INSTRUCTION SHEET

COMAR 26.12.01.01

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

SUPPLEMENT No. 27

Instructions: Supplement 27 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages	Insert Pages (future)
Cover Sheet	Cover Sheet
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A3 through A4	A3 through A4
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Verify to make certain that you have the pages listed above.

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Code of Maryland Regulations 26.12.01.01

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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
1800 WASHINGTON BOULEVARD
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PART J - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

PART T - TRANSPORTATION OF RADIOACTIVE MATERIAL

(ii) Any material that—

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

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

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

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

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

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

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

"CFR" means Code of Federal Regulations.

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

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

"COMAR" means Code of Maryland Regulations

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

"Committed dose equivalent" [See "Dose"]

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

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

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

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

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

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

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

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

"Deep dose equivalent" [see "Dose"]

“Department” [see “Agency”]

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

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

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

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

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

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

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

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

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

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

"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. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

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

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

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

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

PART C

LICENSING OF RADIOACTIVE MATERIAL

Sec. C.1 Purpose and Scope.

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

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

Sec. C.2 Definitions.

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

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

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

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

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

Exemptions from the Regulatory Requirements

Sec. C.3 Source Material.

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

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

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

(1) any quantities of thorium contained in

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

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

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

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

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

(2) source material contained in the following products:

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

(ii) glassware containing not more than 2 percent by weight source material or, for glassware manufactured before August 27, 2013, 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

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

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

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

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

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

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

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

(iii) the exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

(6) natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

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

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

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

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

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

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

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

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

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

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

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

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

(a) Exempt Concentrations.

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

(2) A manufacturer, processor, or producer of a product or material is exempt from this part to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those listed in Appendix A of this part and introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

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

(b) Exempt Quantities.

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

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

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

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

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

Licenses

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

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

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

General Licenses

Sec. C.21 General Licenses - Source Material.

(a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and Federal, state and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of paragraph (a)(1) of this section; or

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

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

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

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

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

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this Part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under Part C of this regulation; or

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

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

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

(c) Any person who receives, possesses, uses, or transfers source material in accordance with this Part shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Agency in writing within 30 days of cessation.

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

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

(f) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of C.21(e)(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in C.21(e)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to C.28(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

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

(a) name and address of the general licensee;

(b) a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in C.21(e)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(c) name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in C.21(e)(3)(i)(b).

(ii) The general licensee possessing or using depleted uranium under the general license established by C.21(e)(1) shall report in writing to the Agency any changes in information furnished under C.21(e)(3)(i). The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by C.21(e)(1):

(i) shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) shall not abandon such depleted uranium;

(iii) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of C.40. In the case where the transferee receives the depleted uranium pursuant to the general license established by C.21(e)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of the information required by C.21(e)(3). In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.21(e)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of the information required by C.21(e)(3) accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation;

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

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

_____
Name of manufacturer or importer

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

(iv) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(h) Reserved.

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in C.22(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by C.22(i)(1) shall comply with the following:

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

(a) - (b) Reserved.

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

Effective October 1, 2013, a specific license shall be obtained from the Agency in accordance with Sections C.24 and C.25 for the possession and use of sealed source devices containing radioactive material which contain at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element (i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label).

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

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

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

(i) Initial training;

(ii) On-the-job training;

(iii) Annual safety reviews provided by the licensee;

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

(v) Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

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

(4) The applicant shall establish and submit to the Agency its program for annual inspections of the job performance of each logging supervisor to ensure that the Agency’s regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for 3 years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the Agency. The description must include the:

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

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

(7) A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

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

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

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

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

(v) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

(a) Each irretrievable well logging source must be immobilized and sealed in place with a cement plug;

(b) A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

(c) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm [7 inches] square and 3 mm [$^{1}/_{8}$-inch] thick. The plaque must contain:

(i) The word "CAUTION";

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

(iii) The date the source was abandoned;

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

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

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

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

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

under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

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

(4) Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of C.27(d).

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

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

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

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

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

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

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

(i) Each person licensed under C.28(b)(1) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words "radioactive material."

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

(iii) Each person licensed under C.28(b)(1) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under C.21. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

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

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

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

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

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

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

(2) For each general licensee under C.21 to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(3) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

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

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

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

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

(c) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under C.21 during the current period, a report shall be submitted to the Agency, the NRC, or responsible Agreement State Agency indicating so.

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

(c) [Reserved]

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

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

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

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

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

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in the table in D.201(a) of these regulations, and

(c) under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . . . 15 rems (150 mSv)

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

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

(d) the device has been manufactured so that:

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

(2) There is not an accessible air gap of 18 inches (0.46 meters) or greater between the radiation source and detector which would allow insertion of a 12 inch (0.30 meter) diameter sphere into the radiation beam.

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

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information,

(b) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

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

(1) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ [9/], are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

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

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

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

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

(d) Licensees having possession limits exceeding the upper bounds of Table 2 or as required by (c)(5) or (6) of this section must base financial assurance on a decommissioning funding plan.

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

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(a) The cost of an independent contractor to perform all decommissioning activities;

(b) The cost of meeting the Section D.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of Section D.1403 Criteria for License Termination Under Restricted Conditions, the cost estimate may be based on meeting the Section D.1403 criteria;

(c) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(d) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the Decommissioning Cost Estimate;

(iii) A description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 36 months, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(e) The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment*. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trustee and the trust must be acceptable to the Agency.

(2) *A surety method, insurance, or other guarantee method*. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this part. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix G of this part. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix J of this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix K of this part. Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning cost. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State and federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or State agency.

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

(3) *An external sinking fund* in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (e)(2) of this section.

(4) In the case of federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on Table 2 of this section, and indicating that funds for decommissioning will be obtained when necessary.

PART I

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

Sec. I.1 Purpose and Scope.

(a) This part establishes procedures for the registration and the use of particle accelerators.

(b) In addition to the requirements of this part, all registrants are subject to the requirements of Parts A, B, D, and J of these regulations. Registrants engaged in industrial radiographic operations are subject to the requirements of Part E of these regulations, and registrants engaged in the healing arts are subject to the requirements of Parts F and G of these regulations. Registrants whose operations result in the production of radioactive material are subject to the requirements of Part C of these regulations.

Registration Procedure

Sec. I.2 Registration Requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to Part B of these regulations.

Sec. I.3 General Requirements for the Issuance of a Registration for Particle Accelerators. In addition to the requirements of Part B of these regulations, a registration application for use of a particle accelerator will be approved only if the Agency determines that:

(a) the applicant is qualified by reason of training and experience to use the accelerator for the purpose requested in accordance with this part and Parts D and J of these regulations in such a manner as to minimize danger to public health and safety or property;

(b) the applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

(c) the issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in I.4;

(d) the applicant has appointed a properly qualified radiation safety officer;

(e) the applicant and the applicant's staff have substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

(f) the applicant has established a radiation safety committee, whenever deemed necessary by the Agency, to approve in advance, proposals for uses of particle accelerators; and

(g) the applicant has an adequate training program for operators of particle accelerators.

Sec. I.4 Human Use of Particle Accelerators. In addition to the requirements of Part B of these regulations, a registration for use of a particle accelerator in the healing arts will be issued only if:

(a) the applicant has appointed a medical committee, whenever deemed necessary by the Agency, of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

(b) the individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

(c) the individual designated on the application as the user is a physician.

Radiation Safety Requirements for the Use of Particle Accelerators

Sec. I.5 Operating and Emergency Procedures.

Each registrant shall operate a particle accelerator in compliance with

(1) all information submitted to the Agency in the registrant's Form RX 3 "Application for Certified Registration of Particle Accelerator", including but not limited to operating and emergency procedures, and

(2) the accelerator manufacturer's operating, maintenance, and emergency procedures.

Sec. I.6 Limitations.

(a) No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) has received copies of and instruction in this part and the applicable requirements of Parts D and J of these regulations, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

(b) The radiation safety committee and the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

PART J

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Sec. J.1 Purpose and Scope. This part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this part apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the Agency pursuant to Parts B and C of these regulations.

General Regulatory Provisions and Specific Requirements

Sec. J.11 Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this part, Part D and each applicable part of these regulations that apply to the activities authorized by the specific license or registration;

(2) The license, radiation machine certificate of registration, conditions and documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to activities under the license or registration; and

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part A of these regulations, and any response from the licensee or registrant.

(b) If posting of a document specified in J.11(a)(1), (2), (3) or (4) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Agency MDE 279 "Notice to Employees" shall be posted by each licensee or registrant as required by these regulations.

(d) Agency documents posted pursuant to J.11(a)(4) shall be posted within two (2) working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five (5) working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 30 working days or until action correcting the violation has been completed and this correction has been verified by the Agency.

(e) Documents, notices, or forms posted pursuant to J.11 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

Sec. J.12 Instructions to Workers.

(a) All individuals who in the course of employment potentially may receive in a year an occupational dose in excess of 100 mrem (1 mSv):

(1) Shall be kept informed of the storage, transfer, or use of radiation or radioactive materials;

(2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in the precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or radioactive material;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(6) Shall be advised as to the radiation exposure reports which workers may request pursuant to J.13.

(b) In determining those individuals subject to the requirements of paragraph (a) of this section, licensees or registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility. The extent of these instructions shall be commensurate with potential radiological health protection problems in the work place.

Sec. J.13 Notifications and Reports to Individuals.

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in J.13. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations. Each notification and report shall:

(1) Be in writing;

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(3) Include the individual's exposure information; and

(4) Contain the following statement:

"This report is furnished to you under the provisions of COMAR 26.12.01.01 Part J. You should preserve this report for further reference."

(b) Each licensee or registrant shall furnish a report to each worker annually, and within 90 days following termination, of the worker's dose as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations.

(c) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly or presently engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to D.502 of these regulations. Such report shall be furnished within 30 days from date the request was made, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever

PART T

PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

GENERAL PROVISIONS

Sec.T.1 Purpose and Scope. The regulations in this Part establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any licensee authorized by specific or general license issued by the Agency to receive, possess, use or transfer radioactive material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in its Agency license, or transports that material on public highways. No provision of this Part authorizes possession of licensed material.

Sec.T.2 Reserved.

Sec. T.3 Requirement for License. Except as authorized in a general license or a specific license issued by the Agency pursuant to Section T.17 through T.23 of these regulations, or as exempted in this Part, no licensee may –

(a) Deliver licensed material to a carrier for transport; or

(b) Transport licensed material.

Sec. T.4 Definitions. To ensure compatibility with international transportation standards, all limits in this Part are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this Part, either unit may be used. As used in this Part, the following definitions apply:

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package. "A_2" means the maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a Type A package. These values are either listed in Appendix A of this Part, Table A-1, or may be derived in accordance with the procedures prescribed in Appendix A of this Part.

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

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

"Certificate of Compliance (CoC)" means the certificate issued by the NRC which approves the design of a package for the transportation of radioactive material.

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

"Conveyance" means:

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

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

(3) "For transport by aircraft" any aircraft.

"Criticality Safety Index (CSI)" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in T.22, T.23, and 10 CFR 71.59.

"Deuterium" means, for the purposes of T.15 and T.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

"DOT" means the U.S. Department of Transportation.

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

"Fissile material" means the radionuclides plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in T.15.

"Graphite" means, for the purposes of T.15 and T.22, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

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

"Low Specific Activity (LSA) material" means radioactive material with limited specific activity which is nonfissile or is excepted under T.15, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(1) LSA-I.

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

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

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

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

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

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters.

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

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

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A-1 of this Part, or may be determined by procedures described in Appendix A of this Part.

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

"Unirradiated uranium" means uranium containing not more than 2 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3}g of uranium-236 per gram of uranium-235.

"Uranium-natural, depleted, enriched":

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

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

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

Sec. T.5 Transportation of Licensed Material.

(a) In addition to the requirements of this Part, each licensee who transports licensed material outside the site of usage, as specified in its Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

(1) The licensee shall particularly note DOT regulations in the following areas:

(i) Packaging--49 CFR Part 173: Subparts A, B, and I.

(ii) Marking and labeling--49 CFR Part 172: Subpart D; and §§ 172.400 through 172.407 and §§ 172.436 through 172.441 of Subpart E.

(iii) Placarding--49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519 and §172.556; and Appendices B and C.

(iv) Accident reporting--49 CFR Part 171: §§ 171.15 and 171.16.

(v) Shipping papers and emergency information--49 CFR Part 172: Subparts C and G.

(vi) Hazardous material employee training--49 CFR Part 172: Subpart H.

(vii) Security plans--49 CFR Part 172: Subpart I.

(viii) Hazardous material shipper/carrier registration--49 CFR Part 107: Subpart G.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(i) Rail--49 CFR Part 174: Subparts A through D and K.

(ii) Air--49 CFR Part 175.

(iii) Vessel--49 CFR Part 176: Subparts A through F and M.

(iv) Public Highway--49 CFR Part 177 and Parts 390 through 397.

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Maryland Agency of the Environment, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230.

Secs. T.6 – T.12 Reserved.

Sec. T.87 Routine Determinations.

Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this Part and of the license. The licensee shall determine that-

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(h) Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of 10 CFR 71.45;

(i) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is As Low As Reasonably Achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in T.47 at any time during transportation; and

(k) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

Sec. T.88 Air Transport of Plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Part or included indirectly by citation of 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(1) The plutonium is contained in a medical device designed for individual human application; or

(2) The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Appendix A, Table A-2, of this Part, and in which the radioactivity is essentially uniformly distributed; or

(3) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form, and is shipped in accordance with T.5; or

(4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.

(b) Nothing in paragraph (a) of this section is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

(c) For a shipment of plutonium by air which is subject to paragraph (a)(4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, DOT regulations applicable to the air transport of plutonium.

Sec. T.89 Opening Instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with Sec. D.906(e).

Sec. T.90 – T.96 Reserved.

Sec. T.97 Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste.

(a) (1) As specified in paragraphs (b), (c) and (d) of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(2) As specified in paragraphs (b), (c), and (d) of this section, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (c)(3)(iii) of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

(1) The licensed material is required by this Part to be in Type B packaging for transportation;

(2) The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(3) The quantity of licensed material in a single package exceeds the least of the following:

(i) 3000 times the A_1 value of the radionuclides as specified in Appendix A, Table A-1 for special form radioactive material;

(ii) 3000 times the A_2 value of the radionuclides as specified in Appendix A, Table A-1 for normal form radioactive material; or

(iii) 1000 TBq (27,000 Ci).

(c) Procedures for submitting advance notification.

(1) The notification must be made in writing to:

(i) The office of each appropriate governor or governor's designee;

(ii) The office of each appropriate Tribal official or Tribal official's designee; and

(iii) The Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(ii) The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for 3 years.

(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) The 7-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

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

(e) Revision notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee or to a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years.

(f) Cancellation notice.

(1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for 3 years.

Secs. T.98 – T.100 Reserved.

QUALITY ASSURANCE

Sec. T.101 Quality Assurance Requirements.

(a) Purpose. Secs. T.101 through T.137 describe quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this these sections, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. The licensee is responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to these sections.

(b) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Secs. T.101 through T.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall apply each of the applicable criteria in a graded approach, i.e., to an extent that is consistent with its importance to safety.

(c) Approval of program. Before the use of any package for the shipment of licensed material subject to Secs. T.101 through T.137, each licensee shall obtain NRC approval of its quality assurance program in accordance with 10 CFR Part 71 Subpart H.