatment days; and

(3) The Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

(e) Therapeutic radiation machines subject to H.7 shall have the following safety quality assurance checks performed at intervals not to exceed one (1) week:

(1) Proper operation of the **"BEAM-ON"**, interrupt and termination switches;

(2) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(3) Electrically operated treatment room door(s) from inside and outside the treatment room;

(f) The registrant shall promptly repair any system identified in H.7.21(a) and H.7.21(e) that is not operating properly; and

(g) The registrant shall maintain a record of each quality assurance check required by H.7.21(a) and H.7.21(e) for three (3) years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

H.7.22 **Quality Assurance Checks for IMRT**. Quality assurance checks for IMRT shall:

(a) Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans;[88] and

(b) Be performed in accordance with the manufacturer's contractual specifications.

[88] IMRT is a rapidly evolving modality and the QA program shall also evolve to handle new issues that arise. "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: AAPM Report No. 82", prepared by the IMRT subcommittee of the AAPM radiation therapy committee, provides some suggestions on establishing such a QA program.

H.8 CALIBRATION OF SURVEY INSTRUMENTS

H.8.1 The registrant shall ensure that the survey instruments used to show compliance with Part H have been calibrated before first use, at intervals not to exceed twelve (12) months, and following repair.

H.8.2 To satisfy the requirements of H.8.1, the registrant shall:

(a) 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).

(b) Calibrate at least two (2) points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale.

H.8.3 To satisfy the requirements of H.8.2, the registrant shall:

(a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent. and

(b) 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.

H.8.4 The registrant shall retain a record of each calibration required in H.8.1 for three (3) years. The record shall include:

(a) A description of the calibration procedure. and

(b) 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.

H.8.5 The registrant may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform calibrations of survey instruments. Records of calibrations which contain information required by H.8.4 shall be maintained by the registrant.

H.9 SHIELDING AND SAFETY DESIGN REQUIREMENTS

H.9.1 Each therapeutic radiation machine subject to H.6 or H.7 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with A.2.3 and A.2.11.

H.9.2 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 H.

H.10 QUALITY ASSURANCE FOR RADIATION THERAPY SIMULATION SYSTEMS.

(a) Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance; and

(b) Be performed in accordance with "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Committee Task Group 40, for a conventional simulator; or

(c) Be performed in accordance with "Quality assurance for computed tomography simulators and the computed tomography-simulation process: AAPM Report No. 83", prepared by AAPM Radiation Therapy Committee Task Group 66, for a virtual simulator.

H.11 ELECTRONIC BRACHYTHERAPY

H.11.1 **Applicability**. Electronic brachytherapy devices shall be subject to the requirements of H.11, and shall be exempt for the requirements of H.6.

(a) An electronic brachytherapy device that does not meet the requirements of H.11 shall not be used for irradiation of patients; and

(b) An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

H.11.2 **Possession of Survey Instrument(s).** Each facility location authorized to use an electronic brachytherapy device in accordance with H.11 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 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with H.8 for the applicable electronic brachytherapy source energy.

H.11.3 **Facility Design Requirements for Electronic Brachytherapy Devices**. In addition to shielding adequate to meet requirements of H.9, the treatment room shall meet the following design requirements:

(a) If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.

(b) Access to the treatment room shall be controlled by a door at each entrance.

(c) Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.

(d) For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield and/or as localized shielded material around the treatment site.

(e) For electronic brachytherapy devices capable of operating at greater than 150 kV:[89]

(1) The control panel shall be located outside the treatment room;

(2) Interlocks shall be provided such that all entrance doors 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 electronic brachytherapy device to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(3) When any door referred to in H.11.3(e(2)) is opened while the X-ray tube is activated, the air kerma rate at a distance of one (1) meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

H.11.4. **Electrical Safety for Electronic Brachytherapy Devices**.

(a) The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

[89] Facility design requirements for electronic brachytherapy devices which would operate in the 50-150 kV range have intentionally been omitted because an evaluation of this technology, as it existed at the time this subpart was finalized, appears to indicate that such devices are not likely to be produced.

H.11.4(b)

(b) The high voltage transformer shall be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

(c) The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

(d) Equipment manufactured after 1 January 2006 shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

(1) IEC 60601-1:1998+A1+A2:1995;

(2) IEC 60601-1-2:2001;

(3) IEC 60601-2-8:1999; and

(4) IEC 60601-2-17:2004.

H.11.5 **Control Panel Functions.** The control panel, in addition to the displays required by other provisions in H.11, shall:

(a) Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

(b) Provide an indication of whether x-rays are being produced;

(c) Provide a means for indicating electronic brachytherapy source potential and current;

(d) Provide the means for terminating an exposure at any time; and

(e) Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

H.11.6 **Timer.** A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

(a) A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;

(b) The timer shall not permit an exposure if set at zero;

(c) The timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(d) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

(e) The timer shall permit setting of exposure times as short as 0.1 second; and

(f) The timer shall be accurate to within one percent (1%) of the selected value or 0.1 second, whichever is greater.

H.11.7 **Qualified Medical Physicist Support.**

(a) The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:

(1) Evaluation of the output from the electronic brachytherapy source;

H.11.7(a)(2)

(2) Generation of the necessary dosimetric information;

(3) Supervision and review of treatment calculations prior to initial treatment of any treatment site;

(4) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in H.11.11;

(5) Consultation with the Authorized User in treatment planning, as needed; and

(6) Performing calculations/assessments regarding patient treatments that may constitute a misadministration.

(b) If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by H.11.8 shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

H.11.8. **Operating Procedures.**

(a) Only individuals approved by the Authorized User, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;

(b) Electronic brachytherapy devices shall not be made available for medical use unless the requirements of H.4.1, H.11.9 and H.11.10 have been met;

(c) The electronic brachytherapy device shall be rendered inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

(d) During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent unshielded exposure from the treatment beam;

(e) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(f) Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

(1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

(2) The names and telephone numbers of the Authorized Users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(g) A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console[90];

(h). Instructions shall be posted at the electronic brachytherapy device control console[30] to inform the operator of the names and telephone numbers of the Authorized Users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and

(i) The Radiation Safety Officer, or his/her designee, and an Authorized User shall be notified as soon as possible if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist shall inform the manufacturer of the event.

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[90] If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation.

H.11.9 **Safety Precautions for Electronic Brachytherapy Devices.**

(a) A Qualified Medical Physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

(b) An Authorized User and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

(c) A Qualified Medical Physicist and either an Authorized User or a physician or electronic brachytherapy device operator, under the supervision of an Authorized User, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

(d) When shielding is required by H.11.3(d), the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of A.2.3 of these Regulations for any individual, other than the patient, in the treatment room; and

(e) All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

H.11.10 **Electronic Brachytherapy Source Calibration Measurements.**

(a) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to H.11 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist;

(b) Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

(c) Calibration of the electronic brachytherapy source output shall utilize a dosimetry system as described in H.4.3;

(d) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

(1) The output within two percent (2%) of the expected value, if applicable, or determination of the output if there is no expected value;

(2) Timer accuracy and linearity over the typical range of use;

(3) Proper operation of back-up exposure control devices;

(4) Evaluation that the relative dose distribution about the source is within five percent (5%) of that expected; and

(5) Source positioning accuracy to within one (1) millimeter within the applicator;

(e) Calibration of the x-ray source output required by H.11.10(a) through (d) shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

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H.11.10(f)

(f) 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 electronic brachytherapy device and a unique identifier for it's electronic brachytherapy source; the model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

H.11.11 **Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices.**

(a) Quality assurance checks shall be performed on each electronic brachytherapy device subject to H.11:

(1) At the beginning of each day of use;

(2) Each time the device is moved to a new room or site[91]; and

(3) After each x-ray tube installation.

(b) The registrant shall perform periodic quality assurance checks required by H.11.11(a) in accordance with procedures established by the Qualified Medical Physicist;

(c) To satisfy the requirements of H.11.11(a), radiation output quality assurance checks shall include as a minimum:

(1) Verification that output of the electronic brachytherapy source falls within three percent (3%) of expected values, as appropriate for the device, as determined by:

(i) Output as a function of time, or

(ii) Output as a function of setting on a monitor chamber.

(2) Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by X.11.10; and

(3) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one (1) mm; and

(d) The registrant shall use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in H.4.3(a) to make the quality assurance checks required in H.11.11(c);

(e) The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

(1) An Authorized User and Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

(2) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within two (2) days; and

(3) The Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

[91] *Site* is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer. See H.11.14 for additional clarification.

H.11.11(f)

(f) To satisfy the requirements of H.11.11(a), safety device quality assurance checks shall, at a minimum, assure:

(1) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

(2) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

(3) Proper operation of radiation monitors, if applicable;

(4) The integrity of all cables, catheters or parts of the device that carry high voltages; and

(5) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

(g) If the results of the safety device quality assurance checks required in H.11.11(f) indicate any malfunction, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning items.

(h) The registrant shall maintain a record of each quality assurance check required by H.11.11(c). and H.11.11(g) in an auditable form for three (3) years.

(1) The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the Qualified Medical Physicist who reviewed the quality assurance check;

(2) For radiation output quality assurance checks required by H.11.11(c)., the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

H.11.12 **Therapy-Related Computer Systems.** The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer’s acceptance testing protocol shall be followed.

(a) Acceptance testing shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays;

(4) The accuracy of the software used to determine radiation source positions from radiographic images; and

(5) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(b) The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

H.11.12(c)

(c) Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Authorized User and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

H.11.13 **Training.**

(a) A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in H.11.8. If the interval between patients exceeds one year, retraining of the individuals shall be provided before the next treatment is administered.

(b) In addition to the requirements of H.3.3 for therapeutic radiation machine Authorized Users and H.3.4 for Qualified Medical Physicists, these individuals shall also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but nor be limited to:

(1) Device-specific radiation safety requirements;

(2) Device operation;

(3) Clinical use for the types of use approved by the FDA;

(4) Emergency procedures, including an emergency drill; and

(5) The registrant's Quality Assurance Program.

(c) A registrant shall retain a record of individuals receiving instruction required by H.11.13(a) and (b) for three (3) years. The record shall 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.

H.11.14 **Mobile Electronic Brachytherapy Service.** A registrant providing mobile electronic brachytherapy service shall, as a minimum:

(a) Check each survey instrument for consistent response with a dedicated check source before medical use at each address of use or on each day of use, whichever is more restrictive. The registrant is not required to keep records of these checks.

(b) Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

(c) Perform, at each location on each day of use, all of the required quality assurance checks specified in H.11.11 to assure proper operation of the device.

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H.12 OTHER USE OF ELECTRONICALLY-PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE.

H.12.1 A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

(a) The applicant or registrant has, at a minimum, provided the Agency with:

(1) A detailed description of the device and its intended application(s);

(2) Facility design requirements, including shielding and access control;

(3) Documentation of appropriate training for Authorized User physician(s) and qualified medical physicist(s)

(4) Methodology for measurement of dosages to be administered to patients or human research subjects;

(5) Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

(6) Radiation safety precautions and instructions; and

(7) Other information requested by the Agency in its review of the application; and

(b) The applicant or registrant has received written approval from the Agency to utilize the device in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the device.

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PART H

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. ALL THERAPEUTIC RADIATION MACHINES

1. 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).
2. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.
3. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. THERAPEUTIC RADIATION MACHINES UP TO 150 kV (PHOTONS ONLY)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

1. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.
2. 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/human research subject, along with the anticipated number of patients to be treated per day or week.
3. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth 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 A.2.3.
4. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
5. 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.

III. THERAPEUTIC RADIATION MACHINES OVER 150 kV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

1. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [ie: photon, electron]. The target to isocenter distance shall be specified.

2. 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.
3. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze.
4. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
5. 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.
6. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [ie: 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.
7. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [ie: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

IV. NEUTRON SHIELDING

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

1. The structural composition, thickness, minimum density and location of all neutron shielding material.
2. 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.
3. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [ie: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.
4. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

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V. REFERENCES

1. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).
2. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).
3. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).
4. NCRP Report 151, “Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities. (2006)

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RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

PART I

X-RAY AND RADIOACTIVE MATERIALS FEES

JULY 2001

As Amended:

September 2004
September 2006
June 2007
September 2007
OCTOBER 2008
OCTOBER 2013

PART I

X-RAY AND RADIOACTIVE MATERIALS FEES

I.1 GENERAL PROVISIONS

I.1.1 **Applicability.** Persons and individuals who are subject to licensure and/or registration with the Agency pursuant to the statutory and regulatory provisions of the Radiation Control Act, Chapter 23-1.3 of the General Laws of Rhode Island, 1956, as amended, and these Regulations, shall be assessed fees, established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*, and in accordance with Subpart I.2 for X-ray registrants and/or Subpart I.3 for radioactive materials licensees.

I.1.2 **Fee Exempt.** Notwithstanding the requirement of §I.1.1 of these Regulations, no fees shall be required for radioactive materials licenses authorizing the use of source material as shielding only in devices and containers, provided, however, that all other licensed radioactive material in the device or container will be subject to the fees required by Subpart I.3 of these Regulations.

I.1.3 **Payment of Fees.** All fees specified in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* shall be submitted to the Agency.

I.1.4 **Inquiries.** Any inquiry regarding Agency fees should be addressed to:

Rhode Island Department of Health
Radiation Control
3 Capitol Hill - Room 305
Providence, RI 02908-5097
Telephone: (401) 222-2566

I.2 X-RAY FEES

I.2.1 **Submission of Initial Fee**

(a) Each initial application for a Registration Certificate in a category for which a fee has been established in *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* shall be accompanied by a fee in the amount of the Annual Fee specified for that registration category. A registration application shall not be considered prior to payment of the full amount specified. Registration applications for which no remittance is received shall be returned to the applicant.

(b) Initial applications, accompanied by the appropriate registration fee and which are received by the Agency during the period 1 July through 31 August of a calendar year shall also constitute a renewal application for the period ending 31 August of the following calendar year, without payment of an additional annual registration fee.

I.2.2 **Nonstandard Facilities and Services Fee**. Facilities and services which are approved by the Agency for registration but which do not fit the descriptions of the categories in Appendix B to this Part shall be assessed at a rate which coincides with an appropriate category, as determined by the Agency.

I.2.3

I.2.3 **Fee Rebates Not Authorized**. Rebates shall not be made for existing registrants who terminate operations prior to the expiration of their Registration Certificates.

I.2.4 **Late Fees**. Failure of any registered facility or service to submit the indicated annual registration fee for renewal of registration prior to the expiration date of current Registration Certificate shall be assessed a late fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* in addition to the required registration fee.

I.2.5 **Annual Fees.** The Agency shall issue an annual fee invoice to each registrant, based on the applicable annual fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*. Fees shall be payable prior to the expiration date of the registrant's current Registration Certificate.

I.3 RADIOACTIVE MATERIALS FEES

I.3.1 **Application Fee.** Each initial application for a license in a category for which a fee has been established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* shall be accompanied by a non-refundable fee in the amount of the Annual Fee specified for that license category. A license application shall not be considered prior to payment of the full amount specified. License applications for which no fee is received shall be returned to the applicant.

I.3.2 **Annual Fees**.

(a) **Assessment of Fees.** The Agency shall issue an annual fee invoice to each licensee, based on the applicable annual fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*. Fees shall be payable within thirty (30) days after receipt of a fee invoice.

(b) **Eligibility for Waiver of Annual Fee.** Any broad-scope (academic or medical) licensee, or any licensee which is a governmental agency[92] of the State of Rhode Island, that provides in-kind services to the Agency and/or performs services pursuant to an accepted written agreement with the Agency, and which are valued at an amount equal to or greater than their annual license fee, may submit a written request for a waiver from payment of the annual license fee. Upon approval by the Agency, this waiver shall only remain in effect for that annual licensing period. A new waiver request must be submitted for each subsequent annual licensing period.

(c) **Revocation of Annual Fee Waiver**. Upon written notice of noncompliance to the licensee, the Agency may revoke any waiver, approved pursuant to I.3.2(b), for failure to provide or perform all services pursuant to the accepted written agreement. The Agency may also invoice the licensee for any difference between the originally waived annual fee and the value of services already performed during that annual licensing period.

[92] For the purposes of this regulation, "governmental agency" shall be construed to include any department, office, commission or similar public entity established by Executive Order or pursuant to the Rhode Island General Laws.

I.3.3

I.3.3 **Amendment Fees.**

(a) **Assessment of Fees.** A licensee shall notify the Agency prior to submitting an amendment so that the appropriate amendment fee can be determined. Amendment fees are established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* and shall be assessed in accordance with written criteria established by the Agency. The written criteria shall be based on the Agency's estimate of the typical time and effort required to complete action on that general category of amendment request.

(b) **Nonstandard Amendment Fees.** A nonstandard amendment request which is not addressed by the Agency's written criteria shall be assessed an amendment fee which most closely approximates the time and effort necessary to complete action on the amendment request, as determined by the Agency.

(c) **Submission of Amendment Fees.** The appropriate amendment fee shall accompany the amendment request when it is submitted to the Agency. If the time and effort required to complete Agency action on the amendment request is significantly different than the basis for assessing the amendment fee, the Agency shall refund any overcharges or bill the licensee for an additional amendment fee up to a total maximum fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.

I.3.4 **Reciprocity Fees.**

(a) (1) Each annual application to operate in Rhode Island under reciprocity shall be accompanied by a non-refundable fee equal to the amount established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* for the specified category of activity. There will be no pro-rating of reciprocity fees.

(i) **Category 1:** Activities equivalent to those authorized by Categories 3d, 3k (broad-scope only) or 4b in Appendix A to this Part.

(ii) **Category 2:** Activities equivalent to those authorized by Categories 1b, 2c, 3i, 3k (other than broad-scope), 4c or 5a in Appendix A to this Part.

(iii) **Category 3:** Activities equivalent to those authorized by Categories 1a, 3l or 8a in Appendix A to this Part.

(iv) Any activity which is not specifically identified in I.3.4(a)(1)(i),(ii) or (iii) shall be assessed a fee which coincides with the appropriate Category, as determined by the Agency.

(2) Notwithstanding the provisions of I.3.4(a)(1), a reciprocity application based on a radioactive materials license which authorizes activities comparable to Appendix A-Category 3i, but which only requests authorization to perform "electronic checks" or other activities which do not involve disassembly of shielding or actual manipulation of sealed sources, shall be accompanied by a non-refundable fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.

(b) A reciprocity application shall not be considered prior to payment of the full amount specified. Reciprocity applications for which no remittance is received shall be returned to the applicant.

(c) No additional reciprocity fees shall be required for the same category of activity during the remainder of that calendar year. All reciprocity authorizations shall expire on December 31st of the year in which the application was submitted. Any additional reciprocity activity beyond December 31st of that year shall require a renewal application.

I.3.5 **Evaluation and SS&D Registry Maintenance Fees. [RESERVED].**

I.3.6

I.3.6 **Registration of General Licenses Pursuant to C.4.2(b)(6).**

(a) Each initial application for registration of a generally licensed device pursuant to C.4.2(b)(6) shall be accompanied by a fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* for each address or location of use and/or storage, as defined in C.4.2(b)(6). There will be no pro-rating of registration fees.

(b) No additional fees shall be required for:

(1) Registration of additional generally licensed devices at the same address or location of use and/or storage.

(2) Annual renewal of registrations pursuant to C.4.2(b)(6).

(c) All C.4.2(b)(6) registrations shall expire on December 31st of the year for which the registration information was submitted.

I.3.7 **Non-Routine Inspection Fees.** A non-routine inspection is only conducted in response to a significant regulatory event including, but not limited to, a reportable incident or overexposure, loss of radioactive material or unresolved non-compliance with license conditions or regulatory requirements. The Agency shall issue a non-routine inspection fee invoice to each licensee whenever the Agency conducts an inspection of the licensee's activities at an interval more frequent than currently established for that category of licensee. The fee shall be based on fifty percent (50%) of the applicable annual fee established in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*. Fees shall be payable within thirty (30) days after receipt of a fee invoice.

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PART I

APPENDIX A

RADIOACTIVE MATERIALS LICENSES

LICENSE CATEGORY

1) Special Nuclear Material

a) Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems including X-ray fluorescence analyzers. [*See Note 1.*]

b) All other licenses for possession and use of special nuclear material in unsealed form and in quantities not sufficient to form a critical mass.

2) Source Material

a) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap leaching, refining uranium mill concentrates to uranium hexafluoride, ore buying stations, ion exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of radioactive waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.

b) Licenses for possession and use of source material for shielding, except as provided for in Paragraph 1.0(b) of these Regulations.

c) All other source material licenses.

3) Radioactive Material Other Than Source Material and Special Nuclear Material

a) Licenses of broad scope for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.

Other licenses for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.

b) Licenses authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing radioactive material.

Licenses and approvals authorizing the distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices not involving processing of radioactive material.

c) **[RESERVED].**

APPENDIX A
RADIOACTIVE MATERIALS LICENSES

LICENSE CATEGORY

3) Radioactive Material Other Than Source Material and Special Nuclear Material

d) Licenses for possession and use of radioactive material for industrial radiography operations.

e) Licenses for possession and use of radioactive material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).

f) Licenses for possession and use of less than 10,000 curies of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes.

Licenses for possession and use of 10,000 curies or more of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes.

g) Licenses to distribute items containing radioactive material that require sealed source and/or device review to persons generally licensed, except specific licenses authorizing redistribution of items that have been authorized for distribution to generally licensed persons.

Licenses to distribute items containing radioactive material that do not require sealed source and/or device review to persons generally licensed, except specific licenses authorizing redistribution of items that have been authorized for distribution to generally licensed persons.

h) Licenses to distribute items containing radioactive material that require device review to persons exempt from the licensing requirements of Part C, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Part C.

Licenses to distribute items containing radioactive material that do not require device review to persons exempt from the licensing requirements of Part C, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Part C.

i) Licenses that authorize service for other licensees, except (1) licenses that authorize leak testing and/or calibration services only are subject to the fees specified in Category 3L, and (2) licenses that authorize waste disposal services are subject to fees specified in Categories 4A, 4B and 4C.

j) **[RESERVED]**.

k) Licenses of broad scope for possession and use of radioactive material for research and development that do not authorize commercial distribution.

Other licenses for possession and use of radioactive material for research and development that do not authorize commercial distribution.

l) All other specific radioactive materials, except those in Categories 4A through 10. [*See Note 1 for gauging devices.*]

LICENSE CATEGORY

4) Waste Disposal

a) Licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of commercial disposal by land burial by the licensee; or licenses for treatment or disposal by incineration, packaging of residues resulting from incineration and transfer of packages to another person authorized to dispose of waste material.

b) Licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.

c) Licenses specifically authorizing the receipt of prepackaged waste radioactive material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.

5) Well Logging

a) Licenses specifically authorizing use of radioactive material for well logging, well surveys and tracer studies other than field flooding tracer studies.

b) Licenses for possession and use of radioactive material for field flooding tracer studies.

6) Nuclear Laundries

a) Licenses for commercial collection and laundry of items contaminated with radioactive material.

7) Human Use of Radioactive Material

a) Licenses for human use of radioactive material in sealed sources contained in teletherapy devices.

b) Licenses issued for human use of radioactive material, except radioactive material in sealed sources contained in teletherapy devices.

c) **[RESERVED]**.

d) Licenses of broad scope issued to medical institutions or two or more physicians authorizing research and development, including human use of radioactive material, except radioactive material in sealed sources contained in teletherapy devices.

8) Civil Defense

a) Licenses for possession and use of radioactive material for civil defense activities.

9) Device, Product or Sealed Source Safety Evaluation

a) **[RESERVED].**

b) **[RESERVED].**

c) **[RESERVED].**

LICENSE CATEGORY

9) Device, Product or Sealed Source Safety Evaluation

d) **[RESERVED].**

e) **[RESERVED].**

f) **[RESERVED].**

10) Other Licenses and Authorizations

a) Radioactive materials licenses and other approvals authorizing decommissioning, decontamination, reclamation or site restoration activities in accordance with Part C. [*See Note 2 below*.]

NOTES:

1. Licenses that cover both byproduct/NARM and special nuclear material in sealed sources for use in gauging devices will only be subject to the fee for Category 1a.
2. All references to Part C (or its subparts) are references to those sections of Part C of these Regulations.

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PART I

APPENDIX B

X-RAY REGISTRATION CATEGORIES

HEALING ARTS REGISTRATION CATEGORIES

DEF
- Facilities performing diagnostic radiography limited to intra-oral dental procedures and/ or extra-oral dental procedures, including panoramic procedures and cephalometric procedures.

HRF
- Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) in an institution licensed by the State of Rhode Island as a hospital.

RAD
- Facilities performing general purpose diagnostic radiographic procedures (including fluoroscopy) outside of an institution licensed by the State of Rhode Island as a hospital.

RTF
- Facilities utilizing one or more therapeutic radiation machines, including dedicated therapy simulator(s).

SRF
- Facilities performing diagnostic radiography (excluding fluoroscopy) limited to a single category of specific radiographic procedures, as specified on the facility's application. The category shall also include facilities performing only chiropractic or podiatric procedures.

SRM
- Facilities performing two (2) or more categories of specific diagnostic radiography procedures (excluding fluoroscopy), as specified on the facility's application.

VEF
- Facilities performing diagnostic radiography limited to veterinary procedures.

SERVICES REGISTRATION CATEGORIES

PXS
- Individuals or facilities providing installation and/or servicing of X-ray equipment and associated components for Agency registrants.
- Individuals or facilities providing NVLAP certified personnel dosimetry services for Agency registrants and/or radioactive materials licensees.

RPS
- Calibration of health physics instrumentation for Agency registrants and/or radioactive materials licensees.
- General radiation physics services for Agency registrants and/or radioactive materials licensees.
- Diagnostic X-ray Physics services for Agency registrants. [Calibration and surveys of diagnostic X-ray equipment]
- Diagnostic X-ray Physics services for Agency registrants. [Calibration and surveys of computed tomography (CT) X-ray systems]
- Radiotherapy Physics services for Agency registrants. [Calibration and surveys of therapeutic radiation machines]
- Radiotherapy Physics services for Agency materials licensees. [Calibration and surveys of remote afterloader units, teletherapy units, and/or gamma stereotactic radiosurgery units]

STO
- Facilities limited to storage of X-ray equipment, excluding X-ray equipment exempt from registration under these Regulations.

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APPENDIX B
X-RAY REGISTRATION CATEGORIES

NON-HEALING ARTS REGISTRATION CATEGORIES

IRF ✦ Facilities utilizing X-ray equipment to perform industrial radiographic procedures.

IRA ✦ Facilities utilizing a Category A industrial radiation machines as defined in Subpart E.3.

IRB ✦ Facilities utilizing a Category B industrial radiation machines as defined in Subpart E.3.

OTH ✦ Facilities utilizing X-ray equipment for non-healing arts applications not otherwise defined in these Regulations.

PAF ✦ Facilities utilizing particle accelerators not authorized for human use.

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RULES AND REGULATIONS FOR THE CONTROL OF RADIATION

[R23-1.3-RAD]

ANNEX

RADIATION CONTROL AGENCY FORMS

JUNE 1978

As Amended:

February 1979
June 1981
October 1984
February 1994

RHODE ISLAND RADIATION CONTROL AGENCY

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

IN THE RHODE ISLAND RULES AND REGULATIONS FOR THE CONTROL OF RADIATION, THE RHODE ISLAND RADIATION CONTROL AGENCY HAS ESTABLISHED STANDARDS FOR YOUR PROTECTION AGAINST RADIATION HAZARDS. IN THE RHODE ISLAND RULES AND REGULATIONS FOR THE CONTROL OF RADIATION, THE RHODE ISLAND RADIATION CONTROL AGENCY HAS ESTABLISHED CERTAIN PROVISIONS FOR THE OPTIONS OF WORKERS ENGAGED IN WORK UNDER AN AGENCY LICENSE OR REGISTRATION.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to--

1. Apply these Regulations to work involving sources of radiation.
2. Post or otherwise make available to you a copy of the Rhode Island Radiation Control Agency regulations, the license and documents incorporated into the license by reference and amendments thereto, and the operating procedures which apply to work you are engaged in, and explain their provisions to you.
3. Post any Notice of Violation involving radiological working conditions, proposed imposition of civil penalties, or orders issued, and any response from the licensee or registrant.

WHAT IS COVERED BY THESE REGULATIONS

1. Limits on exposure to radiation and radioactive material in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys, and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding Agency inspections; and
7. Related matters.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the Rhode Island Radiation Control Agency regulations, and the operating procedures which apply to the work you are engaged in. You should observe their provisions for your own protection and protection of your co-workers.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The Rhode Island Radiation Control Agency regulations require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in Sections A.2.3 and A.2.9 of these Regulations. These sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air.
2. If you work where personnel monitoring is required:
   (a) Your employer must give you a written report, upon termination of your employment, of your radiation exposures; and
   (b) Your employer must advise you annually of your exposure to radiation.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Rhode Island Radiation Control Agency. In addition, any worker or representative of workers who believes that there is a violation of the Radiation Control Act, the regulations issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Rhode Island Radiation Control Agency. The request must set forth the specific grounds for the notice, and must be signed by the worker or the representative of the workers. During inspections, Agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he believes contributed to or caused any violation as described above.

POSTING REQUIREMENT

COPIES OF THIS NOTICE MUST BE POSTED IN A SUFFICIENT NUMBER OF PLACES IN EVERY ESTABLISHMENT WHERE EMPLOYEES ARE EMPLOYED IN ACTIVITIES LICENSED OR REGISTERED, PURSUANT TO PART B OR PART C OF THE RHODE ISLAND RULES AND REGULATIONS FOR THE CONTROL OF RADIATION, BY THE RHODE ISLAND RADIATION CONTROL AGENCY, TO PERMIT EMPLOYEES WORKING IN OR FREQUENTING ANY PORTION OF A RESTRICTED AREA TO OBSERVE A COPY ON THE WAY TO OR FROM THEIR PLACE OF EMPLOYMENT.

FORM RCA-1 (1/94) - PREVIOUS EDITIONS OBSOLETE

RHODE ISLAND RADIATION CONTROL AGENCY

CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX MALE _____ FEMALE _____	5. DATE OF BIRTH

6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ___ ESTIMATE __ NO RECORD ___	10. ROUTINE ___ PSE ___
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ___ ESTIMATE __ NO RECORD ___	10. ROUTINE ___ PSE ___
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ___ ESTIMATE __ NO RECORD ___	10. ROUTINE ___ PSE ___
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ___ ESTIMATE __ NO RECORD ___	10. ROUTINE ___ PSE ___
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ___ ESTIMATE __ NO RECORD ___	10. ROUTINE ___ PSE ___
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ___ ESTIMATE __ NO RECORD ___	10. ROUTINE ___ PSE ___
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

19. SIGNATURE OF MONITORED INDIVIDUAL	20. DATE SIGNED	21. CERTIFYING ORGANIZATION	22. SIGNATURE OF DESIGNEE	23. DATE SIGNED

FORM RCA-2 (1/94) - PREVIOUS EDITIONS OBSOLETE

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF FORM RCA-2

(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee, registrant, or facility not licensed by the Agency that provided monitoring.

8. Enter the Agency license or registration number or numbers.

9. Place an "X" in Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee or registrant intends to assign the record dose on the basis of TLD results that are not yet available.

10. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all PSEs.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE, ME).

15. Enter the committed effective dose equivalent (CEDE).

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ.

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.

20. Enter the date this form was signed by the monitored individual.

21. [OPTIONAL] Enter the name of the licensee, registrant or facility not licensed by the Agency, providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is not employed by the licensee or registrant and the employer chooses to maintain exposure records for its employees.

22. [OPTIONAL] Signature of the person designated to represent the licensee, registrant or employer entered in item 21. The licensee, registrant or employer who chooses to countersign the form should have on file documentation of all the information on the Agency Form RCA-2 being signed.

23. [OPTIONAL] Enter the date this form was signed by the designated representative.

RHODE ISLAND RADIATION CONTROL AGENCY

OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX MALE _____ FEMALE _____	5. DATE OF BIRTH

6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER	9. RECORD ___ ESTIMATE ___ NO RECORD ___	10. ROUTINE ___ PSE ___

INTAKES

10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN µCi

DOSES (in rem)

DEEP DOSE EQUIVALENT (DDE)	**11.**
EYE DOSE EQUIVALENT TO THE LENS OF THE EYE (LDE)	**12.**
SHALLOW DOSE EQUIVALENT, WHOLE BODY (SDE,WB)	**13.**
SHALLOW DOSE EQUIVALENT, MAX EXTREMITY (SDE,ME)	**14.**
COMMITTED EFFECTIVE DOSE EQUIVALENT (CEDE)	**15.**
COMMITTED DOSE EQUIVALENT, MAXIMALLY EXPOSED ORGAN (CDE)	**16.**
TOTAL EFFECTIVE DOSE EQUIVALENT (BLOCKS 11+15)(TEDE)	**17.**
TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN (BLOCKS 11+16)(TODE)	**18.**

19. COMMENTS

20. SIGNATURE -- LICENSEE OR REGISTRANT	**21. DATE PREPARED**

FORM RCA-3(1/94) - PREVIOUS EDITIONS OBSOLETE

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF FORM RCA-3

(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee or registrant.

8. Enter the Agency license or registration number or numbers.

9A. Place an "X" in Record or Estimate. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

9B. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSEs.

10A. Enter the symbol for each radionuclide that resulted in an internal exposure recorded for the individual, using the format "Xx-###x," for instance, Cs-137 or Tc-99m.

10B. Enter the lung clearance class as listed in Appendix B to Part A (D, W, Y, V, or O for other) for all intakes by inhalation.

10C. Enter the mode of intake. For inhalation, enter "H." For absorption through the skin, enter "B." For oral ingestion, enter "G." For injection, enter "J."

10D. Enter the intake of each radionuclide in μCi.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).

15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated".

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the person designated to represent the licensee or registrant.

20. Enter the date this form was prepared.

21. COMMENTS.
In the space provided, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE, ME was the result of exposure from a discrete hot particle. Another possibility would be to indicate that an overexposed report has been sent to the Agency in reference to the exposure report.