INSTRUCTION SHEET

COMAR 26.12.01.01

Title: Regulations for the Control of Ionizing Radiation (1994)

SUPPLEMENT No. 20

Instructions: Supplement 20 to the document "Regulations for the Control of Ionizing Radiation (1994)" is effective September 19, 2011. Supplement 20 includes the following pages (all pages are inclusive):

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Verify to make certain that you have the pages listed above.

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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION MANAGEMENT ADMINISTRATION
MARYLAND DEPARTMENT OF THE ENVIRONMENT

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PART A

GENERAL PROVISIONS

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

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

"A1" means the maximum activity of special form radioactive material permitted in a Type A package. "A2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix A of Part T of these regulations, Table I, or may be derived in accordance with the procedure prescribed in Appendix A of Part T of these regulations.

"Absorbed dose" [See "Dose"]

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

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

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

"Adult" means an individual 18 or more years of age.

"Agency" means the Maryland Department of Environment, Radiological Health Program.

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

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

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material exists in concentrations:

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

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

"Annually" means either:

(1) at intervals not to exceed one year, or

(2) once per year, at about the same time per year (plus or minus one month).

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

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

"Authorized nuclear pharmacist" means a pharmacist who:

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

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

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

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

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

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

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

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

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

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

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

"Byproduct material" means:

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

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

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

(ii) Any material that—

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

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

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

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

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

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

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

"CFR" means Code of Federal Regulations.

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

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

"COMAR" means Code of Maryland Regulations

"Committed dose equivalent" [See "Dose"]

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

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

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

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^{7} tps. One microcurie (μCi) = 0.000001 curie = 3.7×10^{4} tps (See A.12 for SI equivalent becquerel).

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

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

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

"Deep dose equivalent" [see "Dose"]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(11) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in D.1107(a)(6) of these regulations.

"Dose equivalent" [see "Dose"]

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

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

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

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

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

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

"Limits" [See "Dose Limits"]

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

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

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

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

"Minor" means an individual less than 18 years of age.

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

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

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

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

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

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involved exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. This includes exposure to radiation from registered and unregistered radiation machines or exposure to radioactive material from licensed and unlicensed sources of radiation. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Sec. G.75, from voluntary participation in medical research programs, or as a member of the public.

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

"Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

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

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

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

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

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

“Prescribed dose” means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

"Source material milling" means any activity that results in the production of byproduct material as defined by definition (2) of byproduct material.

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

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

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

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

(3) It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985, 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 January 1, 1983), and constructed before 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 U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[3] At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

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

"Week" means 7 consecutive days starting on Sunday.

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

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red Bone Marrow	0.12
Lung	0.12
Thyroid	0.03
Bone Surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

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

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

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

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

"Working level" means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 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.

“Written directive” means:

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

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

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

Exemptions from the Regulatory Requirements

Sec. A.3 Exemptions.

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

PART C

LICENSING OF RADIOACTIVE MATERIAL

Sec. C.1 Purpose and Scope.

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

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

Sec. C.2 Definitions.

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

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

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

"Waste collector" means an entity, operating under a Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste processor" means an entity, operating under a Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Exemptions from the Regulatory Requirements

Sec. C.3 Source Material.

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

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

(c) Any person is exempt from 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;

(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 or ceramic used in construction,

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

(iv) piezoelectric ceramic containing not more than 2 percent by weight source material;

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

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

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

(i) 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,

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

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

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

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

(x) [Reserved]

(2) Self-Luminous Products Containing Radioactive Material.

(i) Tritium, Krypton-85, or Promethium-147. 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.4(c)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

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

(3) Gas and Aerosol Detectors Containing Byproduct Material.

(i) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in Parts A, C through E, G, J, W, and X to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC 2/ pursuant to 10 CFR 32.26; or an Agreement State pursuant to C.25, which authorizes the initial transfer of the detectors to persons who are exempt from regulatory requirements. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by an Agreement State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under C.4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of C.25.

(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under C.4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of C.25.

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

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

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

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

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

Sec. C.5 - C.19 Reserved.

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

regulations except that such persons shall comply with the provisions of D.1001, D.1201, D.1202, and D.1207.

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

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

(k) Registration of Generally Licensed Devices.

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

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

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

(4) Persons generally licensed by the U.S. Nuclear Regulatory Commission or another Agreement State with respect to devices meeting the criteria in C.22(k)(5)(i) are required to register those devices with the Agency, if used in Maryland for a period of greater than 180 days in any calendar year.

(5) The registration of generally licensed devices shall be conducted as follows:

(i) All persons who possess generally licensed devices as defined in C.22(d)(1) that contain at least 370 MBq (10mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element (i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label), shall register the devices by submitting the following information to the Agency:

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

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

(c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under C.22(k)(5)(i)(e).

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

(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.

(ii) All persons who possess generally licensed devices as defined in C.22(a) and (e) excluding tritium signs, and all persons who possess generally licensed devices in C.22(d) that contain types or quantities of radionuclides less than defined in C.22(k)(5)(i), shall submit registration information to the Agency in accordance with C.22(k)(5)(i)(a-d).

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

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

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

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

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

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

(v) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of the paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

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

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

(i) Shall notify the Agency should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Radiological Health Program, Maryland Department of the Environment, 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days.

(ii) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 10 CFR 20.2008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Agency, another Agreement State, or the NRC.

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

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

(v) Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information, including the length of the extension requested and a written justification for the request, to the Radiological Health Program, Maryland Department of the Environment, 1800 Washington Boulevard, Baltimore, Maryland 21230.

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

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EMERGENCY PLAN

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

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

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

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

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

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

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

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

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

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

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

(7) Other factors appropriate for the specific facility.

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

(1) Facility Description

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

(2) Types of Accidents

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

(3) Classification of Accidents

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

(4) Detection of Accidents

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

(5) Mitigation of Consequences

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

(6) Assessment of Release

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

(7) Responsibilities

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

(8) Notification and Coordination

A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(9) Information to Be Communicated

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

(10) Training

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

(11) Safe Shutdown

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

(12) Exercises

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

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

Specific Licenses

Sec. C.24 Filing Application for Specific Licenses.

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

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

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

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

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

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

(g) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must identify the source or device by manufacturer and model number as registered with the NRC and must meet the requirements of Section C.37.

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

(a) A license application will be approved if the Agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

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

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

(5) the applicant maintains an office in Maryland;

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

(ii) where records are immediately available for inspection,

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

(a) at either the office location, or

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

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

(4) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

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

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

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

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

(7) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Agency, an Agreement State or the NRC to load or unload irradiator sources.

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

(g) Specific License for a PET License. An application from a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part C, equivalent Agreement State requirements, or 10 CFR Part 35 shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part C, another Agreement State, or an NRC license with requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Section C.28(j)(1)(ii).

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in Section C.28(j)(2)(ii).

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

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

(a) The different types of broad scope licenses are set forth below:

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

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

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

(c) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(e) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

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

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

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

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under C.22(e) will be approved if:

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

(2) the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32, or their equivalent.

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

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

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

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

(ii) Details of construction and design;

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

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

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

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

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

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

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

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

(ii) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by Appendix I of this section.

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

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

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

CAUTION – RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226)
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

_____
(Name of Manufacturer or Initial Transferor)

(h) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.22(i) will be approved if:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in D.1001 of these regulations.

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

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

(2) the criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

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

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

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

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

(a) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

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

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

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

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

(iii) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(iv) The applicant 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 100 days, the time may be omitted.

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

(2) A licensee described in C.28(j)(1)(ii)(c) or (d):

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

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

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

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

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

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

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

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

(b) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Agency.

(v) Shall provide to the Agency:

(a) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, NRC, or an Agreement State as specified in Section G.55(a) of this regulation with the written attestation signed by a preceptor as required by Section G.55(b)(2) of this regulation; or

(b) The Agreement State or NRC license; or

(c) The NRC master materials licensee permit; or

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

(e) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Agency; and

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

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

(i) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

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

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

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

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

(2) the applicant submits evidence that:

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

(ii) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to G.200 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by C.28(k) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

10/ Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to G.200 of these regulations may submit the pertinent information specified in C.28(k).

(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part G for use as a calibration, transmission, or reference source, or for diagnostic, brachytherapy or teletherapy sources for the uses listed in G.400, G.500, G.600, and G.1000 of these regulations, will be approved if:

(1) the applicant satisfies the general requirements in C.25 of this part;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form, and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to G.400, G.500, G.600, and G.1000 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(4) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(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 or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

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

(m) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.21(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

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

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in D.201 of these regulations; and

(iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under C.28(m) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under C.28(m) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.28(m)(1) shall:

(i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) label or mark each unit to:

(a) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(b) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

(iii) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(iv) (a) furnish a copy of the general license contained in C.21(e) to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in C.21(e), or

(b) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.21(e) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.21(e) to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in C.21(e);

(v) report to the Agency all transfers of industrial products or devices to persons for use under the general license in C.21(e). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under C.21(e) during the reporting period, the report shall so indicate;

(vi) (a) report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,

(b) report to the responsible State agency all transfers of devices manufactured and distributed pursuant to C.28(m) for use under a general license in that State's regulations equivalent to C.21(e),

(c) such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

(d) if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and

(e) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

(vii) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.21(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(n) Requirement for Sealed Source and Device Sheets. Any applicant or specific licensee who wishes to manufacture and distribute a sealed source or a device containing a sealed source shall provide sufficient information to complete a sealed source and device registration.

(o) Calibration or Reference Sources Containing Americium-241 or Radium-226: Leak Testing of Each Source Under Section C.28(f). Each person licensed under Section C.28(f) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under Section C.22(g). This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under Section C.22(g) or equivalent Agreement State regulations or NRC regulations.

Sec. C.29 Financial Assurance and Recordkeeping for Decommissioning:

(a) (1) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material in quantities exceeding the amounts specified in Table 1 shall submit a decommissioning funding plan as described in paragraph (d) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix E.

TABLE 1

TYPE	EXCEEDING
SPECIAL NUCLEAR MATERIAL	10^5 times Appendix E. (Also, when R divided by 10^5 is greater than 1.)*
SOURCE MATERIAL	100 mCi in readily dispersible form.
BYPRODUCT MATERIAL	Half-life greater than 120 days and 10^5 times Appendix E. (Also, when R divided by 10^5 is greater than 1.)*

* For a combination of radionuclides, R is the sum of the fractions of the radionuclide divided by the Appendix E value for that radionuclide.

(2) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix E (or when a combination of isotopes is involved if R, as defined in paragraph (a)(1) of this section, divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in paragraph (d) of this section. The decommissioning funding plan must be submitted to the Agency no later than two years after the effective date of this regulation.

(b) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Table 2 of this section shall either:

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

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

(c) (1) Each holder of a specific license issued on or after October 15, 1998 which is of a type described in paragraph (a) or (b) of this section, shall provide a decommissioning funding plan in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before October 15, 1998 and of a type described in paragraph (a) of this section shall submit, on or before October 15, 1998, a decommissioning funding plan as described in paragraph (d) of this section or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance instead of a decommissioning funding plan, the licensee shall provide a decommissioning funding plan on or before October 15, 2000.

(3) Each holder of a specific license issued before October 15, 1998, and of a type described in paragraph (b) of this section shall submit, on or before October 15, 1998, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before October 15, 1998, for renewal of license in accordance with C.33 shall provide financial assurance for decommissioning in accordance with paragraph (a) and (b) of this section. This assurance must be submitted on or before October 15, 2000.

(5) Waste collectors and waste processors, as defined in Section C.2 of this part, must provide financial assurance in an amount based on a decommissioning funding plan as described in paragraph (d) of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of Part D of this regulation. The decommissioning funding plan must be submitted no later than two years after the effective date of this regulation.

TABLE 2

TYPE OF RADIOACTIVE MATERIAL	EXCEEDING	ASSURANCE AMOUNT
SPECIAL NUCLEAR MATERIAL	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix E. (For a combination of radionuclides, if R divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)*	$1,125,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix E. (For a combination of radionuclides, if R divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)*	$225,000
SOURCE MATERIAL	Greater than 10 mCi but less than or equal to 100 mCi in readily dispersible form.	$225,000
BYPRODUCT MATERIAL	Half-Life greater than 120 days and in quantities:	
	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix E in unsealed form. (For a combination of radionuclides, if R divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)*	$1,125,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix E in unsealed form. (For a combination of radionuclides, if R divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)*	$225,000
	Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix E in sealed sources or plated foils. (For a combination of radionuclides, if R divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1.)*	$113,000

* For a combination of radionuclides, R is the sum of the fractions of the radionuclide divided by the Appendix E value for the radionuclide.

(2) No person shall receive, possess, use, transfer, own or acquire radioactive material of a type described in paragraph (a) or (b) of this section for more than 180 days following the dates prescribed in this section for submittal of a decommissioning funding plan or certification, if that decommissioning funding plan or certification has not been approved by the Agency.

(h) Financial assurance for decommissioning pursuant to termination under restricted conditions as described in Section D.1403 of Part D shall not be considered a potential financial mechanism until such time as the licensee has submitted its intent to decommission in accordance with C.32 and has submitted a License Termination Plan (LTP) in accordance with Section D.1403(d).

Sec. C.30 Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

Sec. C.31 Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(e) Each specific licensee, or general licensee possessing radioactive material as defined in C.22(k)(5)(i), shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) the licensee;

(2) an entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(f) The notification specified in C.31(e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Section G.204. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h) Production of PET Radioactive Drugs.

(1) Authorization under Section C.26(g) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Section C.28(j)(1)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Section C.28(j)(3).

(3) A licensee that is a pharmacy authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Section C.28(j)(2), or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Section G.27.

(4) A pharmacy, authorized under Section C.26(g) to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirement of Section C.28(j)(2)(v).

Sec. C.32 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas. (See also D.1301 "Vacating Premises.")

(a) Except as provided in Md. Code Ann., State Gov't Sec. 10-226 (1996), and provided that the licensee is applying for the same activities as allowed in the current license, each specific license expires at the end of the day, in the month and year stated in the license.

(b) No less than 30 days before expiration of a license, the licensee shall notify the Agency promptly, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license.

(c) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing, as specified in subsections (d) and (f)(1)(i)-(iv) or by license conditions, of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (f)(1) of this section, and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to subsection (a) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or

(3) No principal activities under the license have been conducted for a period of 24 months;

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or

(5) The licensee's right to operate has been terminated either by court action or by action of law or regulation.

(d) Coincident with the notification required by paragraph (c) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to C.29 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (f)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before the effective date of this regulation.

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(i) As the final step in decommissioning, the licensee shall—

(1) Certify to the Agency in writing the disposition of all licensed material, including accumulated wastes; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406. The licensee shall, as appropriate—

(i) Report levels of gamma radiation in units of millisieverts (microroentgens) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters—removable and fixed—for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instruments(s) used and certify that each instrument is properly calibrated and tested.

(3) Forward all records required by Sec. C.38 to the Agency.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

(1) Radioactive material has been properly disposed of;

(2) Reasonable effort (as determined by the Agency) has been made to eliminate residual radioactive contamination if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406.

Sec. C.33 Application for Renewal of Licenses. Subject to C.32(a), an application for renewal of a specific license must be filed on a form prescribed by the Agency, in accordance with C.24.

Sec. C.34 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.24 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Sec. C.35 Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in C.25, C.26, C.27, and C.28 and in Parts E, G, or W of these regulations, as applicable.

Sec. C. 36 Person Possessing a License for Medical Use of Radioactive Material on Effective Date of These Regulations. Any person or institution possessing a specific license for the medical use of radioactive material issued prior to October 9, 1995 when the licensee was authorized according to Groups I through VI of Schedule C, Part C, shall be deemed to possess a license issued under the revised regulations, according to Part G. The existing license will be valid until its stated expiration date and the renewal will be issued in accordance with the regulations dated October 9, 1995.

Sec. C.37 Registration of Sources or Devices Containing Radioactive Materials.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific or general license may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

(b) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(c) The Agency normally evaluates a sealed source or device using radiation safety criteria in accordance with accepted industry standards. If these standards and criteria do not readily apply to a particular case, the agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(d) After completion of the evaluation, the Agency may issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(e) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(1) The statements and representation, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

(f) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Agency under Section C.37, with the NRC under 10 CFR 32.210, or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in Section C.37, the applicant shall provide:

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

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

Sec. C.38 Records.

(a) Each person who receives radioactive material through a license issued pursuant to the regulations in this part shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

(1) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

Part C

Appendix C

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material[1]	Release Fraction	Quantity (curies)
Actinium-228	.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9(20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	2,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holminum-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material[1]	Release Fraction	Quantity (curies)
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorous-32	.5	100
Phosphorous-33	.5	1,000
Polonuim-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000

Appendix H

Nationally Tracked Source Thresholds

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1600	0.6	16
Americium-241/Be	60	1600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1400	0.5	14
Cesium-137	100	2700	1	27
Gadolinium-153	1000	27000	10	270
Iridium-192	80	2200	0.8	22
Plutonium-238	60	1600	0.6	16
Plutonium-239/Be	60	1600	0.6	16
Polonium-210	60	1600	0.6	16
Promethium-147	40000	1100000	400	11000
Radium-226	40	1100	0.4	11
Selenium-75	200	5400	2	54
Strontium-90	1000	27000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20000	540000	200	5400
Ytterbium-169	300	8100	3	81

Appendix I

Prototype Tests for Calibration or Reference Sources Containing Americium-241 or Radium-226

An applicant for a license under Section C.28(f) shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

(a) *Initial measurement*. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(b) *Dry wipe test*. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(c) *Wet wipe test*. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(d) *Water soak test*. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(e) *Dry wipe test*. On completion of the preceding test in this section, the dry wipe test described in paragraph (b) of this section shall be repeated.

(f) *Observations*. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Agency shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

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

(2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

ii. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

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

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

b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See D.206e.i. and ii.

c. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Agency. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

d. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See D.1107.

e. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

f. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See D.205e.

Sec. D.202 Compliance with Requirements for Summation of External and Internal Doses.

a. If the licensee or registrant is required to monitor pursuant to both D.502a. and b., the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to D.502a. or only pursuant to D.502b., then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to D.202b., c. and d. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

ii. The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

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

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

Sec. D.301 Dose Limits for Individual Members of the Public.

a. Each licensee or registrant shall conduct operations so that:

i. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under G.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with D.1003, and

ii. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Sec. G.75, does not exceed 0.002 rem (0.02 mSv) in any one hour.

b. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

c. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

d. Notwithstanding paragraph (a)(i) of this section, a licensee may permit visitors to an individual who cannot be released, under Sec. G.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

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

ii. The authorized user, as defined in Part G, has previously determined that the visit is appropriate.

e. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

Sec. D.302 Compliance with Dose Limits for Individual Members of the Public.

a. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in D.301.

b. At intervals not to exceed twelve months, a licensee or registrant shall show compliance with the annual dose limit in D.301a.i. for each calendar year by:

    i. Demonstrating compliance with D.101a.; and

    ii. (1) Demonstrating by measurement, or calculation, or appropriate simulation model that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered source of radiation does not exceed the annual dose limit of D.301; or

        (2) Demonstrating that:

            (a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

            (b) If an individual were continually present in an unrestricted area, at the point of highest potential exposure from the licensed or registered source of radiation, the dose to that individual would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in any year.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

Sec. D.401 Testing for Leakage or Contamination of Sealed Sources.

a. Each sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, shall be tested for leakage or contamination prior to initial use and, unless otherwise authorized by the Agency, at intervals not to exceed 6 months. If, at any other time, there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use. In the absence of a certificate from a transferor indicating that a test for leakage has been made within 6 months prior to the transfer, the sealed source shall not be put into use until tested and the results received.

    i. Tests for leakage for all sealed sources, except those manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate.

Sec. D.1007 Transfer for Disposal and Manifests.

a. The requirements of D.1007 are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

b. The above requirements shall be conducted in accordance with the requirements in Appendix D and E to this Part.

c. Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2 intended for ultimate disposal at a land disposal facility licensed under NRC regulation 10 CFR Part 61 must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G of 10 CFR Part 20.

Sec. D.1008 Compliance with Environmental and Health Protection Regulations.

Nothing in Part D relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to Part D.

Sec. D.1009 Disposal of Certain Byproduct Material.

a. Licensed material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2 may be disposed of in accordance with NRC's 10 CFR Part 61, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under NRC's 10 CFR Part 61, must meet the requirements of Section D.1007.

b. A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RECORDS

Sec. D.1101 General Provisions.

a. Each licensee or registrant shall use the units curie, disintegrations per minute, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part D.

b. In the records required by this Part, the licensee or registrant may record quantities in SI units in parentheses following each of the units specified in D.1101(a).

c. Notwithstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in Section D.1007, information must be recorded in the International System of Units (SI) or in SI and units as specified in D.1101(a).

d. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

Sec. D.1102 Records of Radiation Protection Programs.

a. Each licensee or registrant shall maintain records of the radiation protection program, including:

   i. The provisions of the program; and

   ii. Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by D.1102a.i. until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by D.1102a.ii. for 3 years after the record is made.

Sec. D.1103 Records of Surveys.

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by D.501 and D.906b. The licensee or registrant shall retain these records for 3 years after the record is made.

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

   i. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

   ii. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

   iii. Records showing the results of air sampling, surveys, and bioassays required pursuant to D.703a.iii.(1) and (2); and

   iv. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

Sec. D.1104 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by D.401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency or until the sealed source is transferred or disposed.

Sec. D.1105 Records of Prior Occupational Dose.

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in D.205 on Agency Form MDE 217 or equivalent until the Agency terminates each pertinent license or registration requiring this record or for such time as the Agency shall determine.

b. The licensee or registrant shall retain records used in preparing Agency Form MDE 217 or equivalent for 3 years after the record is made or for such time as the Agency shall determine.

Sec. D.1207 Annual Reports from General Licensees.

a. A licensee granted a general license under Section C.22(e), (g), (i), or (j) shall report annually, the following information on a form provided by the Agency:

   i. The amount and kind of radioactive material received during the previous year;

   ii. The form of the radioactive material;

   iii. The amount possessed by the licensee at the time of the report; and

   iv. The pathways and amounts of radioactive material disposed of by that person during the previous year.

b. The information required by D.1207a.iv. shall be estimated using a technique that is acceptable to the Department.

c. The report required by D.1207a. shall cover the calendar year from January 1 to December 31 and shall be forwarded to the Department not later than March 1 of the following year.

Sec. D.1208 Report and Notification of a Misadministration.

a. Licensees and registrants shall establish appropriate procedures, through compliance with the written directive, to prevent the occurrence of a misadministration.

b. A licensee or registrant shall report any misadministration in which the administration of byproduct material, or radiation from byproduct material or a radiation machine results in:

   i. A dose from byproduct material that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

      (1) The total dose delivered differs from the prescribed dose by 20 percent or more;

      (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

      (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

   ii. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

      (1) An administration of a wrong radioactive drug containing byproduct material;

      (2) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

      (3) An administration of a byproduct material dose or dosage to the wrong individual or human research subject;

      (4) An administration of a byproduct material dose or dosage delivered by the wrong mode of treatment; or

      (5) A leaking sealed source.

iii. A byproduct material dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

iv. A teletherapy radiation dose or dose from a radiation machine:

(1) Involving the wrong individual, wrong mode of treatment, or wrong treatment site, or of a type other than the one intended; or

(2) When the treatment consists of three or fewer fractions, a difference of the calculated total administered dose from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(3) A calculated weekly administered dose that is 30 percent greater than the weekly prescribed dose; or

(4) A calculated total administered dose that differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

c. The licensee or registrant shall notify by telephone the Agency no later than the next calendar day after discovery of the misadministration.

d. The licensee or registrant shall submit a written report to the Agency within 15 days after discovery of the misadministration.

i. The written report must include:

(1) The licensee's or registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

(5) The effect, if any, on the individual(s) who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) A certification signed by the appropriate authorized user or registrant that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

ii. The report may not contain the individual's name or any other information that could lead to identification of the individual.

e. The licensee or registrant shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee or registrant upon request. The licensee or registrant shall provide such a written description if requested.

f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees, registrants or physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

g. A licensee or registrant shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the individual who is the subject of the misadministration; and

(2) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration; and

ii. Provide the appended report in Sec. D.1208g.i. to the referring physician, if other than the licensee or registrant, no later than 15 days after the discovery of the misadministration.

h. Each licensee or registrant shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

Sec. D.1209 Reserved.

Sec. D.1210 Report and Notification of a Dose to an Embryo/fetus or a Nursing Child.

a. A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

b. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

i. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

ii. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

c. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210a. 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 D.1210(a) or (b).

i. The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

ii. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

e. The licensee shall provide notification of the misadministration to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of a misadministration that would require reporting under D.1210a. or b., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of D.1210e., the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. A licensee shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the pregnant individual or the nursing child who is the subject of the misadministration; and

(2) 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 misadministration; and

ii. Provide the appended report in D.1210f.i. to the referring physician, if other than the licensee, no later than 15 days after the discovery of the misadministration.

Sec. D.1211 Additional Reporting Requirements for Radioactive Materials.

a. Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or release of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

i. An unplanned contamination event that:

(1) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

LIST OF ELEMENTS

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Actinium	Ac	89	Molybdenum	Mo	42
Aluminum	Al	13	Neodymium	Nd	60
Americium	Am	95	Neptunium	Np	93
Antimony	Sb	51	Nickel	Ni	28
Argon	Ar	18	Niobium	Nb	41
Arsenic	As	33	Nitrogen	N	7
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Oxygen	O	8
Berkelium	Bk	97	Palladium	Pd	46
Beryllium	Be	4	Phosphorus	P	15
Bismuth	Bi	83	Platinum	Pt	78
Bromine	Br	35	Plutonium	Pu	94
Cadmium	Cd	48	Polonium	Po	84
Calcium	Ca	20	Potassium	K	19
Californium	Cf	98	Praseodymium	Pr	59
Carbon	C	6	Promethium	Pm	61
Cerium	Ce	58	Protactinium	Pa	91
Cesium	Cs	55	Radium	Ra	88
Chlorine	Cl	17	Radon	Rn	86
Chromium	Cr	24	Rhenium	Re	75
Cobalt	Co	27	Rhodium	Rh	45
Copper	Cu	29	Rubidium	Rb	37
Curium	Cm	96	Ruthenium	Ru	44
Dysprosium	Dy	66	Samarium	Sm	62
Einsteinium	Es	99	Scandium	Sc	21
Erbium	Er	68	Selenium	Se	34
Europium	Eu	63	Silicon	Si	14
Fermium	Fm	100	Silver	Ag	47
Fluorine	F	9	Sodium	Na	11
Francium	Fr	87	Strontium	Sr	38
Gadolinium	Gd	64	Sulfur	S	16
Gallium	Ga	31	Tantalum	Ta	73
Germanium	Ge	32	Technetium	Tc	43
Gold	Au	79	Tellurium	Te	52
Hafnium	Hf	72	Terbium	Tb	65
Holmium	Ho	67	Thallium	Tl	81
Hydrogen	H	1	Thorium	Th	90
Indium	In	49	Thulium	Tm	69
Iodine	I	53	Tin	Sn	50
Iridium	Ir	77	Titanium	Ti	22
Iron	Fe	26	Tungsten	W	74
Krypton	Kr	36	Uranium	U	92
Lanthanum	La	57	Vanadium	V	23
Lead	Pb	82	Xenon	Xe	54
Lutetium	Lu	71	Ytterbium	Yb	70
Magnesium	Mg	12	Yttrium	Y	39
Manganese	Mn	25	Zinc	Zn	30
Mendelevium	Md	101	Zirconium	Zr	40
Mercury	Hg	80			

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 Inhalation DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[1]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{7}Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
8	Oxygen-15[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
9	Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Ti, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	-	9E+4	4E-5	1E-7	-	-
		Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	9E+1	4E-8	1E-10	-	-
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
		Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see ^{31}Si	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-

(4) After replacement, each personnel dosimeter must be processed as soon as possible.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personnel dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with Sec. E.82.

(c) Pocket dosimeters, or electronic personnel dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with Sec. E.82. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personnel dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use or radiation machines until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with Sec. E.82.

(e) If the personnel dosimeter that is required by Sec. E.47(a) is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in Sec. E.47(a) is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with Sec. E.82.

(f) Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with Sec. E.82.

(g) Each alarm ratemeter must--

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with Sec. E.82(b).

Sec. E.49 Radiation Surveys.

The licensee shall:

(a) Not conduct a radiographic operation unless at least one calibrated and operable radiation survey instrument, as described in E.25, is available and used by each radiographic person at the site of each exposure.

(b) Survey with a radiation survey instrument after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube. If using a radiation machine, a similar survey shall be performed to determine if the machine has turned off.

(c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in Sec. E.3), to ensure that the sealed source is in its shielded position.

(d) Maintain records in accordance with Sec. E.85.

Sec. E.51 Surveillance.

During each radiographic operation the radiographer, or the other individual present, as required by Sec. E.41, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part D of this chapter except at permanent radiographic installations where all entryways are locked and the requirements of Sec. E.33 are met.

Sec. E.53 Posting.

All areas in which industrial radiography is being performed must be conspicuously posted as required by Sec. D.902 of this chapter. Exceptions listed in Sec. D.903 of this chapter do not apply to industrial radiographic operations.

Subpart E - Recordkeeping Requirements

Sec. E.61 Records of the Specific License for Industrial Radiography.

Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license.

Sec. E.63 Records of Receipt and Transfer of Sealed Sources.

Sec. F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, or Computed Tomography X-Ray Systems.

(a) Beam Limitation. The useful beam shall be limited to the area of clinical interest.

(1) General Purpose Stationary and Mobile X-Ray Systems.

(i) There shall be provided a means for stepless adjustment of the size of the x-ray field.

(ii) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(2) Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of F.6(a)(1), stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

(i) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(ii) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(iii) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems Designed for Mammography.

(i) Radiographic systems designed only for mammography shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in F.6(a)(5)(iii). When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in F.6(a)(5)(iii)(a) and (b) shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(ii) Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography.

(5) X-Ray Systems Other Than Those Described in F.6(a)(1),(2),(3), and (4).

(i) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Podiatry units with a circular beam are exempted from the 2% limit provided the diameter of the x-ray field shall not exceed the diagonal dimension of the image receptor.

(ii) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(iii) F.6(a)(5)(i) and (ii) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.6(a)(1) or, when alignment means are also provided, may be met with either:

(a) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(b) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(6) Source to Image Distance

Except for certified systems, a method shall be provided to indicate the SID to within 2 inches.

(7) Positive Beam Limitation (PBL). This regulation applies only to radiographic systems which contain PBL.

(i) PBL shall prevent the production of x-rays when:

(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by F.6(a)(5)(iii), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

(b) The sum of the length and width differences as stated in F.6(a)(7)(i)(a) without regard to sign exceeds 4 percent of the SID; or

(c) The beam limiting device is at an SID for which PBL is not designed for sizing;

(ii) PBL systems shall function as described in Section F.6(a)(5)(i) whenever all the following conditions are met:

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$\overline{T} \geq 5\ (T_{max} - T_{min})$$

(5) Linearity. When the equipment allows a choice of current settings, for any fixed x-ray tube potential within the range of 40-100 percent of the maximum rating, the average ratio of exposure, or air kerma, to the indicated milliamp-second product obtained at any two consecutive tube current settings shall not differ by more than 0.20 times their sum:

$$|\overline{Y}_1 - \overline{Y}_2| \leq 0.20\ (\overline{Y}_1 + \overline{Y}_2),$$

where $\overline{Y}_1 - \overline{Y}_2$ are the average mR/mAs (microcoulomb/kilogram per mAs, or milligray/mAs) values obtained at each of 2 consecutive tube current settings.

(c) Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.

(d) Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\overline{E} \geq 5\ (E_{max} - E_{min})$$

(e) kVp Accuracy. Except for certified systems, the true value of kVp shall not be different from the indicated value by greater than ten percent.

(f) Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 μC/kg or 0.02 milligray) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(g) Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure, or air kerma, to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\overline{X}_1 - \overline{X}_2| \leq 0.10\,(\overline{X}_1 + \overline{X}_2),$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs (average microcoulomb/kilogram per mAs or milligray per mAs) values obtained at each of 2 consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

(i) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field, and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(iv) A method shall be provided to indicate the SID to within 2 percent of its true value when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(5) Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of F.6(a)(1) and F.6(g)(4).

(6) Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(d) A licensee shall also perform checks and tests required by G.60.B(b) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each check and test required by G.60.B(b) for 3 years. The records required by G.60.B(b) shall include:

(1) For G.60.B(b)(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For G.60.B(b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the identity of the individual performing the test;

(3) For G.60.B(b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test; and

(4) For G.60.B(b)(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the identity of the individual performing the test.

Sec. G.61 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, annually, and following repair.

(b) To satisfy the requirements of G.61(a), the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(c) To satisfy the requirements of G.61(b), the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(d) A licensee shall check each survey instrument for proper operation with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each calibration required in G.61(a) for 3 years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(f) To meet the requirements of G.61(a), G.61(b), and G.61(c), the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by G.61(e) shall be maintained by the licensee.

Sec. G.62 Reserved.

Sec. G.63 Determination of Dosages of Unsealed Radioactive Material for Medical Use.

(a) A licensee shall determine and record the activity of each dosage before medical use;

(b) For a unit dosage, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer or preparer licensed under Sec. C.28, or equivalent NRC or Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC regulations.

(c) For other than unit dosages, this determination must be made by:

(1) Direct measurement of radioactivity;

(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 under Sec. C.28 or equivalent Agreement State or NRC requirements; or

(ii) A PET radioactive drug producer licensed under C.26(g) or equivalent Agreement State or NRC requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(c) A licensee shall conduct the surveys required by G.70(a) and G.70(b) so as to be able to measure dose rates as low as 0.1 millirem (1 μSv) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by G.70(a) and G.70(b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by G.70(e) so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute (33.3 Bq).

(g) A licensee shall establish removable contamination action levels for the surveys required by G.70(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by G.70(a), (b), and (e) for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Secs. G.71 – G.74 Reserved.

Sec. G.75 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, in any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with G.2075(b).

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[1] The current version of NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

Secs. G.76 – G.79 Reserved.

Sec. G.80 Provision of Mobile Medical Service.

(a) A licensee providing mobile medical service shall--

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(3) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at the client's location of use;

(4) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(5) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(6) Carry two calibrated survey meters in each vehicle that is being used to transport radioactive material. Survey instruments shall be checked for proper operation with a dedicated check source before use at each client's address; and

(7) Before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed. Contamination smears of the client's address confirming unrestricted release of the area must be less than 220 disintegrations per minute for 100 square centimeters.

(b) Provide to the Agency a signed certification from all proposed authorized users that they are willing and able to perform the responsibilities of authorized user as described in G.11(b) and G.27.

(c) Radioactive material may be delivered to a mobile medical service client if that client has a license allowing possession of the radioactive material. Radioactive material delivered to the licensed client must be received and handled in conformance with the client's license.

(d) A mobile medical service shall have radioactive material delivered from the manufacturer or the distributor to an unlicensed client's address only if the radioactive material is directly received by mobile medical service licensed personnel in accordance with procedures approved under the mobile medical service license.

(e) A licensee providing mobile medical services shall retain the letter required in G.80(a)(1) and the record of each survey required in G.80(a)(6) in accordance with G.2080(a) and (b), respectively.

(f) A licensee conducting mobile medical services shall provide accurate advance written notification to the Agency, describing client's addresses and times of work using a method and frequency approved by the Agency.

Secs. G.81 – G.99 Reserved.

Unsealed Radioactive Material—Written Directive Not Required

Sec. G.100 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for which a Written Directive is Not Required.

Except for quantities that require a written directive under G.40(b), a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from a manufacturer or preparer licensed by the Agency pursuant to C.28(j), or licensed by the NRC or any other Agreement State pursuant to provisions equivalent to C.28(j); or

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or an individual under the supervision of either as specified in G.27. The authorization given in G.100(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

(d) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(e) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Secs. G.101 – G.189 Reserved.

Sec. G.190 Training for Uptake, Dilution, and Excretion Studies.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.100 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.190(c)(2). (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

> (1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in G.190(c)(1)(i) through G.190(c)(1)(ii)(f); and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under G.290, G.390, or equivalent NRC or Agreement State requirements; or

(c) Has completed the following:

(1) 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in G.190, G.290, G.390, or equivalent NRC or Agreement State requirements, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.190, G.290, or G.390, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in G.190(a)(1) or G.190(c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100.

Secs. G.191 – G.199 Reserved.

Sec. G.200 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.

Except for quantities that require a written directive under G.40(b), a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

(a) Obtained from a manufacturer or preparer licensed under Sec. C.28(j) or equivalent Agreement State or NRC requirements; or

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, or G.390 and G.290(c)(1)(ii)(g); or an individual under the supervision of either as specified in G.27. The authorization given in G.200(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

(d) Obtained from and prepared by an Agreement State licensee or NRC for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(e) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Secs. G.201 – G.203 Reserved.

Sec. G.204 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with G.204(a).

(c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with G.2204.

Secs. G.205 – G.289 Reserved.

Sec. G.290 Training for Imaging and Localization Studies.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.200 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the NRC and who meets the requirements in G.290(c)(2). (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in G.290(c)(1)(i) through G.290(c)(1)(ii)(g); and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under G.390 and meets the requirements in G.290(c)(1)(ii)(g), or equivalent Agreement State or NRC requirements; or

(c) Has completed the following:

(1) 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use;

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in G.290, or G.290(c)(1)(ii)(g), and G.390, or equivalent Agreement State or NRC requirements, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in G.290, or G.390 and G.290(c)(1)(ii)(g), or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in G.290(a)(1) or G.290(c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under G.100 and G.200.

Secs. G.291 – G.299 Reserved.

Unsealed Radioactive Material—Written Directive Required

Sec. G.300 Use of Unsealed Radioactive Material for Which a Written Directive is Required.

A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(a) Obtained from a manufacturer or preparer licensed under Sec. C.28(j) or equivalent NRC or Agreement State requirements; or

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent Agreement State or NRC requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, G.390; or an individual under the supervision of either as specified in G.27. The authorization given in G.300(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

(d) Obtained from and prepared by an Agreement State or NRC licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(e) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Secs. G.301 – G.309 Reserved.

Sec. G.310 Safety Instruction.

In addition to the requirements of Sec. J.12:

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including:

(i) Routine visitation to hospitalized individuals in accordance with Sec. D.301(a)(1); and

(ii) Visitation authorized in accordance with Sec. D.301(d);

(b) A licensee shall retain the record of each survey required by G.80(a)(6) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Secs. G.2081 – G.2203 Reserved.

Sec. G.2204 Records of Molybdenum-99 Concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by G.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

Secs. G.2205 – G.2309 Reserved.

Sec. G.2310 Records of Safety Instruction.

A licensee shall maintain a record of safety instructions required by G.310, G.410, and G.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Secs. G.2311 – G.2403 Reserved.

Sec. G.2404 Records of Surveys after Source Implant and Removal.

A licensee shall maintain a record of the surveys required by G.404 and G.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Sec. G.2405 Reserved.

Sec. G.2406 Records of Brachytherapy Source Accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by G.406 for 3 years.

(b) For temporary implants, the record must include:

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

Secs. G.2407 – G.2431 Reserved.

Sec. G.2432 Records of Calibration Measurements of Brachytherapy Sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by G.432 for 3 years after the last use of the source.

(b) The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Sec. G.2433 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by G.433 for the life of the source.

(b) The record must include:

(1) The date and initial activity of the source as determined under G.432; and

(2) For each decay calculation, the date and the source activity as determined under G.433.

Secs. G.2434 – G.2604 Reserved.

Sec. G.2605 Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(6) Operability of the emergency source return control required by Section X.31(c);

(7) Leak-tightness of systems through which pool water circulates (visual inspection);

(8) Operability of the heat and smoke detectors and extinguisher system required by Section X.27 (but without turning extinguishers on);

(9) Operability of the means of pool water replenishment required by Section X.33(c);

(10) Operability of the indicators of high and low pool water levels required by Section X.33(d);

(11) Operability of the intrusion alarm required by Section X.23(i), if applicable;

(12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

(13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by Section X.35;

(14) Amount of water added to the pool to determine if the pool is leaking;

(15) Electrical wiring on required safety systems for radiation damage;

(16) Pool water conductivity measurements and analysis as required by Section X.63(b); and

(17) Leak tightness as required in Section X.33(a)(1).

(b) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

Sec. X.63 Pool Water Purity.

(a) The pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 10 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 10 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 10 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

Section X.65 Attendance During Operation.

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite: (1) Whenever the irradiator is operated using an automatic product conveyor system; and (2) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in Section X.51(g) must be onsite.

(c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in Sections X.51(f) and (g). Static irradiations may be performed without a person present at the facility.

Sec X.67 Entering and Leaving the Radiation Room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(1) Visually inspect the entire radiation room to verify that it is unoccupied; and

(2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by Section X.29(b) is operating with backup power.

Sec. X.69 Irradiation of Explosive or Flammable Materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(b) Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Records

Sec. X.81 Records and Retention Periods. The licensee shall maintain the following records at the irradiator for the periods specified.

(a) A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Agency terminates the