PART C

LICENSING OF RADIOACTIVE MATERIAL

1. Purpose and Scope.

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

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

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

EXEMPTIONS FROM THE REGULATORY REQUIREMENTS

2. Source Material.

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

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

C. Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers:

(1) any quantities of thorium contained in:

(a) incandescent gas mantles,

(b) vacuum tubes,

(c) welding rods,

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

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

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

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

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

(2) source material contained in the following products:

(a) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

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

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

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

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

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

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

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

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

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

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

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

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

(b) the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm);

(7) thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either

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

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

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

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

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

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

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

3. Radioactive Material Other Than Source Material.

A. Exempt Concentrations

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

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

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

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

B. Exempt Quantities.

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

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

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

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.3.B or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32.18 which license states that the radioactive material may be transferred by the licensee to persons exempt under C.3.B or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

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

C. Exempt Items.

(1) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who desire to initially transfer for sale or distribute the following products containing radioactive material, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products[3]/

(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

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

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

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

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

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

(vi) 2.22 MBq (60 mCi) of promethium-147 per watch dial or 4.44 MBq (120 mCi) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(vii) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a) For wrist watches, 1 μGy (0.1 mR) per hour at 10 centimeters from any surface.

(b) For pocket watches, 1 μGy (0.1 mR) per hour at 1 centimeter from any surface.

(c) For any other timepiece, 2 μGy (0.2 mR) per hour at 10 centimeters from any surface.

(viii) 37 kBq (1μCi) of radium-226 per timepiece in timepieces manufactured prior to the November 30, 2007.

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

(c) Marine compasses containing not more than 27.8 GBq (750 mCi) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 mCi) of tritium gas manufactured before December 17, 2007.

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

(i) 5.55 GBq (150 mCi) of tritium per microwave receiver protector tube or 370 MBq (10 mCi) of tritium per any other electron tube.

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

(ii) 37 kBq (1 µCi) of cobalt-60.

(iii) 185 kBq (5 µCi) of nickel-63.

(iv) 1.11 MBq (30 µCi) of krypton-85.

(v) 185 kBq (5 µCi) of cesium-137.

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

And provided further, that the radiation dose rate from each electron tube containing radioactive material does not exceed 10 µGy (1 mRad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[4]/

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

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

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

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

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

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

(3) Self-Luminous Products Containing Radioactive Material.

(a) Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in C.3.C(3) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(b) Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq (0.1 µCi) of radium-226 which were or manufactured prior to July 1, 1999.

(c) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to C.3.C.(3) (a), should apply for a license pursuant to10 CFR 32.22, which license states that the product may be transferred by the licensee to persons exempt from C.3.C.(3)(a).or equivalent regulations of an Agreement State.

[4]/ For purposes of C.3.C.1.(g), "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(4) Gas and Aerosol Detectors Containing Radioactive Material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution, gas and aerosol detectors containing radioactive material, any person is exempt from the requirements set forth in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission [5]/ pursuant to Section 32.26 of 10 CFR Part 32; This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by the Agency, the NRC, or an Agreement State authorizing distribution to persons exempt from regulatory requirements.

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

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

(5) Exemptions for Capsules Containing Carbon-14 Urea for *in –vivo* Diagnostic Use for Humans.

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

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

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

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

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

LICENSES

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

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

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

B. 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.

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

D. Each general licensee or registrant that is required to register by this Part shall make all necessary reports as required by C.14.D of this Part.

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

GENERAL LICENSES

5. General Licenses - Source Material.

A. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and State and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

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

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

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

E. Depleted Uranium in Industrial Products and Devices.

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

(2) The general license in C.5.E(1). applies only to industrial products or devices which have been manufactured or initially transferred either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to C.11.L. or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) (a) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by C.5.D(1) shall file Agency Form HHE 860 "Registration Certificate - Use of Depleted Uranium Under General License," with the Agency and pay the registration fee referenced in Appendix A of this Part. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium or 30 days after the effective date of these regulations for depleted uranium acquired prior to the effective date. The registrant shall furnish on Agency Form HHE 860 the following information and such other information as may be required by that form:

(i) name and address of the registrant;

(ii) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in C.5.D(1). and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

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

(b) The registrant possessing or using depleted uranium under the general license established by C.5.D(1). shall report in writing to the Agency any changes in information furnished by him in Agency Form HHE 860 "Registration Certificate - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by C.5.E(1):

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

(b) Shall not abandon such depleted uranium.

(c) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of C.21. In the case where the transferee receives the depleted uranium pursuant to the general license established by C.5.E(1), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form HHE 860. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulations equivalent to C.5.E(1)., the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form HHE 860 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation.

(d) Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.

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

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

6. General Licenses - Radioactive Material Other Than Source Material.

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

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

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

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

C. Certain Measuring, Gauging or Controlling Devices.

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

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

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.6.C(1) shall file Agency Form HHE 861 "Registration Certificate - Use of Fixed Measuring, Gauging or Controlling Devices", Agency Form HHE 862 "Registration Certificate - Use of Portable Measuring, Gauging or Controlling Devices" or Agency Form HHE 864 “Registration Certificate for use of Static Eliminators, Electron Capture Devices, Gas Chromatographs, or Other Devices which Contain Radioactive Material Under a General License” with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such device or 30 days after the effective date of these regulations for devices acquired prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part and:

(a) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(b) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however,

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

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

(c) shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

(ii) by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;

(d) shall maintain records showing compliance with the requirements of C.6.B(3)(b) and c. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.6.B(3)(b) shall be maintained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by C.6.B(3)(b) shall be maintained for 3 years after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by C.6.B(3)(c) shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed;

(e) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 Bq (0.005 μCi) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;

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

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

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

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

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

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

(c) The date of the transfer.

(iii) shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

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

(b) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (a) of this section) so that the device is labeled in compliance with Part D.1904; however the manufacturer, model number, and serial number must be retained;

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

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

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

(i) where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this Section, a copy of Sections 10 CFR 31.2, 30.51, C.25, D.2201,D.2202, and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency: the manufacturer's (or initial transferor's) name and model and serial number of device transferred, the name , address for the location of use of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or

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

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

(k) shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Radiation Control Program and provide written justification as to why it cannot comply.

(l) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(m) (i) shall register, in accordance with C.6.C.(3)(m)(ii) and (iii), devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic ((i)e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph C.6.C.(3)(m)(iii)(d), represents a separate general licensee and requires a separate registration and fee.

(ii) If in possession of a device meeting the criteria of C.6.C(3)(m)(i), shall register these devices annually with the Agency and shall pay the required fee. Registration must be done by verifying, correcting and/or adding to the information provided in a request for registration received from the Agency. The registration information must be submitted to the Agency within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general license holding devices meeting the criteria of C.6.C.(3)(m)(i) is subject to bankruptcy notification requirement in Part C.

(iii) In registering devices, shall furnish the following information and any other information specifically requested by the Agency:

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

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

(c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph C.6.C(3)(l). of this section.

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

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

(f) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(iv) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph C.6.C.(3)(m)(i) this section are not subject to registration requirements if the devices are used in areas subject to Agency jurisdiction for a period less than 180 days in any calendar year. The Agency will not request registration information from such licensees.

n. shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Radiation Control Program Manager within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

o. shall not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by C.6.C(3)(c) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in C.6.B(1) does not authorize the manufacture of devices containing radioactive material.

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

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

E. Calibration and Reference Sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of C.6.E. (4) and (5), americium-241 in the form of calibration or reference sources:

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

(b) any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

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

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

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

(5) The general licenses provided in C.6.E(1), (2) and (3) are subject to the provisions of A.4 through A.9, C.14, C.21, C.22, and Parts D, J and L of these regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) shall not possess at any one time, at any one location of storage or use, more than 185 kBq (5 µCi) of americium-241, 185 kBq (5 µCi) of plutonium, or 185 kBq (5 µCi) of radium-226 in such sources;

(b) shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes the following statement, as appropriate, or a substantially similar statement which contains the information called for in the following statement, as appropriate:

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

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)[6]/
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
(Name of manufacturer or importer)

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

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

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

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

F. General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing.

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

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

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

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

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

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

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

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

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

[6]/ Showing only the name of the appropriate material

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

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

(b) the location of use; and

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

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

(a) The general licensee shall not possess at any one time, pursuant to the general license in C.6.F.(1)., at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 7.4 MBq (200 µCi).

(b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(c) The general licensee shall use the radioactive material only for the uses authorized by C.6.F.(1).

(d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(e) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.6.F.(1). as required by D.1310. of these regulations.

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

(a) Except as prepackaged units, which are labeled in accordance with the provisions of an applicable specific license, issued pursuant to C.11.G. or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under C.6.F or its equivalent, and

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

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

(5) The registrant possessing or using radioactive material under the general license of C.6.F.1 shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In-Vitro Testing with Radioactive Material Under General License", Agency Form HHE 863. The report shall be furnished within 30 days after the effective date of such change.

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

G. Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 µCI) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such device pursuant to the licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in C.6.G.(1).,

(a) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of D.1310 of these regulations;

(b) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(c) are exempt from the requirements of Part D and Part J of these regulations except that such person shall comply with the provisions of D.2001, D.2201, and D.2202.

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

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

H. Self Luminous Products Containing Radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of C.6.H.(2) through (4), radium-226 contained in the following products manufactured prior to November 30, 2007:

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

(b) Intact timepieces containing greater than 1 microcurie (0.037 MBq), non-intact timepieces, and timepiece hands and dials no longer installed in timepieces.

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

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

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

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

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

(a) Notify the Agency should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Agency within 30 days.

(b) Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to D.2008 of these regulations or by transfer to a person authorized by a specific license to receive the radium- 226 in the product or as otherwise approved by the Agency.

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

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

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

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

I General License to Install Devices Generally Licensed in C.6.C.

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

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

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

J. Luminous Safety Devices for Aircraft.

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

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

(b) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

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

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

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

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

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

SPECIFIC LICENSES

7. Filing Application for Specific Licenses.

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

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

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on their behalf.

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

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

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

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

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

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

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

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

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

H. An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part G or equivalent Agreement State requirements shall include:

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

(2). Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in C.11.J(1)(b).

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in C.11.J(2)(b).

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

I. Emergency Planning

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

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

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

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

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

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

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

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

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

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

(g) Other factors appropriate for the specific facility.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8. General Requirements for the Issuance of Specific Licenses. A license application will be approved if the Agency determines that:

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

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

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

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

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

F. Financial Surety for Decommissioning, Recovery or Site Reclamation.

(1) Each applicant for a specific license authorizing the possession and use of special nuclear material, source material, or unsealed radioactive material in quantities and amounts in excess of those indicated in Table F.1 shall submit a decommissioning funding plan, as described in paragraph (3) of this section, in the event of planned or unplanned decommissioning, recovery, or site reclamation. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of quantity of each isotope to the applicable value in Part C, Appendix E.

TABLE F.1

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

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

(a) Submit a decommissioning funding plan as described in paragraph (3) of this section; or

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

(3) Each funding plan must contain a cost estimate for decommissioning, recovery or reclamation, and a description of the method of assuring funds for such including means of adjusting cost estimates and associated funding levels over the life of the facility.

Table F.2

Type of Radioactive Material	Exceeding	Assurance Amount
Special Nuclear	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities*	$1,125,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities*	$225,000
Source Material	Greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form	$225,000
Radioactive Material	Half life greater than 120 days and in quantities:	
	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in unsealed form*	$1,125,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in unsealed form*	$225,000
	Greater than 10^{10} times the applicable quantities in sealed sources	$113,000

**As indicated in Part C, App. E

(4) Financial assurance must be provided by one or more of the following methods:

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the facility and that are in an amount such that the principal plus accumulated earnings would be sufficient to pay the necessary costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

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

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

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

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

(c) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficient to pay the necessary costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

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

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

(f) Each person licensed under this Part shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. Before licensed activities are transferred or assigned in accordance with this Part, licensees shall transfer all records described in this paragraph to the new licensee. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

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

These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

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

(iii) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

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

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

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

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

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

9. Special Requirements for The Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in C.8, a specific license for use of sealed sources in industrial radiography will be issued if the applicant meets the requirements set forth in Part E of these regulations.

10. Special Requirements for Specific Licenses of Broad Scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses. [7]/

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with C.10.C.(2) prior to use of the radioactive material.

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

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

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

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

(b) at least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessa4 -61(ar)-6. a8(es)-7.8(s)-7u8(a)-24.3(4 .1(e)0 .8(s)-7.8(a)-2(of)-4 .1(e)0 o.2(per

[redacted]

(b) the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A, the re-concentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Each person licensed under C.11.A. shall file an annual report with the Agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to C.11.A during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

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

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

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

D. Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under C.6.D.

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

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

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

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

(ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10 percent of the limits specified in D.6., and

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

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

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

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

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

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

The receipt, possession, use, and transfer of this device, Model_____[9]/, 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)

(d) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, “Caution-Radioactive Material," the radiation symbol described in Part D.1901 of these regulations, and the name of the manufacturer or initial distributor.

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

[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.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information, which includes, but is not limited to:

(a) primary containment (source capsule);

(b) protection of primary containment;

(c) method of sealing containment;

(d) containment construction materials;

(e) form of contained radioactive material;

(f) maximum temperature withstood during prototype tests;

(g) maximum pressure withstood during prototype tests;

(h) maximum quantity of contained radioactive material;

(i) radiotoxicity of contained radioactive material; and

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

(3) In the event the applicant desires that the general licensee under C.6.D, or under equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive in one year a dose in excess of 10 percent of the limits specified in D.1201.A.

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

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

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

(ii) a copy of C.25, 2201 and D.2202 of these regulations;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The identity of each general licensee by name and address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

(b) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(c) the date of transfer;

(d) the type, model number and serial number of the device transferred; and

(e) the quantity and type of radioactive material contained in the device.

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

(iii) For devices received from a C.11.D general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(iv) If the licensee makes changes to a device possessed by a C.11.D general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

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

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

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

(d) Reports to Other Agencies.

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

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

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

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

(v) If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State Agency upon request of the agency.

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

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

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

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

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

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

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

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

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

E. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft.

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

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

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

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

(ii) Details of construction and design;

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

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

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

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

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

(d) The Agency determines that:

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

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

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

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

(2) Labeling of devices.

(a) A person licensed under C.11.E. to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under C.6.C of this chapter shall, except as provided in C.11.E(2)(b) affix to each device a label containing the radiation symbol prescribed by D.1901 of this chapter, such other information as may be required by the Agency including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:[1/]

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

CAUTION--RADIOACTIVE MATERIAL

_____

(Name of manufacturer, assembler, or initial transferor.) *

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

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

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

(b) The type of radioactive material; and

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

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

(b) The type and quantity of radioactive material,

(c) The model number,

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

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

(3) Quality assurance; prohibition of transfer.

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[1] Devices licensed under C.28.E prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

[*/] The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

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

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

(i) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Step 5. The internal temperature of the chamber shall be raised to +85' C (185' F) at atmospheric pressure. The temperature of the device shall be stabilized at +85' C and maintained for 2 hours. The device shall then be visually inspected to determine the extent of any deterioration.

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

Step 7. The chamber temperature shall be reduced to +55 C (130 F) at atmospheric pressure. The temperature of the device shall be stabilized at this temperature for a period of 4 hours.

Step 8. The internal temperature of the chamber shall be reduced to +30' C (86' F) and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

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

Step 10. The internal pressure of the chamber shall be maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to +20' C (68' F) and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

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

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

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

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

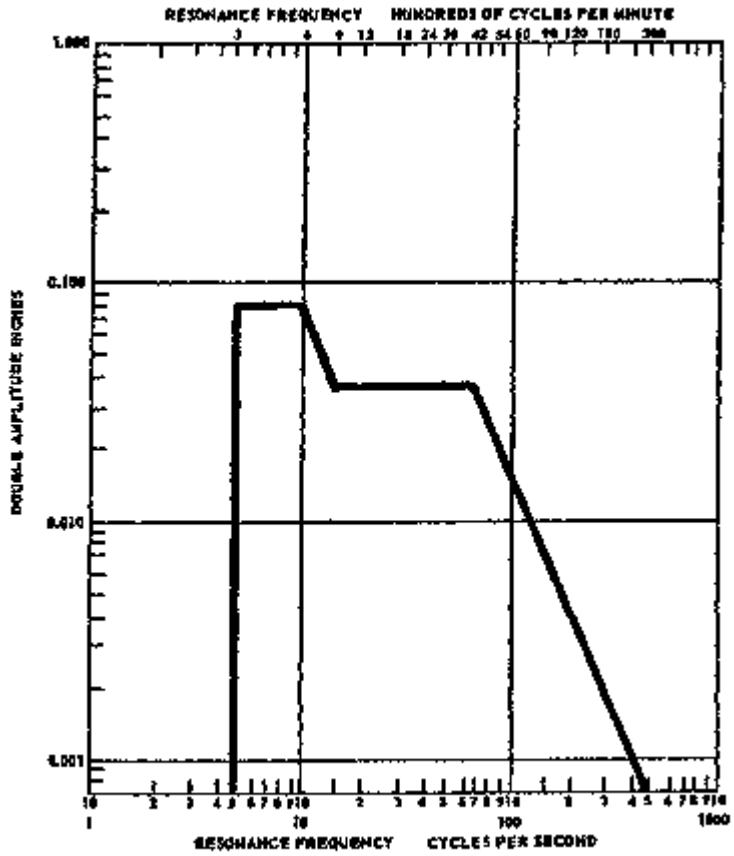

FIGURE 1—Amplitude of vibration at resonance frequency.

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

(iii) Cycling. Devices to be mounted only on vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10 and 55 cycles per second in 1-minute cycles for the periods and temperature conditions shown in Table (I) Devices to be installed in aircraft without vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.036 inch or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15-minute cycles for the periods and temperature conditions shown in Table (I).

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

(d) Shock test. The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to equivalent treatment in a test device simulating such a free fall. The drop test shall be repeated 100 times from random orientations.

(e) Hermetic seal and waterproof test. On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the device, or water entering the device, shall be considered leakage.

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

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

F. Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.6.E.

(1) An application for a specific license to manufacture or initially transfer, calibration or reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under C.6.E will be approved if:

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

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

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

(ii) Details of construction and design;

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

(iv) Procedures for and results of prototype testing of sources, which are designed to contain more than 185 Bq (0.005 μCi) of americium-241, radium-226 to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

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

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

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

(c) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent;

(d) Each source will contain no more than 185 kBq (5 μCi) of americium-241 or radium-226; and

(e) The Agency determines, with respect to any type of source containing more than 185 Bq (0.005 μCi) of americium-241 or radium-226, that:

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

(ii) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by C.11.F(2), Schedule C, of this part.

(2) Schedule C--prototype tests for calibration or reference sources containing americium-241, plutonium or radium-226. An applicant for a license pursuant to C.11.F shall, for any type of source which is designed to contain more than 185 Bq (0.005 μCi) of americium-241, plutonium or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 185 Bq (0.005 μCi) of americium-241, plutonium or radium-226, as follows:

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

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

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

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

(e) Dry wipe test. On completion of the preceding test in this section, the dry wipe test described in C.11.F.(2)(b) shall be repeated.

(f) Observations. Removal of more than 185 Bq (0.005 μCi) of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted
to the Agency shall be given in terms of radioactivity in microcuries (Bq) and percent of removal from the total amount of radioactive material deposited on the source.

(3). Labeling of devices. Each person licensed under C.11.F. shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[1/]

The receipt, possession, use and transfer of this source, Model No.__, Serial No. __, are subject to a general license and the regulations of the NRC or an Agreement State. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL--

THIS SOURCE CONTAINS AMERICIUM-241 OR RADIUM-226].

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or initial transferor

(4) Leak testing of each source. Each person licensed under C.11.F shall perform a dry wipe test upon each source containing more than 3.7 kBq (0.1 µCi) of americium-241 or radium 226 prior to transferring the source to a general licensee under C.6. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 185 Bq (0.005 µCi) of americium-241or radium-226. If any such test discloses more than 185 Bq (0.005 µCi) of radioactive material, the source shall be deemed to be leaking or losing americium-241, or radium-226 and shall not be transferred to a general licensee under C.6 or equivalent regulations of an Agreement State.

G. Serialization of Nationally Tracked Sources. Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

H. Manufacture and Distribution of Radioactive Material for Certain *In-Vitro* Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.6.F will be approved if:

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

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

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

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

(c) Carbon-14 in units not exceeding 370 kBq (10 µ) each.

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

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

(f) Cobalt-57 in units not exceeding 370 kBq (10 µ Ci) each.

(g) Selenium-75 in units not exceeding 370 kBq (10 µCi) each.

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

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

[1/] Sources licensed under C.28f prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

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

(b) displaying the radiation caution symbol described in D.1901.A and the words, **"CAUTION, RADIOACTIVE MATERIAL**", and **"Not for Internal or External Use in Humans or Animals**".

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

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

(Name of manufacturer)

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in D.2001 of these regulations.

(I) Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium-90.

(1) An application for a specific license to manufacture or initially transfer ice detection devices to persons generally licensed under C.6.G. will be approved if:

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

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

(i) Chemical and physical form and maximum quantity of strontium-90 in the device;

(ii) Details of construction and design of the source of radiation and its shielding;

(iii) Radiation profile of a prototype device;

(iv) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

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

(vi) Description of labeling to be affixed to the device;

(vii) Instructions for handling and installation of the device;

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

(c) Each device will contain no more than 1.85 MBq (50 µCi) of strontium-90 in an insoluble form;

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by D.1901(a) of these regulations, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices; and

(e) The Agency determines that:

(i) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(ii) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 5 mSv (0.5 rem) in a year under ordinary circumstances of use;

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

(iv). The device has been subjected to and has satisfactorily passed the prototype tests prescribed by C.11.(I)(1)(c); and

(v). Quality control procedures have been established to satisfy the requirements of C.11.(I)(2).

(2) Quality assurance; prohibition of transfer.

(a) Each person licensed under C.11.I shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under C.11.I shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 37 Bq (2,200 disintegrations per minute) of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

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

(i) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, shall be considered as a defective unit.

(ii) The immersion test water from the preceding test in C.11.(I)(2)(c)(i) of this section shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90 in any device, the device shall be considered as a defective unit.

(d) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by C.11.I(2)(c). and proposed criteria for acceptance under those procedures. The Agency will approve the proposed alternative procedures if the applicant demonstrates that:

(i) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

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

(e) No person licensed under C11.I (2) shall transfer to persons generally licensed under C.6.G. of this chapter:

(i) Any device which has been tested and found defective under the criteria and procedures specified in this C.11.I unless the defective units have been repaired or reworked and then met the tests set out in C.11.I(2)(c); or

(ii) Any inspection lot which has been rejected as a result of the procedures in C.11.I(2) or alternative procedures in C.11.(I)(2)(d) unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in C.11.(I)(2)(c)

(3) Schedule D--prototype tests for ice detection devices containing strontium-90. An applicant for a license pursuant to C.11.I shall conduct prototype tests on each of five prototype ice detection devices as follows:

(a)Temperature-altitude test. The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in Step 1 through Step 10 of C.11.E.(4) (a)

(b) Vibration tests. The device shall be subjected to vibration tests as set forth in C.11.E.(4)(b).

(c) Shock test. The device shall be subjected to shock test as set forth in C.11.E.(4)(d).

(d) Hermetic seal and waterproof test. On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium-90 shall be considered leakage.

(e) Observations. After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of strontium-90. Any evidence of leakage or damage to or failure of any device which could affect containment of the strontium-90 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of strontium-90 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of strontium-90 in the water used in the hermetic seal and waterproof test prescribed in C.11.I(2)(d) shall also be measured. The detection on the filter paper of more than 37 Bq (2,200 disintegrations per minute) of strontium-90 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of strontium-90 in any device, shall be cause for rejection of the tested device.

J. Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Part G Licenses.

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

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

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

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

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

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

(iv) Operating as a nuclear pharmacy within a Federal medical institution.

(v) A Positron Emission Tomography (PET) drug production facility registered with a State Agency.

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

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words **"CAUTION, RADIOACTIVE MATERIAL**" or **"DANGER, RADIOACTIVE MATERIAL**"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

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

(2) A licensee described by paragraph (1)(b)(iii) or (iv) of this section:

(a) May prepare radioactive drugs for medical use, as defined in Part G.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (2)(b) and (2)(d) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in Part G.

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

(i) This individual qualifies as an authorized nuclear pharmacist as defined in Part G.2,

(ii) This individual meets the requirements specified in Part G and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (2)(d) of this section.

(c) The actions authorized in paragraphs (2)(a) and (2)(b) of this section are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in Part A .2)as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Agency under this part.

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

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

(e) Shall provide to the Agency a copy of each individual's:

(i) Certification by a specialty board whose certification process has been recognized by the Agency, the NRC or an Agreement State as specified in G.55.A with the written attestation signed by a preceptor as required by G.55B(2); or

(ii) The Agency, the NRC the Board of Pharmaceutical Specialties, the Commission or an Agreement State license, or

(iii) NRC master materials license permit, or

(iv) The permit issued by a licensee or NRC masters materials permittee of broad scope, or the authorization form from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, and

(v) Copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, the individual to work as an authorized nuclear pharmacist under paragraphs C.11.J.(2)(b)(i) and C.11.J.(2)(b)(ii).

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

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

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

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

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

K. Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Part G.200 will be approved if:

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

(2) the applicant submits evidence that:

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

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

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

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

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

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

(b) a statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Agency pursuant to Part G.200 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State. The labels, leaflets or brochures required by C.11.J are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to Part G.200 may submit the pertinent information specified in C.11.J.

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

(1) The applicant satisfies the general requirements in C.8 of this part.

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

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

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

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

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

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

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

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

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

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of source or device is licensed by the Agency for distribution to persons licensed pursuant to Part G.65, G.400, G.500 and G.600 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State, provided, that such labeling for sources which do not require long term storage (e.g., gold-198 seeds) may be on a leaflet or brochure which accompanies the source.

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

(5) In determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

(a) primary containment (source capsule),

(b) protection of primary containment,

(c) method of sealing containment,

(d) containment construction materials,

(e) form of contained radioactive material,

(f) maximum temperature withstood during prototype tests,

(g) maximum pressure withstood during prototype tests,

(h) maximum quantity of contained radioactive material,

(i) radiotoxicity of contained radioactive material, and

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

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

(1) An application for specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.5.D or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

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

(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in one year a radiation dose in excess of 10 percent of the limits specified in D.1201.; and

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

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under C.11.L only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under C.11.L if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.11.L a shall:

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

(b) label or mark each unit to:

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

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

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

(d) (i) furnish a copy of the general license contained in C.5.D and a copy of HHE Form 860 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in C.5.D, or

(ii) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.5.D and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.5.D and a copy of HHE Form 860 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in C.5.D;

(e) report to the Agency all transfers of industrial products or devices to persons for use under general license in C.5.D. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under C.5.D during the reporting period, the report shall so indicate;

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

(ii) report to the responsible State Agency all transfers of devices manufactured and distributed pursuant to C.11.L for use under a general license in that State's regulations equivalent to C.5.D,

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

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

(v) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State Agency; and

(g) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.5.D or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

12. Special Requirements for Issuance of Specific Licenses for Source Material Milling. *Reserved.*

13. Issuance of Specific Licenses.

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

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

C. Each person licensed by the Agency pursuant to the regulations in this Part shall confine his possession and use of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part shall carry with it the right to receive, possess, and use radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with Part L of these regulations.

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

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

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

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

(4) protect restricted data

14. Specific Terms and Conditions of License.

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

B. No license issued or granted pursuant to these regulations nor any right to possess or utilize radioactive material granted by any license issued pursuant to these regulations shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect and to all valid rules, regulations and orders of the Agency and shall give its consent in writing.

C. Each person licensed by the Agency pursuant to these regulations shall confine his use and possession of the radioactive material licensed to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to these regulations shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport shall be in accordance with Part L.

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

E. Each licensee shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

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

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

(4) This notification must indicate:

(a) The bankruptcy court in which the petition for bankruptcy was filed; and

(b) The date of the filing of the petition.

F. Security Requirements For Portable Gauges: Each portable gauge licensee or registrant shall use a minimum of two independent physical controls that for tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

G. Positron Emission Tomography (PET) Production

(1) Authorization under C.7.H. to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under C.7.H. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in C.11.J for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in C.11.J of this chapter.

(3) A licensee that is a pharmacy authorized under C.7.H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(a) authorized nuclear pharmacist that meets the requirements in C.11.J, or

(b) an individual under the supervision of an authorized nuclear pharmacist as specified in Part G.

(4) A pharmacy, authorized under C.7.H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of C.11.J.

15. Expiration and Termination of Licenses

A. Except as provided in C.16.B and paragraph D of this section, each specific license expires at the end of the day, in the month and year stated in the license.

B. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. The notification and request for termination of the license must include the reports and information specified in paragraphs .E.(1) d and e of this section. The licensee is subject to the provisions of paragraphs E and F of this section, as applicable.

C. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when no principal activities under the license have been conducted for a period of 24 months, or no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

D. No less than 30 days before the expiration date specified in a specific license the licensee shall either:

(1) Submit an application for license renewal under C.16; or

(2) Notify the Agency in writing if the licensee decides not to renew the license.

E. (1) If a licensee does not submit an application for license renewal under C.16, the licensee shall, on or before the expiration date specified in the license:

(a) Terminate use of radioactive, source, or special nuclear material, as appropriate;

(b) Remove radioactive contamination to the extent practicable except for those procedures covered by paragraph C.15.E(3) of this section;

(c) Properly dispose of source material;

(d) Submit a completed form, Certificate of Disposition of Material; and

(e) Submit a radiation survey report of the premises to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:

(i) Report levels of radiation in units of microrads (mGy) per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries/Bq) per 100 square centimeters for removable and fixed surfaces, microcuries (or Bq) per milliliter for water, and picocuries per gram for contaminated solids such as soils, or concrete; and

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

(2) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the information submitted under this paragraph and paragraphs E(1) d and e of this section is adequate, the Agency will notify the licensee in writing that the license is terminated.

(3) (a) If detectable levels of residual radioactive contamination attributable to activities conducted under a license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Agency notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of paragraph E of this section.

(b) In addition to the information submitted under paragraphs E.(1)d and e of this section the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

(c) The licensee shall also submit a plan for completion of decommissioning, recovery, or site reclamation if the procedures necessary to carry these out have not been previously approved by the Agency.

F. The proposed decommissioning, recovery, or site reclamation plan, if required by paragraph C.15.E(3) or by license condition, must include:

(1) Discussion of these planned activities;

(2) Description of methods used to assure protection of workers and the environment against radiation hazards during such activities;

(3) A description of the planned final radiation survey; and

(4) An updated detailed cost estimate, comparison of that estimate with present funds set aside, and plans for assuring the availability of adequate funds for completion of decommissioning, recovery or site reclamation.

(5) The proposed plan will be approved by the Agency if the information therein demonstrates that the objectives of the plan will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

G. Each licensee who possesses residual radioactive material, source material, or special nuclear material under paragraph C.15.E(3), following the expiration date specified in the license, shall:

(1) Limit actions involving source radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

H. As the final step in decommissioning, the licensee shall-

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting Maine Form HHE-892 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in D.60 through D.65. The licensee shall, as appropriate-

(a) Report levels of gamma radiation in units if millirem (or mSv) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of microcuries (or Bq) per 100 square centimeters - removable or fixed - for surfaces, microcuries per milliliter for water, and picocuries per gram for solids such as soils or concrete; and

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

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

(1) Radioactive material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

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

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

(4) Records required by Part D have been received.

16. Renewal of Licenses.

A. Applications for renewal of specific licenses shall be filed in accordance with C.7.

B. In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Agency.

17. Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.7. and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment**.**

18. Agency Action on Application to Renew and Amend. In considering an application by a licensee to renew or amend his license, the Agency will apply the criteria set forth in C.8, and C.9., C.10 or C.11 and Part E, Part G, Part K, and Part N of these regulations as applicable.

19. Persons Possessing a License for Source, Radioactive or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of These Regulations.

Any person who, on the effective date of these regulations, possesses a general or specific license for source, radioactive, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under this part and the Act, such license to expire either 90 days after receipt from the Agency of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

20. Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material on Effective Date of These Regulations. Any person who, on the effective date of these regulations, possesses NARM for which a specific license is required by the Act or this part shall be deemed to possess such a license issued under the Act and this part. Such license shall expire 90 days after the effective date of these regulations; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Agency. NARM radionuclides are shown in Appendix B to Part C**.**

21. Transfer of Material.

A. No licensee shall transfer radioactive material except as authorized pursuant to this section.

B. Except as otherwise provided in the license and subject to the provisions of C.21.C and D, any licensee may transfer radioactive material:

(1) to the Agency with prior approval of the agency;

(2) to the U.S. Department of Energy;

(3) to any person exempt from these regulations to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the Nuclear Regulatory Commission or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency or any Agreement State; or

(5) as otherwise authorized by the Agency in writing.

C. Before transferring radioactive material to a specific licensee of the Agency, the Nuclear Regulatory Commission or an Agreement State, or to a general licensee who is required to register with the Agency, the Nuclear Regulatory Commission or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

D. The following methods for the verification required by C.21.C are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) the transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date provided, that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the Nuclear Regulatory Commission, the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) when none of the methods of verification described in C.21.D (1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain a record confirmation from the Agency, the Nuclear Regulatory Commission or the licensing agency of an Agreement that the transferee is licensed to receive the radioactive material.

(6) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Part L.

22. Modification, Revocation and Termination of Licenses.

A. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations and orders issued by the Agency.

B. Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts of conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

D. The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

23. Deliberate Misconduct.

A. Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

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

(2) Deliberately submit to the Agency, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

B. A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures Part B.

C. For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Agency; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

RECIPROCITY

24. Reciprocal Recognition of Licenses.

A. Licenses of Radioactive, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the Nuclear Regulatory Commission or any Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State provided that:

(a) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(b) the out-of-state licensee notifies the Agency in writing at least 3 working days prior to engaging in such activity and receive Agency approval. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document and HHE form 865. If, for a specific case, the 3 working day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Agency, obtain permission to proceed sooner. The Agency requires that the applicable Maine annual license fee accompany the initial request for reciprocity (see table 1 to appendix A of this part). This reciprocity fee will cover a period of one year from the time of application, at which time a new fee submittal will be required. This requirement does not waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.24.A(1).

(c) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

(d) the out-of-state licensee supplies such other information as the Agency may request;

(e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.24.A(1) except by transfer to a person:

(i) specifically licensed by the Agency or by the. Nuclear Regulatory Commission to receive such material, or

(ii) exempt from the requirements for a license for such material under C.3; and

(f) the out-of-state licensee shall not, under the general license concerning activities within this State, possess or use radioactive materials, or engage in the activities authorized in paragraph A of this section, for more than 180 days accumulative in any calendar year.

(2) Notwithstanding the provisions of C.24.A(1), any person who holds a specific license issued by the Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in C.6.B(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

(a) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Nuclear Regulatory Commission or an Agreement State;

(b) such person shall assure that any labels required to be affixed to the device under regulations of the authority, which licensed manufacture of the device, bear a statement that **"Removal of this label is prohibited";**

(c) Such person shall file Agency Form HHE 867 "Registration Certificate – Service of Generally Licensed devices". The form shall be submitted within 30 days after the first entry or 30 days after the effective date of these regulations for persons in state prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part. This registration fee will cover a period of one year from the time of application, at which time a new fee submittal will be required.

B. The Agency may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

RECORDS

25. Records.

A. Each person who receives radioactive material pursuant to a license issued pursuant to this Part and Parts E, G, I, M, N and Q of these regulations shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

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

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of these regulations dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Agency terminates each license that authorizes disposal of the material.

B. The licensee shall retain each record that is required by the regulations in this Part and Parts E, G, and N of these regulations or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

C. (1) Records which must be maintained pursuant to this Part and Parts E, G, and N of these regulations may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Agency's regulations in this Part and Parts E, G, and N of these regulations, license condition, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Part and Parts E, G, and N of these regulations for such records shall apply unless the Agency, pursuant to A..3.A. or C.4, has granted a specific exemption from the record retention requirements specified in the regulations in this Part or Parts E, G, and , N of these regulations

D. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

(1) Records of disposal of licensed material made under Part D.2001 (including burials authorized before January 28, 1981), Part D.2003, Part D.2004, and Part D; and

(2). Records required by Part D.2103(b)iv. of these regulations.

E. If licensed activities are transferred or assigned in accordance with C.3.A(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under Part D.2001 (including burials authorized before January 28, 1981), Part D.2003, Part D.2004, Part D.2005; and

(2) Records required by D.2103(b)iv. of these regulations.

F. Prior to license termination, each licensee shall forward the records required by these regulations, to the Agency.

SCHEDULE A

EXEMPT CONCENTRATIONS OF RADIOACTIVE MATERIALS WHICH ARE INTRODUCED INTO PRODUCTS *(PART C.3.A)*

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml 1/	Column II Liquid and Solid Concentration μCi/ml 2/
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1X10^{-3}$
Argon (18)	Ar-37	$1X10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1X10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1X10^{-3}$
	Co-60		$5X10^{-4}$
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165		$4X10^{-3}$
	Dy-166		$4X10^{-4}$
Erbium (68)	Er-169		$9X10^{-4}$
	Er-171		$1X10^{-3}$
Europium (63)	Eu-152		$6X10^{-4}$
	(Tr=9.2 hr)		
	Eu-155		$2X10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ μCi/gm for solids.

C. Schedule A

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml 1/	Column II Liquid and Solid Concentration μCi/ml 2/
Fluorine (9)	F-18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd-153		$2X10^{-3}$
	Gd-159		$8X10^{-4}$
Gallium (31)	Ga-72		$4X10^{-4}$
Germanium (32)	Ge-71		$2X10^{-2}$
Gold (79)	Au-196		$2X10^{-3}$
	Au-198		$5X10^{-4}$
	Au-199		$2X10^{-3}$
Hafnium (72)	Hf-181		$7X10^{-4}$
Hydrogen (1)	H-3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In-113m		$1X10^{-2}$
	In-114m		$2X10^{-4}$
Iodine (53)	I-126	$3X10^{-9}$	$2X10^{-5}$
	I-131	$3X10^{-9}$	$2X10^{-5}$
	I-132	$8X10^{-8}$	$6X10^{-4}$
	I-133	$1X10^{-8}$	$7X10^{-5}$
	I-134	$2X10^{-7}$	$1X10^{-3}$
Iridium (77)	Ir-190		$2X10^{-3}$
	Ir-192		$4X10^{-4}$
	Ir-194		$3X10^{-4}$
Iron (26)	Fe-55		$8X10^{-3}$
	Fe-59		$6X10^{-4}$
Krypton (36)	Kr-85m	$1X10^{-6}$	
	Kr-85	$3X10^{-6}$	
Lanthanum (57)	La-140		$2X10^{-4}$
Lead (82)	Pb-203		$4X10^{-3}$
Lutetium (71)	Lu-177		$1X10^{-3}$
Manganese (25)	Mn-52		$3X10^{-4}$
	Mn-54		$1X10^{-3}$
	Mn-56		$1X10^{-3}$
Mercury (80)	Hg-197m		$2X10^{-3}$
	Hg-197		$3X10^{-3}$
	Hg-203		$2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147		$6X10^{-4}$
	Nd-149		$3X10^{-3}$
Nickel (28)	Ni-65		$1X10^{-3}$
Niobium (Columbium (41)	Nb-95		$1X10^{-3}$
	Nb-97		$9X10^{-3}$
Osmium (76)	Os-185		$7X10^{-4}$
	Os-191m		$3X10^{-2}$
	Os-191		$2X10^{-3}$
	Os-193		$6X10^{-4}$
Palladium (46)	Pd-103		$3X10^{-3}$
	Pd-109		$9X10^{-4}$
Phosphorus (15)	P-32		$2X10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ μCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml 1/	Column II Liquid and Solid Concentration µCi/ml 2/
Platinum (78)	Pt-191		$1X10^{-3}$
	Pt-193m		$1X10^{-2}$
	Pt-197m		$1X10^{-2}$
	Pt-197		$1X10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142		$3X10^{-4}$
	Pr-143		$5X10^{-4}$
Promethium (61)	Pm-147		$2X10^{-3}$
	Pm-149		$4X10^{-4}$
Rhenium (75)	Re-183		$6X10^{-3}$
	Re-186		$9X10^{-4}$
	Re-188		$6X10^{-4}$
Rhodium (45)	Rh-103m		$1X10^{-1}$
	Rh-105		$1X10^{-3}$
Rubidium (37)	Rb-86		$7X10^{-4}$
Ruthenium (44)	Ru-97		$4X10^{-3}$
	Ru-103		$8X10^{-4}$
	Ru-105		$1X10^{-3}$
	Ru-106		$1X10^{-4}$
Samarium (62)	Sm-153		$8X10^{-4}$
Scandium (21)	Sc-46		$4X10^{-4}$
	Sc-47		$9X10^{-4}$
	Sc-48		$3X10^{-4}$
Selenium (34)	Se-75		$3X10^{-3}$
Silicon (14)	Si-31		$9X10^{-3}$
Silver (47)	Ag-105		$1X10^{-3}$
	Ag-110m		$3X10^{-4}$
	Ag-111		$4X10^{-4}$
Sodium (11)	Na-24		$2X10^{-3}$
Strontium (38)	Sr-85		$1X10^{-3}$
	Sr-91		$7X10^{-4}$
	Sr-92		$7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$
Technetium (43)	Tc-96m		$1X10^{-1}$
	Sr-89		$1X10^{-4}$
	Tc-96		$1X10^{-3}$
Tellurium (52)	Te-125m		$2X10^{-3}$
	Te-127m		$6X10^{-4}$
	Te-127		$3X10^{-3}$
	Te-129m		$3X10^{-4}$
	Te-131m		$6X10^{-4}$
	Te-132		$3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/gm for solids.

C. Schedule A

Element (atomic number)	Isotope	Column I Gas Concentration μCi/ml 1/	Column II Liquid and Solid Concentration μCi/ml 2/
Thallium (81)	Tl-200		$4X10^{-3}$
	Tl-201		$3X10^{-3}$
	Tl-202		$1X10^{-3}$
	Tl-204		$1X10^{-3}$
Thulium (69)	Tm-170		$5X10^{-4}$
	Tm-171		$5X10^{-3}$
Tin (50)	Sn-113		$9X10^{-4}$
	Sn-125		$2X10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4X10^{-3}$
	W-187		$7X10^{-4}$
Vanadium (23)	V-48		$3X10^{-4}$
Xenon (54)	Xe-131m	$4X10^{-6}$	
	Xe-133	$3X10^{-6}$	
	Xe-135	$1X10^{-6}$	
Ytterbium (70)	Yb-175		$1X10^{-3}$
Yttrium (39)	Y-90		$2X10^{-4}$
	Y-91m		$3X10^{-2}$
	Y-91		$3X10^{-4}$
	Y-92		$6X10^{-4}$
	Y-93		$3X10^{-4}$
Zinc (30)	Zn-65		$1X10^{-3}$
	Zn-69m		$7X10^{-4}$
	Zn-69		$2X10^{-2}$
Zirconium (40)	Zr-95		$6X10^{-4}$
	Zr-97		$2X10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		$1X10^{-10}$	$1X10^{-6}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ μCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes, which are also radioactive. In expressing the concentrations in Schedule A the activity stated is that of the parent isotope and takes into account the daughters.
NOTE 2: For purposes of Part C. where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" ((i)e., unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = 1$$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

SCHEDULE B

EXEMPT QUANTITIES OF INDIVIDUAL RADIOACTIVE MATERIALS *(C.3.B)*

Radioactive Material	MicroCuries	Radioactive Material	MicroCuries
Antimony-122 (Sb 122)	100	Gallium-67 (Ga 67)	100
Antimony-124 (Sb 124)	10	Gallium-72 (Ga 72)	10
Antimony-125 (Sb 125)	10	Germanium-68 (Ge 68)	10
Arsenic-73 (As 73)	100	Germanium-71 (Ge 71)	100
Arsenic-74 (As 74)	10	Gold-195 (Au 195)	10
Arsenic-76 (As 76)	10	Gold-198 (Au 198)	100
Arsenic-77 (As 77)	100	Gold-199 (Au 199)	100
Barium-131(Ba 131)	10	Hafnium-181 (Hf 181)	10
Barium-133 (Ba 133)	10	Holmium-166 (Ho 166)	100
Barium-140 (Ba 140)	10	Hydrogen-3 (H 3)	1,000
Bismuth-210 (Bi 210)	1	Indium-111 (In 111)	100
Bromine-82 (Br 82)	10	Indium-113m (In 113m)	100
Cadmium-109 (Cd 109)	10	Indium-114m (In 114m)	10
Cadmium-115m Cd 115m)	10	Indium-115m (In 115m)	100
Cadmium-115 (Cd 115)	100	Indium-115 (In 115)	10
Calcium-45 (Ca 45)	10	Iodine-123 (I 123)	100
Calcium-47 (Ca 47)	10	Iodine-125 (I 125)	1
Carbon-14 (C 14)	100	Iodine-126 (I 126)	1
Cerium-141 (Ce 141)	100	Iodine-129 (I 129)	0.1
Cerium-143 (Ce 143)	100	Iodine-131 (I 131)	1
Cerium-144 (Ce 144)	1	Iodine-132 (I 132)	10
Cesium-129 (Cs 129)	100	Iodine-133 (I 133)	1
Cesium-131 (Cs 131)	1,000	Iodine-134 (I 134)	10
Cesium-134m (Cs 134m)	100	Iodine-135 (I 135)	10
Cesium-134 (Cs 134)	1	Iridium-192 (Ir 192)	10
Cesium-135 (Cs 135)	10	Iridium-194 (Ir 194)	100
Cesium-136 (Cs 136)	10	Iron-52 (Fe 52)	10
Cesium-137 (Cs 137)	10	Iron-55 (Fe 55)	100
Chlorine-36 (Cl 36)	10	Iron-59 (Fe 59)	10
Chlorine-38 (Cl 38)	10	Krypton-85 (Kr 85)	100
Chromium-51 (Cr 51)	1,000	Krypton-87 (Kr 87)	10
Cobalt-57 (Co 57)	100	Lanthanum-140 (La 140)	10
Cobalt-58m (Co 58m)	10	Lutetium-177 (Lu 177)	100
Cobalt-58 (Co 58)	10	Manganese-52 (Mn 52)	10
Cobalt-60 (Co 60)	1	Manganese-54 (Mn 54)	10
Copper-64 (Cu 64)	100	Manganese-56 (Mn 56)	10
Dysprosium-165 (Dy 165)	10	Mercury-197m (Hg 197m)	100
Dysprosium-166 (Dy 166)	100	Mercury-197 (Hg 197)	100
Erbium-169 (Er 169)	100	Mercury-203 (Hg 203)	10
Erbium-171 (Er 171)	100	Molybdenum-99 (Mo 99)	100
Europium-152(Eu152)9.2h	100	Neodymium-147 (Nd 147)	100
Europium-152(Eu152)13yr	1	Neodymium-149 (Nd 149)	100
Europium-154 (Eu 154)	1	Nickel-59 (Ni 59)	100
Europium-155 (Eu 155)	10	Nickel-63 (Ni 63)	10
Fluorine-18 (F 18)	1,000	Nickel-65 (Ni 65)	100
Gadolinium-153 (Gd 153)	10	Niobium-93m (Nb 93m)	10
Gadolinium-159 (Gd 159)	100	Niobium-95 (Nb 95)	10

C.Schedule B

Radioactive Material	MicroCuries	Radioactive Material	MicroCuries
Niobium-97 (Nb 97)	10	Strontium 92 (Sr 92)	10
Osmium-185 (Os 185)	10	Sulphur-35 (S 35)	100
Osmium-191m (Os 191m)	100	Tantalum-182 (Ta 182)	10
Osmium-191 (Os 191)	100	Technetium-96 (Tc 96)	10
Osmium-193 (Os 193)	100	Technetium-97m (Tc 97m)	100
Palladium-103 (Pd 103)	100	Technetium-97 (Tc 97)	100
Palladium-109 (Pd 109)	100	Technetium-99m (Tc 99m)	100
Phosphorus-32 (P 32)	10	Technetium-99 (Tc 99)	10
Platinum-191 (Pt 191)	100	Tellurium-125m (Te 125m)	10
Platinum-193m (Pt 193m)	100	Tellurium-127m (Te 127m)	10
Platinum-193 (Pt 193)	100	Tellurium-127 (Te 127)	100
Platinum-197m (Pt 197m)	100	Tellurium-129m (Te 129m)	10
Platinum-197 (Pt 197)	100	Tellurium-129 (Te 129)	100
Polonium-210 (Po 210)	0.1	Tellurium-131m (Te 131m)	10
Potassium-42 (K 42)	10	Tellurium-132 (Te 132)	10
Potassium-43 (K 43)	10	Terbium-160 (Tb 160)	10
Praseodymium-142(Pr142)	100	Thallium-200 (Tl 200)	100
Praseodymium-143(Pr143)	100	Thallium-201 (Tl 201)	100
Promethium-147 (Pm 147)	10	Thallium-202 (Tl 202)	100
Promethium-149 (Pm 149)	10	Thallium-204 (Tl 204)	10
Rhenium-186 (Re 186)	100	Thulium-170 (Tm 170)	10
Rhenium-188 (Re 188)	100	Thulium-171 (Tm 171)	10
Rhodium-103m (Rh 103m)	100	Tin-113 (Sn 113)	10
Rhodium-105 (Rh 105)	100	Tin-125 (Sn 125)	10
Rubidium-81 (Rb 81)	10	Tungsten-181 (W 181)	10
Rubidium-86 (Rb 86)	10	Tungsten-185 (W 185)	10
Rubidium-87 (Rb 87)	10	Tungsten-187 (W 187)	100
Ruthenium-97 (Ru 97)	100	Vanadium-48 (V 48)	10
Ruthenium-103 (Ru 103)	10	Xenon-131m (Xe 131m)	1,000
Ruthenium-105 (Ru 105)	10	Xenon-133 (Xe 133)	100
Ruthenium-106 (Ru 106)	1	Xenon-135 (Xe 135)	100
Samarium-151 (Sm 151)	10	Ytterbium-175 (Yb 175)	100
Samarium-153 (Sm 153)	100	Yttrium-87 (Y 87)	10
Scandium-46 (Sc 46)	10	Yttrium-88 (Y 88)	10
Scandium-47 (Sc 47)	100	Yttrium-90 (Y 90)	10
Scandium-48 (Sc 48)	10	Yttrium-91 (Y 91)	10
Selenium-75 (Se 75)	10	Yttrium-92 (Y 92)	100
Silicon-31 (Si 31)	100	Yttrium-93 (Y 93)	100
Silver-105 (Ag 105)	10	Zinc-65 (Zn 65)	10
Silver-110m (Ag 110m)	1	Zinc-69m (Zn 69m)	100
Silver-111 (Ag 111)	100	Zinc-69 (Zn 69)	1,000
Sodium-22 (Na 22)	10	Zirconium-93 (Zr 93)	10
Sodium-24 (Na 24)	10	Zirconium-95 (Zr 95)	10
Strontium-85 (Sr 85)	10	Zirconium-97 (Zr 97)	10
Strontium-89 (Sr 89)	1	Any radioactive material not listed above other than alpha emitting radioactive material	0.1
Strontium 90 (Sr 90)	0.1		
Strontium 91 (Sr 91)	10		

NOTE: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above by 37.

SCHEDULE C

LIMITS FOR BROAD LICENSES *(C.10)*

Radioactive Material	Col I* Curies	Col II** Curies	Radioactive Material	Col I* Curies	Col II** Curies
Antimony-122	1	0.01	Gallium-72	10	0.1
Antimony-124	1	0.01	Germanium-71	100	1
Antimony-125	1	0.01	Gold-198	10	0.1
Arsenic-73	10	0.1	Gold-199	10	0.1
Arsenic-74	1	0.01	Hafnium-181	1	0.01
Arsenic-76	1	0.01	Holmium-166	10	0.1
Arsenic-77	10	0.1	Hydrogen-3	100	1
Barium-131	10	0.1	Indium-113m	100	1
Barium-140	1	0.01	Indium-114m	1	0.01
Beryllium-7	10	0.1	Indium-115m	100	1
Bismuth-210	0.1	0.001	Indium-115	1	0.01
Bromine-82	10	0.1	Iodine-125	0.1	0.001
Cadmium-109	1	0.01	Iodine-126	0.1	0.001
Cadmium-115m	1	0.01	Iodine-129	0.1	0.001
Cadmium-115	10	0.1	Iodine-131	0.1	0.001
Calcium-45	1	0.01	Iodine-132	10	0.1
Calcium-47	10	0.1	Iodine-133	1	0.01
Carbon-14	100	1	Iodine-134	10	0.1
Cerium-141	10	0.1	Iodine-135	1	0.01
Cerium-143	10	0.1	Iridium-192	1	0.01
Cerium-144	0.1	0.001	Iridium-194	10	0.1
Cesium-131	100	1	Iron-55	10	0.1
Cesium-134m	100	1	Iron-59	1	0.01
Cesium-134	0.1	0.001	Krypton-85	100	1
Cesium-135	1	0.01	Krypton-87	10	0.1
Cesium-136	10	0.1	Lanthanum-140	1	0.01
Cesium-137	0.1	0.001	Lutetium-177	10	0.1
Chlorine-36	1	0.01	Manganese-52	1	0.01
Chlorine-38	100	1	Manganese-54	1	0.01
Chromium-51	100	1	Manganese-56	10	0.1
Cobalt-57	10	0.1	Mercury-197m	10	0.1
Cobalt-58m	100	1	Mercury-197	10	0.1
Cobalt-58	1	0.01	Mercury-203	1	0.01
Cobalt-60	0.1	0.001	Molybdenum-99	10	0.1
Copper-64	10	0.1	Neodymium-147	10	0.1
Dysprosium-165	100	1	Neodymium-149	10	0.1
Dysprosium-166	10	0.1	Nickel-59	10	0.1
Erbium-169	10	0.1	Nickel-63	1	0.01
Erbium-171	10	0.1	Nickel-65	10	0.1
Europium-152(9.2h	10	0.1	Niobium-93m	1	0.01
Europium-152(13y)	0.1	0.001	Niobium-95	1	0.01
Europium-154	0.1	0.001	Niobium-97	100	1
Europium-155	1	0.01	Osmium-185	1	0.01
Fluorine-18	100	1	Osmium-191m	100	1
Gadolinium-153	1	0.01	Osmium-191	10	0.1
Gadolinium-159	10	0.1	Osmium-193	10	0.1

* Type B Specific license ** Type C Specific license

C. SCHEDULE C

Radioactive Material	Col I* Curies	Col II** Curies	Radioactive Material	Col I* Curies	Col II** Curies
Palladium-103	10	0.1	Technetium-96	10	0.1
Palladium-109	10	0.1	Technetium-97m	10	0.1
Phosphorus-32	1	0.01	Technetium-97	10	0.1
Platinum-191	10	0.1	Technetium-99m	100	1
Platinum-193m	100	1	Technetium-99	1	0.01
Platinum-193	10	0.1	Tellurium-125m	1	0.01
Platinum 197m	100	1	Tellurium-127m	1	0.01
Platinum-197	10	0.1	Tellurium-127	10	0.1
Polonium-210	0.01	0.0001	Tellurium-129m	1	0.01
Potassium-42	1	0.01	Tellurium-129	100	1
Praseodymium-142	10	0.1	Tellurium-131m	10	0.1
Praseodymium-143	10	0.1	Tellurium-132	1	0.01
Promethium-147	1	0.01	Terbium-160	1	0.01
Promethium-149	10	0.1	Thallium-200	10	0.1
Radium-226	0.01	0.0001	Thallium-201	10	0.1
Rhenium-186	10	0.1	Thallium-202	10	0.1
Rhenium-188	10	0.1	Thallium-204	1	0.01
Rhodium-103m	1,000	10	Thulium-170	1	0.01
Rhodium-105	10	0.1	Thulium-171	1	0.01
Rubidium-86	1	0.01	Tin-113	1	0.01
Rubidium-87	1	0.01	Tin-125	1	0.01
Ruthenium-97	100	1	Tungsten-181	1	0.01
Ruthenium-103	1	0.01	Tungsten-185	1	0.01
Ruthenium-105	10	0.1	Tungsten-187	10	0.1
Ruthenium-106	0.1	0.001	Vanadium-48	1	0.01
Samarium-151	1	0.01	Xenon-131m	1,000	10
Samarium-153	10	0.1	Xenon-133	100	1
Scandium-46	1	0.01	Xenon-135	100	1
Scandium-47	10	0.1	Ytterbium-175	10	0.1
Scandium-48	1	0.01	Yttrium-90	1	0.01
Selenium-75	1	0.01	Yttrium-91	1	0.01
Silicon-31	10	0.1	Yttrium-92	10	0.1
Silver-105	1	0.01	Yttrium-93	1	0.01
Silver-110m	0.1	0.001	Zinc-65	1	0.01
Silver-111	10	0.1	Zinc-69m	10	0.1
Sodium-22	0.1	0.001	Zinc-69	100	1
Sodium-24	1	0.01	Zirconium-93	1	0.01
Strontium-85m	1,000	10	Zirconium-95	1	0.01
Strontium-85	1	0.01	Zirconium-97	1	0.01
Strontium-89	1	0.01	Any radioactive material other than source material, special nuclear material or alpha emitting radioactive material not listed above.	0.1	0.001
Strontium-90	0.01	0.0001			
Strontium-91	10	0.1			
Strontium-92	10	0.1			
Sulphur-35	10	0.1			
Tantalum-182	1	0.01			

* Type B Specific license ** Type C Specific license

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

SCHEDULE D

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

Radioactive Material[1]	Release Fraction	Quantity (curies)	Radioactive Material	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000	Krypton-85	1	6,000,000
Americium-241	0.001	2	Lead-210	0.01	8
Americium-242	0.001	2	Manganese-56	0.01	60,000
Americium-243	0.001	2	Mercury-203	0.01	10,000
Antimony-124	0.01	4,000	Molybdenum-99	0.01	30,000
Antimony-126	0.01	6,000	Neptunium-237	0.001	2
Barium-133	0.01	10,000	Nickel-63	0.01	20,000
Barium-140	0.01	30,000	Niobium-94	0.01	300
Bismuth-207	0.01	5,000	Phosphorus-32	0.5	100
Bismuth-210	0.01	600	Phosphorus-33	0.5	1,000
Cadmium-109	0.01	1,000	Polonium-210	0.01	10
Cadmium-113	0.01	80	Potassium-42	0.01	9,000
Calcium-45	0.01	20,000	Promethium-145	0.01	4,000
Californium-252	0.001	9 (20 mg)	Promethium-147	0.01	4,000
Carbon-14 (NonCO_2)	0.01	50,000	Radium-226	0.001	100
Cerium-141	0.01	10,000	Ruthenium-106	0.01	200
Cerium-144	0.01	300	Samarium-151	0.01	4,000
Cesium-134	0.01	2,000	Scandium-46	0.01	3,000
Cesium-137	0.01	3,000	Selenium-75	0.01	10,000
Chlorine-36	0.5	100	Silver-110m	0.01	1,000
Chromium-51	0.01	300,000	Sodium-22	0.01	9,000
Cobalt-60	0.001	5,000	Sodium-24	0.01	10,000
Copper-64	0.01	200,000	Strontium-89	0.01	3,000
Curium-242	0.001	60	Strontium-90	0.01	90
Curium-243	0.001	3	Sulphur-35	0.5	900
Curium-244	0.001	4	Technetium-99	0.01	10,000
Curium-245	0.001	2	Technetium-99m	0.01	400,000
Europium-152	0.01	500	Tellurium-127m	0.01	5,000
Europium-154	0.01	400	Tellurium-129m	0.01	5,000
Europium-155	0.01	3,000	Terbium-160	0.01	4,000
Gadolinium-153	0.01	5,000	Thulium-170	0.01	4,000
Germanium-68	0.01	2,000	Tin-113	0.01	10,000
Gold-198	0.01	30,000	Tin-123	0.01	3,000
Hafnium-172	0.01	400	Tin-126	0.01	1,000
Hafnium-181	0.01	7,000	Titanium-44	0.01	100
Holmium-166m	0.01	100	Vanadium-48	0.01	7,000
Hydrogen-3	0.5	20,000	Xenon-133	1	900,000
Indium-114m	0.01	1,000	Yttrium-91	0.01	2,000
Iodine-125	0.5	10	Zinc-65	0.01	5,000
Iodine-131	0.5	10	Zirconium-93	0.01	400
Iridium-192	0.001	40,000	Zirconium-95	0.01	5,000
Iron-55	0.01	40,000			
Iron-59	0.01	7,000			

C.Schedule D

Radioactive Material[1]	Release Fraction	Quantity (curies)	Radioactive Material	Release Fraction	Quantity (curies)
Any other beta-gamma Emitter	0.01	10,000	Irradiated material, solid noncombustible	0.001	10,000
Mixed fission products	0.01	1,000	Mixed radioactive waste, beta-gamma[2/]	0.01	1,000
Mixed corrosion products	0.01	10,000	Packaged mixed waste, beta-gamma	0.001	10,000
Contaminated equipment beta-gamma	0.001	10,000	Any other alpha emitter	0.001	2
			Contaminated equipment alpha	0.0001	20
Irradiated material, any form other than solid noncombustible	0.01	1,000	Packaged waste, alpha[2/]	0.0001	20
			Combinations of radioactive materials listed above[1/]		

1/ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in schedule C exceeds one.

2/ Waste packaged in Type B containers does not require an emergency plan.

APPENDIX A

GENERAL PROVISIONS

A. Purpose.

The regulations in this part set out fees charged for licensing services rendered by the State of Maine, Radiation Control Program (the Agency), as authorized under 22 MRSA Section 690 of Maine's Radiation Protection Act.

B. Scope.

Except for persons who apply for or hold the permits, licenses, or approvals exempted in Part C, the regulations in this section apply to a person who is:

1. An applicant for or holder of a specific radioactive material license, NARM material, source material, or special nuclear material license issued pursuant to Part C of these rules;
2. An applicant for or holder of specific approval of shipping containers issued pursuant to Part L of these rules;
3. An applicant for or holder of a specific approval of sealed sources and devices containing radioactive material, NARM material, source material, or special nuclear material;
4. Required to have routine and non-routine safety and safeguards inspections of activities licensed pursuant to the requirements of these rules; or
5. An applicant for or holder of a license, approval, determination, or other authorization issued by the Agency pursuant to Parts D.22 and D.25 of these rules.
6. An applicant for or holder of a general license established by any of Parts C.5.E, C.6.B, or C.6.F of these rules.

C. Definitions. As used in this part:

1. **Materials license** means a radioactive, NARM, or a source material license issued pursuant to Part C of these rules.
2. **Sealed source** means any radioactive material, or NARM material that is encased in a capsule designed to prevent leakage or escape of the material.
3. **Inspection** means:
   a. Routine inspections designed to evaluate the licensee's activities within the context of the licensee having primary responsibility for protection of the public and environment.
   b. Non-routine inspections in response or reaction to an incident, allegation, follow-up to inspection deficiencies or inspections to determine implementation of safety issues. A non-routine or reactive inspection has the same purpose as the routine inspection.
4. **State agency** means any executive department, commission, independent establishment, corporation, wholly or partly owned by the State of Maine, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the State.

D. Exemptions.

1. No application fees, annual fees, amendment fees , or inspection fees shall be required for:
   a. A license authorizing the export only of a production or utilization facility.
   b. A license authorizing the export only or import only of radioactive material, source material or special nuclear material.
2. A license authorizing the use of source material as shielding only in devices and containers, provided, however, that all other licensed radioactive material, source material, or special nuclear material in the device or container will be subject to the fees prescribed in Table 1 of this appendix.

C. Appendix A

E. Payment of fees.

1. Application fees. Each application for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be accepted for filing or processed prior to payment of the full amount specified. Applications for which no remittance is received may be returned to the applicant. All application fees will be charged irrespective of the Agency's disposition of the application or withdrawal of the application.

2. Full cost. For each application on which the review charges are based on full costs and the application has been pending with the Agency for six months or longer, the first bill for accumulated costs will be sent and will include all of the applicable review time and contractual costs expended. Thereafter, each applicant will be billed at six-month intervals or when the review is completed, whichever is earlier. Each bill will identify the applications and the costs related to each.

3. Non-routine inspection fees. Non-routine inspection fees are payable upon notification by the Agency. Inspection costs will include preparation time, time on site and documentation time and any associated contractual service costs but will exclude the time involved by the staff in the processing and issuance of a notice of violation or civil penalty.

4. Annual fees. A license fee based upon the type of license, number of sources and/or gauges shall be assessed on an annual basis. The licensee has sixty (60) days from the postmark date of the Radioactive Materials License Annual Fees Invoice notice to submit payment in full unless special arrangements are made with the Agency. Failure to pay the annual fee by the due date will result in a penalty not to exceed 9% of the unpaid fee compounded monthly. Failure to remit full payment within six (6) months could , at the Agency's discretion, result in the initiation of license termination procedures.

5. Method of payment. Fee payments shall be by check, draft, or money order made payable to the Treasurer, State of Maine.

F. Average cost per professional staff-hour. Fees for permits, licenses, amendments, renewals, special projects and inspections will be calculated based upon the full costs for the review.

TABLE 1 to Appendix A

RADIOACTIVE MATERIALS SPECIFIC LICENSE AND INSPECTION FEE SCHEDULE

LICENSE CATEGORY	APPLICATION	ANNUAL	NON-ROUTINE INSPECTION
1. SPECIAL NUCLEAR MATERIAL			
A. Sealed sources in devices	$500.00	$ 500.00[5]	$1,300.00
B. Pacemakers	$500.00	$350.00	$800.00
C. Other except critical	$690.00	$1,000.00	$800.00
D. Termination	$500.00	Full cost	
2. SOURCE MATERIAL			
A. Shielding	$110.00	$ 350.00	$350.00
B. Other	$790.00	$1,000.00	$1,500.00
C. Termination	$500.00	Full cost	
3. RADIOACTIVE MATERIAL, NATURALLY OCCURRING RADIOACTIVE MATERIAL OR ACCELERATOR PRODUCED MATERIAL			
A. Processing or manufacturing for commercial distribution			
1. Broad Scope A	$2,300.00	$3,000.00	$2,100.00
2. Broad Scope B	$2,300.00	$3,000.00	$2,100.00
3. Broad Scope C	$2,300.00	$3,000.00	$2,100.00
4. Other	$1,300.00	$1,750.00	$2,000.00
B. Radiopharmaceuticals, reagent kits, sources and devices.			
1. Processing, manufacturing and distribution. This category includes nuclear pharmacies.	$3,400.00	$2,000.00	$1,900.00
2. Distribution only	$1,100.00	$750.00	$1,200.00
C. Sealed sources for irradiation			
1. Fixed, self shielded	$500.00	$500.00	$690.00
2. Exposed source < 10,000 C(i)	$1,200.00	$1,500.00	$1,300.00
3. Exposed source > 10,000 C(i)	$4,600.00	$3,000.00	$1,400.00
D. Distribution to persons exempt (NARM)			
1. Device review required	$2,100.00	$750.00	$690.00
2. No device review required	$2,600.00	$750.00	$690.00
E. Distribution to persons generally licensed			
1. SSD review required	$2,500.00	$750.00	$690.00
2. No SSD review required	$1,900.00	$750.00	$690.00
F. Research and development, no commercial distribution			
1. Broad Scope A	$2,300.00	$1,250.00	$1,200.00
2. Broad Scope B	$2,300.00	$1,000.00	$1,200.00
3. Broad Scope C	$2,300.00	$750.00	$1,200.00
4. Other	$1,100.00	$750.00	$930.00
G. Services for other licensees	$1,400.00	$750.00	$690.00
H. Industrial radiography	$3,000.00	$2,000.00	$2,500.00
(I) All other radioactive and NARM, except 4A through 8D			
1. Portable gauges	$500.00	500.00[5]	$1,200.00
2. Fixed gauges	$500.00	$500.00[5]	$1,200.00
3. X-ray Fluorescence	$500.00	$ 500.00[5]	$1,200.00
4. Laboratory services	$500.00	$350.00	$1,200.00
5. Storage only	$500.00	$350.00	$1,200.00
6. In-Vitro laboratories	$500.00	$500.00	$1,200.00

C. Appendix A. Table 1

LICENSE CATEGORY	APPLICATION	ANNUAL	NON-ROUTINE INSPECTION
7. Gas Chromatographs	$500.00	$350.00	$1,200.00
8. Other	$500.00	$500.00	$1,200.00
4. WASTE DISPOSAL SERVICES			
A. Packaging or repackaging	$2,800.00	$2,500.00	$1,600.00
B. Transferal to another person	$1,900.00	$1,000.00	$2,100.00
C. Incineration or other treatment	$500.00 + full cost	Full cost	
5. WELL LOGGING			
A. Well logging and tracer studies	$3,400.00	$1,000.00	$800.00
B. Field flooding tracer studies	$500.00 + full cost	$1,750.00	$1,200.00
6. NUCLEAR LAUNDRIES	$1,400.00	$2,000.00	$1,900.00
7. HUMAN USE			
A. Teletherapy Devices	$3,400.00	$1,750.00	$1,900.00
B. . Broad Scope	$2,300.00	$2,500.00	$1,800.00
C. Other Medical Use			
1. G.100 – Unsealed radioactive material for uptake, dilution, and excretion studies - written directive not required	$710.00	$750.00	$1,500.00
2. G.200 – Unsealed radioactive material for imaging and localization studies - written directive not required	$710.00	$1,000.00[6]	$1,500.00
3. G.300 – Unsealed radioactive material - written directive required	$710.00	$1,000.00[6]	$1,500.00
4. G.400 – Manual brachytherapy	$710.00	$1,000.00[6]	$1,500.00
5. G.500 – Sealed sources for diagnosis	$710.00	$500.00	$1,500.00
6. Mobile Nuclear Van	$710.00	$1,200.00	$1,500.00
7. HDR Brachytherapy	$710.00	$1,750.00	$1,900.00
8. Gamma Knife Devices	$710.00	$1,750.00	$1,900.00
8. CIVIL DEFENSE ACTIVITIES	$580.00	$350.00	$690.00
9. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION			
A. Devices, for commercial dist.	$3,300.00		
B. Devices, single applicant	$2,000.00		
C. Sources, for commercial dist.	$750.00		
D. Sources, single applicant	$750.00		
10. GENERAL LICENSE REGISTRATION			
A. Submission of form HHE-860	$100.00	$100.00	$1200.00
B. Submission of form HHE-861	$25.00	$25.00	$1200.00
C. Submission of form HHE-862	$100.00	$100.00	$1200.00
D. Submission of form HHE-863	$100.00	$100.00	$1200.00
E. Submission of form HHE-867	$100.00	$100.00	$1200.00

1. Types of material license fees - Separate charges as shown in the schedule will be assessed for applications for new licenses and approvals, issuance of new licenses and approvals, and amendments to existing licenses and approvals. The following guidelines apply to these charges:

   a. Application fees - Applications for materials licenses and approvals must be accompanied by the prescribed application fee for each category, except that applications for licenses covering more than one fee category of special nuclear material or source material to be used at the same location, must be accompanied by the prescribed application fee for the highest fee category. When a license or approval has expired, the application fee for each category shall be due, except for licenses covering more than one fee category of special nuclear material or source material for use at the same location, in which case the application fee for the highest category applies.

   b. License/approval fees - For new licenses and approvals issued in fee Categories 1D, 2C, 4C, and 5B, the recipient shall pay the license or approval fee for each category, as determined by the Agency in accordance with Part E of this Appendix except that a license covering more than one fee category of special nuclear material in Categories 1A through 1D or source material in fee Categories 2A through 2C must pay a license fee for the highest fee category assigned to the license.

   c. Amendment fees - Applications for amendments must be accompanied by the minimum amendment fee of $50.00. The Agency will compute the final amendment fee based upon actual costs, but not more than $500.00, and the applicant will be billed at the completion of the licensing action.

2. Material license fees will not be charged for orders issued by the Agency pursuant to Part B.8 nor for amendments resulting specifically from such orders. However, fees will be charged for approvals issued pursuant to a specific exemption provision of the Agency's regulations regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

3. Types of inspections - Separate charges as shown in this schedule will be the maximum amount assessed for each non-routine inspection, which is performed. The amount that will be charged to the licensee will be based on the staff time and contractual costs expended by the agency.

4. A licensee who is authorized to use licensed radioactive materials at multiple locations that are not immediately adjacent, or on the same campus, will be assessed an additional 25% of their annual fee. This does not apply to broad scope licensees.

5. The following scale of additional fees will be added to the stated annual fee as applicable from the licensed quantity. If a licensee is authorized for use under fee categories 1.A, 3.(I)1, and/or 3.(I)3 the total number of gauges authorized under all types are cumulative. If more than one of the remaining fee categories also applies to a licensee only the highest fee will be charged.

License Category	1 to 5 gauges	6 to 15 gauges	16 gauges plus
1.A.	0	$ 250.00	$ 500.00
3.(I)1.	0	$ 250.00	$ 500.00
3.(I)3.	0	$ 250.00	$ 500.00
License Category	**1 to 10 gauges**	**11 to 30 gauges**	**31 gauges plus**
3.(I)2.	0	$ 250.00	$ 500.00

6. The license fee categories 7.C.1 through 7.C.5 will be charged the stated fee if any of the categories are authorized singly. If multiple categories are authorized an additional fee of $500.00 per category will be added to the annual fee of the highest fee category. If any of the categories 7.C.2 through 7.C.4 are authorized then authorization for 7.C.1 will not incur an additional fee.

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APPENDIX B

NATURALLY OCCURRING OR ACCELERATOR PRODUCED RADIOACTIVE MATERIAL (NARM)

Examples of Naturally Occurring Radioactive Materials. (Naturally occurring radioactive material is any material of natural origin that emits radiation spontaneously, excluding uranium, thorium, and the tailings produced in their extraction)

Hydrogen-3	Indium-115	Lead-210
Beryllium-7	Lanthanum-138	Lead-212
Beryllium-10	Cerium-142	Bismuth-210
Carbon-14	Neodymium-144	Bismuth-212
Sodium-22	Samarium-147	Polonium-210
Silicon-32	Samarium-148	Radon-220
Phosphorus-32	Samarium-149	Radon-222
Phosphorus-33	Gadolinium-152	Radium-224
Sulfur-35	Hafnium-174	Radium-226
Chlorine-36	Lutetium-176	Radium-228
Chlorine-39	Rhenium-187	Actinium-227
Potassium-40	Platinum-190	Actinium-228
Vanadium-50	Platinum-192	Protoactinium-231
Rubidium-87	Lead-204	

Examples of Accelerator-Produced Radioactive Materials. (Accelerator- produced radioactive material is any material made radioactive (emits radiation spontaneously) by a particle accelerator)

Carbon-11	Zinc-62	Iodine-124
Nitrogen-13	Gallium-66	Iodine-125*
Oxygen-15	Gallium--67	Iodine-126
Fluorine-18	Germanium-68	Xenon-127
Sodium-22	Arsenic-73	Cesium-131
Magnesium-28	Selenium-73	Promethium-145
Aluminum-28	Bromine-77	Dysprosium-157
Phosphorus-33	Krypton-77	Osmium-190
Argon-37	Krypton-81	Iridium-190
Potassium-43	Rubidium-81	Iridium-190ml
Scandium-49	Rubidium-82	Platinum-193m
Manganese-52	Rubidium-84	Gold-195
Iron-52	Strontium-82	Mercury-197
Cobalt-57	Strontium-87m	Thallium-199
Cobalt-58	Yttrium-87	Thallium-201
Copper-62	Technetium-97m	Lead-203
Copper-67	Indium-111	Bismuth-204
Zinc-62	Iodine-123	

* Excludes Iodine-125 as radioactive material, which requires licensing by either the U.S. Nuclear Regulatory Commission or an Agreement State.

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APPENDIX C

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

B. Financial Test

1. To pass the financial test, the parent company must meet the criteria of either paragraph 1.a or 2.a of this section:

   a. The parent company must have:

      (1) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

      (2) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

      (3) Tangible net worth of at least $10 million; and

      (4) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

   b. The parent company must have:

      (1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and

      (2) Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

      (3) Tangible net worth of at least $10 million; and

      (4) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

2. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. a. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

   b. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Agency's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

C. Parent Company Guarantee. The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

1. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipts.
2. If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.
3. The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.
4. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

APPENDIX D

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section B of this appendix. The terms of the self-guarantee are in Section C of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

B. Financial Test

1. To pass the financial test, a company must meet all of the following criteria:

   a. Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)).

   b. Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof.

   c. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

2. To pass the financial test, a company must meet all of the following additional requirements:

   a. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

   b. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

   c. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section B.2. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

C. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

1. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

2. The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. Appendix D

3. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

4. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

5. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section B.1. of this appendix.

6. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

APPENDIX E

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*	Material	Microcurie*
Americium-241	0.01	Germanium-71	100
Antimony-122	100	Gold-198	100
Antimony-124	10	Gold-199	100
Antimony-125	10	Hafnium-181	10
Arsenic-73	100	Holmium-166	100
Arsenic-74	10	Hydrogen-3	1,000
Arsenic-76	10	Indium-113m	100
Arsenic-77	100	Indium-114m	10
Barium-131	10	Indium-115m	100
Barium-133	10	Indium-115	10
Barium-140	10	Iodine-125	1
Bismuth-210	1	Iodine-126	1
Bromine-82	10	Iodine-129	0.1
Cadmium-109	10	Iodine-131	1
Cadmium-115m	10	Iodine-132	10
Cadmium-115	100	Iodine-133	1
Calcium-45	10	Iodine-134	10
Calcium-47	10	Iodine-135	10
Carbon-14	100	Iridium-192	10
Cerium-141	100	Iridium-194	100
Cerium-143	100	Iron-55	100
Cerium-144	1	Iron-59	10
Cesium-131	1,000	Krypton-85	100
Cesium-134m	100	Krypton-87	10
Cesium-134	1	Lanthanum-140	10
Cesium-135	10	Lutetium-177	100
Cesium-136	10	Manganese-52	10
Cesium-137	10	Manganese-54	10
Chlorine-36	10	Manganese-56	10
Chlorine-38	10	Mercury-197m	100
Chromium-51	1,000	Mercury-197	100
Cobalt-58m	10	Mercury-203	10
Cobalt-58	10	Molybdenum-99	100
Cobalt-60	1	Neodymium-147	100
Copper-64	100	Neodymium-149	100
Dysprosium-165	10	Nickel-59	100
Dysprosium-166	100	Nickel-63	10
Erbium-169	100	Nickel-65	100
Erbium-171	100	Niobium-93m	10
Europium-152 (9.2 h)	100	Niobium-95	10
Europium-152 (13 yr)	1	Niobium-97	10
Europium-154	1	Osmium-185	10
Europium-155	10	Osmium-191m	100
Florine-18	1,000	Osmium-191	100
Gadolinium-153	10	Osmium-193	100
Gadolinium-159	100	Palladium-103	100
Gallium-72	10	Palladium-109	100

* To convert μCi to kBq, multiply the μCi value by 37.

C.Appendix E

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*	Material	Microcurie*
Phosphorus-32	10	Technetium-97m	100
Platinum-191	100	Technetium-97	100
Platinum-193m	100	Technetium-99m	100
Platinum-193	100	Technetium-99	10
Platinum-197m	100	Tellurium-125m	10
Platinum-197	100	Tellurium-127m	10
Plutonium-239	0.01	Tellurium-127	100
Polonium-210	0.1	Tellurium-129m	10
Potassium-42	10	Tellurium-129	100
Praseodymium-142	100	Tellurium-131m	10
Praseodymium-143	100	Tellurium-132	10
Promethium-147	10	Terbium-160	10
Promethium-149	10	Thallium-200	100
Radium-226	0.01	Thallium-201	100
Rhenium-186	100	Thallium-202	100
Rhenium-188	100	Thallium-204	10
Rhodium-103m	100	Thorium (natural)**	100
Rhodium-105	100	Thulium-170	10
Rubidium-86	10	Thulium-171	10
Rubidium-87	10	Tin-113	10
Ruthenium-97	100	Tin-125	10
Ruthenium-103	10	Tungsten-181	10
Ruthenium-105	10	Tungsten-185	10
Ruthenium-106	1	Tungsten-187	100
Samarium-153	100	Uranium (natural)***	100
Scandium-46	10	Uranium-233	0.01
Scandium-47	100	Uranium-234	0.01
Scandium-48	10	Uranium-235	0.01
Selenium-75	10	Vanadium-48	10
Silicon-31	100	Xenon-131m	1,000
Silver-105	10	Xenon-133	100
Silver-llOm	1	Xenon-135	100
Silver-111	100	Ytterbium-175	100
Sodium-22	1	Yttrium-90	10
Sodium-24	10	Yttrium-91	10
Strontium-85	10	Yttrium-92	100
Strontium-89	1	Yttrium-93	100
Strontium-90	0.1	Zinc-65	10
Strontium-91	10	Zinc-69m	100
Strontium-92	10	Zinc-69	1,000
Sulfur –35	100	Zirconium-93	10
Tantalum-182	10	Zirconium-95	10
Technetium-96	10	Zirconium-97	10

* To convert μCi to kBq, multiply the μCi value by 37.
** Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.
*** Based on alpha disintegration rate of U-238, U-234, and U-235.

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

* To convert μCi to kBq, multiply the μCi value by 37.

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" -- that is, unity