PART C

LICENSING OF RADIOACTIVE MATERIAL

Sec. C.1 - Purpose and Scope.

a. Parts C, E, G, [I], [M], N, Q, and T of these regulations, provide for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own, [dispose,] or acquire radioactive material except as authorized pursuant to Parts C, E, G, [I], [M], N, Q, or T of these regulations, or as otherwise provided in these Parts.[*/]

b. In addition to the requirements of Part C, all licensees are subject to the requirements of Parts A, D, J, O, P, S, and T of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part E of these regulations, licensees using radionuclides in the healing arts are subject to the requirements of Part G of these regulations, [licensees using particle accelerators, excluding medical therapy accelerators are subject to the licensing requirements of Part I of these regulations, licensees engaged in land disposal of radioactive material are subject to the requirements of Part M of these regulations,] licensees using irradiators are subject to the requirements of Part Q and licensees engaged in well logging and subsurface tracer studies are subject to the requirements of Part W of these regulations.

Exemptions from the Regulatory Requirements

Sec. C.2 - Carriers. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this Part and Parts E, G, I, N, Q, and W of these regulations and the requirements for a license set forth in the Act to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

Sec. C.3 - Source Material.

a. Any person is exempt from Part C 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 Part C 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.

[*/] *If State law does not require the licensing of ownership of radioactive material, the word "own" may be deleted from: A.1, C.1a., C.3a., C.4a.i., C.4b.i., C4b.ii., C.4c.i., C.4c.ii., C.4c.iii.(1), C.4c.iv., C.4c.v(1), C.22a., C.22d.i., C.22d.iii., C.22f.i., C.22f.ii., C.22f.iv., and C.27e.i.(2), C.28a.i. and ii., -- ownership --, C.22h.i., C.22h.ii., C.22h.iii., C.22h.v., C.22j.i., C.22j.ii., C.27a.i., ii., and iii., and C.28a. -- owned --. Also, the general license to receive title to source material (C.21c.) and the general license for ownership of radioactive material (C.22g.) may be deleted.*

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

i. Any quantities of thorium contained in:

(1) Incandescent gas mantles,

(2) Vacuum tubes,

(3) Welding rods,

(4) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 mg of thorium,

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

(6) Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight t0horium, uranium, or any combination of these, or

(7) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 mg of thorium;

ii. Source material contained in the following products:

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

(2) 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,

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

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

iii. Photographic film, negatives, and prints containing uranium or thorium;

iv. 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;

v. 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:

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

(2) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";[1/]

(3) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";[1/] and

(4) 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;

vi. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

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

(2) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 3.2 mm (⅛ inch);

vii. 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:

(1) 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

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

viii. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 185 Bq (0.005 μCi) of uranium; or

ix. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy,

[1/] *The requirements specified in Subdivisions C.3c.v.(2) and (3) need not be met by counterweights manufactured prior to December 31, 1969; provided that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the regulations.*

provided that:

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

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

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

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

a. Exempt Concentrations.

i. Except as provided in C.4a.ii. and iv., any person is exempt from Part C to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of Part C.

ii. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.4a.i. or equivalent regulations of any Agreement State, except in accordance with a specific license issued pursuant to 10 CFR 32.11.

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

iv. A manufacturer, processor, or producer of a product or material in an Agreement State 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 Appendix 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.

i. Except as provided in C.4b.iii. through v., 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 Appendix B of Part C.

ii. Any person who possesses radioactive material received or acquired under the general license is exempt from the requirements for a license set forth in Part C to the extent that such person possesses, uses, transfers or owns such radioactive material. Such

exemption does not apply for radium-226.[*/]

iii. C.4b. does not authorize the production, packaging, repackaging or transfer of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

iv. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of Part C, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.4b. or equivalent regulations of the NRC or any Agreement State, except in accordance with a specific license issued by the NRC pursuant to 10 CFR 32.18 or by the Agency pursuant to C.28b. which license states that the radioactive material may be transferred by the licensee to persons exempt under C.4b. or the equivalent regulations of the NRC or an Agreement State .[2/]

v. No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B of Part C, 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.

i. Certain Items Containing Radioactive Material.

(1) 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 such products containing radioactive material, any person is exempt from the Act and these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:[2/]

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

(i) 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).

[*/] *For use by Agreement States whose regulations formerly contained a General License for small quantities of radioactive material.*

[2/] *Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Agency.*

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

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

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

(vii) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 mg/cm^2 of absorber:

(I) For wristwatches, 1 µGy/h (0.1 mrad/h) at 10 cm from any surface.

(II) For pocket watches, 1 µGy/h (0.1 mrad/h) at 1 cm from any surface.

(III) For any other timepiece, 2 µGy/h (0.2 mrad/h) at 10 cm from any surface.

(viii) 37 kBq (1 µCi) of radium-226 per timepiece in intact timepieces acquired prior to [the effective date of this regulation].

(b) Reserved

(c) 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.

(d) Reserved

(e) 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.

(f) Reserved

(g) 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;

(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

(vii) The radiation dose rate from each electron tube containing radioactive material will not exceed 10µGy (1 mrad) per hour at 1 cm (.39 in) from any surface when measured through 7 mg/cm^2 of absorber.[3/]

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

(I) Each source contains no more than one exempt quantity set forth in Appendix B of Part C, 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 Appendix B of Part C, provided that the sum of such fractions shall not exceed unity.

(III) For americium-241, 1.85 kBq (0.05 µCi) is considered an exempt quantity under C.4c.i.(8).

(ix) Ionization chamber smoke detectors containing not more than 1 microcurie (µCi) 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.4c.i.(1), or who desires to initially transfer for sale or distribution such products containing radioactive

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

material, should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from C.4c.i.(1).

ii. Self-Luminous Products Containing Radioactive Material.

(1) Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution 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, or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements or equivalent regulations of an Agreement State. The exemption in C.4c.ii. does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(2) 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 acquired prior to [the effective date of this regulation].

(3) 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.4c.ii.(1), should apply for a license pursuant to 10 CFR 32.22, which license states that the product may be transferred by the licensee to persons exempt from C.4c.ii.(1) or equivalent regulations of an Agreement State.

iii. Gas and Aerosol Detectors Containing Radioactive Material.

(1) 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 Act and 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 NRC[3/] pursuant to 10 CFR 32.26; or an Agreement State pursuant to C.28c., which authorizes the initial transfer of the detectors to persons who are exempt from regulatory

[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 NRC, Washington, D.C. 20555.*

requirements. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by an Agreement State under comparable provisions to C.28c. authorizing distribution to persons exempt from regulatory requirements.

(2) 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.4c., 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.28c.

(3) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use in accordance with C.4c.iii.(1), should apply for a license in accordance with 10 CFR 32.26, which license states that the product may be initially transferred by the licensee to persons exempt from C.4c.iii.(1) or equivalent regulations of an Agreement State.

iv. Exemptions for Capsules Containing Carbon-14 Urea for *in vivo* Diagnostic Use for Humans.

(1) Except as provided in C.4c.i.v.(2) and C.4c.iv.(3), any person is exempt from the requirements for a license set forth in the Act and this Part and from the requirements in Parts C and G of these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing not more than 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.

(2) 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 these regulations.

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

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

v. Additional Exemptions. Additional exemptions are available in Parts A, D, E, G, N, P, S, T and W of these regulations, as applicable.

Licenses

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

a. A general license is provided by regulation, grants authority to a person for certain activities involving radioactive materials and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However registration with the Agency may be required by the particular general license. A general license is issued by the Agency under this Part and Parts N and T of these regulations.

b. The Agency issues a specific license to a named person who has filed an application for the license under the provisions of Parts C, E, G, [I], [M], N, Q and W of these regulations.

c. [The general licenses provided in this Part are subject to the general provisions of Parts A, D and J of these regulations[4/] unless indicated otherwise in the specific provision of the general license.]

General Licenses

Sec. C.21 - General Licenses - Source Material.

a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 6.82 kg (15 lbs) 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 68.2 kg (150 lbs) 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.21a. 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 C.21a.

c. Persons who receive, possess, use, or transfer source material pursuant to the general license in C.21a. are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

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

e. Depleted Uranium in Industrial Products and Devices.

i. A general license is hereby issued to receive, acquire, possess, use, or transfer, in

[4/] *Attention is directed particularly to the provisions of Part D.1904 of these regulations which relate to the labeling of containers.*

accordance with the provisions of C.21e.ii., iii., iv., and v., 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.

ii. The general license in C.21e.i. 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.28m. or in accordance with a specific license issued to the manufacturer by the NRC or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the NRC or an Agreement State.

iii. (1) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by C.21e.i. shall file Agency Form W "Certificate - Use of Depleted Uranium Under General License" with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on Agency Form W the following information and such other information as may be required by that form:

(a) Name and address of the general licensee;

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

(c) Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in C.21e.iii.(1)(b).

(2) The general licensee possessing or using depleted uranium under the general license established by C.21e.i. shall report in writing to the Agency any changes in information furnished by the licensee in Agency Form W "Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

iv. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by C.21e.i. shall:

(1) 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;

(2) Not abandon such depleted uranium;

(3) Transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of C.40 and D.2001a. of these regulations. In the case

where the transferee receives the depleted uranium pursuant to the general license established by C.21e.i., the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form W. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the NRC's or Agreement State's regulation equivalent to C.21e.i., the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form W accompanied by a note explaining that use of the product or device is regulated by the NRC or Agreement State under requirements substantially the same as those in this regulation;

(4) Report in writing to the Agency, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(5) Not export such depleted uranium except in accordance with a license issued by the NRC pursuant to 10 CFR Part 110.

v. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.21e.i. is exempt from the requirements of Parts D and J of these regulations with respect to the depleted uranium covered by that general license.

Sec. C.22 - 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 NRC or Agreement State for use pursuant to 10 CFR 32.14. This general license is subject to the provisions of Parts A.4 through A.9, C.4a.ii., C.31, C.40, C.50 and Parts D[4/], J, and T of these regulations, as applicable.

i. 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.

ii. 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 mCi) 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

[*/] *Note different general licenses are issued in this section, each of which has its own specific conditions and requirements.*

[4/] *Attention is directed particularly to the provisions of Part D.1904 of these regulations which relate to the labeling of containers.*

C.22 is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

c. Reserved.

d. Certain Measuring, Gauging or Controlling Devices.

i. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of C.22d.ii., iii., iv., and v., 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.

ii. The general license in C.22d.i. applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specification contained in a specific license issued in accordance with C.28d.; or an equivalent specific license issued by an NRC or an Agreement State with provisions comparable to C.28d.[5/]

(1) The devices shall have been received from one of the specific licensees described in C.22d.ii.; or

(2) Through a transfer made under C.22d.iii.(9).

iii. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.22d.i. shall:

(1) 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;

(2) 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 6-month intervals or at such other intervals as are specified in the label, however,

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

(b) Devices containing only tritium or not more than 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

[5/] *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 21 CFR 179.21.*

shipping container prior to initial installation need not be tested for any purpose;

(3) Assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(a) In accordance with the instructions provided by the labels, or

(b) By a person holding an applicable specific license from the Agency, the NRC or an Agreement State to perform such activities;

(4) Maintain records showing compliance with the requirements of C.22d.iii.(2) and (3). 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.22d.iii.(2) shall be retained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by C.22d.iii.(2) shall be retained for 3 years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by C.22d.iii.(4) shall be retained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed of;

(5) Immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 Bq (0.005 μCi) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by this Agency, the NRC or by an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Agency, the NRC or an Agreement State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 Bq (0.005 μCi) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, shall be furnished to the Agency within 30 days. Under these circumstances, the criteria set out in Part O of these regulations, Sec. O.9 - Termination of a License Without Restriction, may be applicable, as determined by the Agency on a case-by-case basis;

(6) Not abandon the device containing radioactive material;

(7) Not export the device containing radioactive material except in accordance with 10 CFR Part 110.

(8) Transfer or dispose of the device containing radioactive material:

(a) Only by export as provided by C.22d.iii.(7)., by transfer to another general licensee as authorized in C.22d.iii.(9)., or to a person authorized to receive the device by a specific license of Part C that authorized waste collection, or equivalent regulations of the NRC or an Agreement State, or as otherwise approved under C.22d.iii.(8).

(b) Furnish a report to the Agency within 30 days after the transfer of a device to a specific licensee or export. The report shall contain:

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

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

(iii) The date of the transfer.

(c) Obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in C.22d.iii.(8). 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:

(i) 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;

(ii) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by C.22d.iii.(1)) so that the device is labeled in compliance with D.1904 of these regulations85; however the manufacturer, model number, and serial number must be retained;

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

(iv) Reports the transfer under C.22d.iii.(8)(b).

(9) Transfer the device to another general licensee only:

(a) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of C.22a., Parts D.2101

through D.2111, D.2201, and D.2202 of these regulations, and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency;

(i) The manufacturer's (or initial transferor's) name;

(ii) The model and serial number of the device transferred;

(iii) The transferee's name and mailing address for the location of use; and

(iv) The name, title, and telephone number of the responsible individual identified by the transferee in accordance with C.22d.iii.(12) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(b) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

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

(11) 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 the same time period, request a longer period to supply information by submitting a letter to the Agency and provide written justification as to why it cannot comply.

(12) 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.

(13) Register general license devices:

(a) In accordance with C.22d.iii.(13) (b) & (c), 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 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic[*/], based

[*/] *Transuranic means an element with atomic number greater than uranium (92).*

on the activity indicated on the label. Each address for a location of use, as described in C.22d.iii.(13)(c)(iv.), represents a separate general licensee and requires a separate registration [and fee].

(b) If in possession of a device meeting the criteria of C.22d.iii.(13)(a), shall register these devices annually with the Agency [and shall pay the applicable fee.] Registration shall be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Agency. The registration information shall 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 licensee holding devices that meet the criteria of C.22d.iii.(13)(a) is subject to the bankruptcy notification requirement in C.31e.

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

(i) Name and mailing address of the general licensee;

(ii) Information about each device: the manufacturer or initial transferor, model number, serial number, the radionuclide and activity, as indicated on the label;

(iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee in C.22d.iii.(12);

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

(v) 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; and

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

(d) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in C.22d.iii.(13)(a) 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.

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

(15) Not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by C.22d.iii.(2) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they shall be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

iv. The general license in C.22d.i. does not authorize the manufacture or import of devices containing radioactive material.

v. The general license provided in C.22d.i. is subject to the provisions of Part A.4 through A.9, C.31, C.40, C.50, and Part T of these regulations.

e. General License to Install Devices Generally Licensed in C.22d. 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.22d.i. 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:

i. [Reserved]

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

iii. 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.

f. Luminous Safety Devices for Aircraft.

i. 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:

(1) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq

(300 mCi) of promethium-147; and

(2) Each device has been manufactured, assembled or initially transferred in accordance with a specific license issued by the NRC or an Agreement State, 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 of C.28e.

ii. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in C.22f.i. are exempt from the requirements of Parts D and J of these regulations except that they shall comply with the provisions of Part D.2201 and Part D.2202 of these regulations.

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

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

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

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

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

h. Calibration and Reference Sources.

i. 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.22h.iv. and v., C.28f. and americium-241 in the form of calibration or reference sources:

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

(2) Any person who holds a specific license issued by the NRC which authorizes the licensee to receive, possess, use, and transfer special nuclear material.

ii. 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.22h.iv. and v. to any person who holds a specific license issued by the

Agency which authorizes the licensee to receive, possess, use, and transfer radioactive material.

iii. 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.22h.iv. and v. to any person who holds a specific license issued by the Agency which authorizes the licensee to receive, possess, use, and transfer radioactive material.

iv. The general licenses in C.22h.i., ii. and iii. apply only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency or any Agreement State pursuant to licensing requirements equivalent to those contained in C.28f., 10 CFR 32.57 or 10 CFR 70.39.

v. The general licenses provided in C.22h.i., ii., and iii. are subject to the provisions of Part A.4 through A.9, C.31, C.40, C.50 and Parts D, J, and T 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 shall:

(1) 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;

(2) Not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information :

> The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the 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
THIS SOURCE CONTAINS (AMERICIUM-241).
(PLUTONIUM)[6/] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor

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

(3) Not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the NRC, or an Agreement State to receive the source;

(4) 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

(5) Not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

vi. These general licenses do not authorize the manufacture, import or export, of calibration or reference sources containing americium-241, plutonium, or radium-226.

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

i. A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of C.22i., ii., iii., iv., v. and vi., the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(1) Carbon-14, in units not exceeding 370 kBq (10 µCi) each.

(2) Cobalt-57, in units not exceeding 370 kBq (10 µCi) each.

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

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

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

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

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

ii. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.22i.i. until the person has filed Agency Form V, "Certificate - *In Vitro* Testing with Radioactive Material Under General License",

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

with the Agency and received from the Agency a validated copy of Agency Form V with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form V the following information and such other information as may be required by that form:

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

(2) The location of use; and

(3) 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.22i.i. 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.

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

(1) The general licensee shall not possess at any one time, pursuant to the general license in C.22i.i., 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).

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

(3) The general licensee shall use the radioactive material only for the uses authorized by C.22i.i.

(4) 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 NRC, 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.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.22i.i.(8) as required by Part D.2001a. of these regulations.

iv. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.22i.i.:

(1) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.28h. or in accordance with the provisions of a specific license issued by the NRC 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.22i. or its equivalent, and

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

This radioactive material 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 therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or an Agreement State.

_____
Name of manufacture

v. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of C.22i.i. shall report in writing to the Agency, any changes in the information furnished in the "Certificate - *In Vitro* Testing with Radioactive Material Under General License", Agency Form V. The report shall be furnished within 30 days after the effective date of such change.

vi. Any person using radioactive material pursuant to the general license of C.22i.i. is exempt from the requirements of Parts D and 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.22i.i.(5) shall comply with the provisions of Part D.2001a., D.2201 and D.2202 of these regulations.

j. Ice Detection Devices.

i. 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 initially transferred in accordance with a specific license issued by the NRC or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of such device pursuant to licensing requirements of C.28i. or equivalent to those in 10 CFR 32.61.

ii. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in C.22j.i.,

(1) 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 NRC or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of Part D.2001a. of these regulations;

(2) 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

(3) Are exempt from the requirements of Parts D and J of these regulations except that such persons shall comply with the provisions of Part D.2001a., Part D.2201, and Part D.2202.

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

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

k. Self Luminous Products Containing Radium-226.

i. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of C.22k.ii. through iv., radium-226 contained in the following products manufactured prior to November 30, 2007.

(1) 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.

(2) Intact timepieces containing greater than 0.037 MBq (1 µCi), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

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

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

(5) Small radium sources containing no more than 0.037 MBq (1 µCi) 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.

ii. Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in C.22k.i. are exempt from the provisions of Parts D and J, and

C.95 of these regulations, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this Part.

iii. Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in C.22k.i. shall:

(1) Notify the Agreement State 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.

(2) 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 NRC or an Agreement State.

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

[(4) 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 NRC or an Agreement State.]

(5) Respond to written requests from the Agreement State 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 Agreement State, by an appropriate method listed in 10 CFR 30.6(a), a written justification for the request.

iv. The general license in C.22k.i. does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

Sec. C.23 - Reserved.

Specific Licenses

Sec. C.24 - Filing Application for Specific Licenses.

a. Applications for specific licenses shall be filed [in triplicate] on a form prescribed by the Agency.

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

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

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

e. In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

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, [in accordance with (State open records law)] 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 shall either:

i. 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

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

iii. 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:

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

(2) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information 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 of these regulations or equivalent Agreement State requirements shall include:

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

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

iii. 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.28j.ii.(2).

iv. Information identified in C.28j.i.(3) on the PET drugs to be noncommercially transferred to members of its consortium.

Sec. C.25 - 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.27, C.28, Parts E, G, [I], [M], N, O, P, Q, S,, or W 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, 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 preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.]

f. Reserved.

g. Reserved.

Sec. C.26 - Reserved.

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

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

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

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

iii. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Appendix D of Part C, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed there under, is the quantity specified for that radionuclide in Appendix D, Column II. 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 Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

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

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

ii. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

iii. 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:

(1) 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;

(2) 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

(3) The establishment of appropriate administrative procedures to assure:

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

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

(c) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with C.27b.iii.(3)(b) prior to use of the radioactive material.

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

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

ii. 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:

(1) 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

(2) The establishment of appropriate administrative procedures to assure,

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

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

(c) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with C.27c.ii.(2)(b) prior to use of the radioactive material.

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

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

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

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

(2) 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

iii. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

e. Specific licenses of broad scope are subject to the following conditions:

i. Unless specifically authorized, persons licensed pursuant to C.27 shall not:

(1) Conduct tracer studies in the environment involving direct release of radioactive material;

(2) Receive, acquire, own, possess, use, or transfer devices containing 3.7 PBq (100,000 Ci) or more of radioactive material in sealed sources used for irradiation of materials;

(3) Conduct activities for which a specific license issued by the Agency under C.28 or Parts E, G, [I], [M], N or Q of these regulations is required; or

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

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

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

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

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

a. Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.4a. or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to 10 CFR 32.11.

b. Licensing the Distribution of Radioactive Material in Exempt Quantities.

i. 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 NRC, Washington, D.C. 20555.

ii. An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to C.4b. will be approved if:

(1) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(2) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(3) The applicant submits copies of prototype labels and brochures and the

Agency approves such labels and brochures.

iii. The license issued under C.28b.ii. is subject to the following conditions:

(1) No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(2) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to C.4b. The outer package shall be such that the dose rate at the external surface of the package does not exceed 5 microsieverts (μSv) (0.5 mrem) per hour.

(3) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(a) Identifies the radionuclide and the quantity of radioactivity, and

(b) Bears the words "Radioactive Material".

(4) In addition to the labeling information required by C.28b.iii.(3), the label affixed to the immediate container, or an accompanying brochure, shall:

(a) State that the contents are exempt from NRC or Agreement State requirements,

(b) Bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined", and

(c) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

iv. Each person licensed under C.28b. shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under C.4b. or the equivalent regulations of the NRC or an Agreement State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to C.28b. during the reporting period, the report shall so indicate.

c. Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing

the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under C.4c.iii. will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26. The maximum quantity of radium-226 in each device shall not exceed 3.7 kBq (0.1 µCi).

d. Licensing the Manufacture or Initial Transfer of Devices to Persons Generally Licensed Under C.22d.

i. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.22d. or equivalent regulations of the NRC or an Agreement State will be approved if:

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

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

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

(b) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in the table in Part D.1201a. of these regulations, and

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

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	150 mSv (15 rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm^2	2.0 Sv (200 rem)
Other organs	500 mSv (50 rem); and

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

(a) Instructions and precautions necessary to assure safe installation,

operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information,

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

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

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ [8/], are subject to a general license or the equivalent and the regulations of the NRC or a State with which the NRC 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 initial transferor

(4) 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 radionuclide and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in D.1901 of these regulations, and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of C.22d.iii.(13)(a), bears a permanent, 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 D.1901 of these regulations.

ii. In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the 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:

(1) Primary containment or source capsule;

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

iii. In the event the applicant desires that the general licensee under C.22d., or under equivalent regulations of the NRC 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, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in Part D.1201a. of these regulations.

iv. <u>Conditions of transferring a device for use under a general license in C.22d.</u>

(1) If a device containing radioactive material is to be transferred for use under the general license in C.22d., each person that is licensed under C.28d. 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:

(a) A copy of the general license contained in C.22d.; if paragraphs C.22d.iii.(2) through (4) or (13) do not apply to the particular device, those paragraphs may be omitted.

(b) A copy of C.95, D.2201 and D.2202 of these regulations;

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

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

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

(2) 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.28d. 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:

(a) A copy of the C.22a., C.22d., 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; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

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

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

(d) 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.

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

(4) Each device that is transferred after [insert effective date of these regulations here] shall meet the labeling requirements in C.28d.i.(3). through C.28d.i.(5).

(5) If a notification of bankruptcy has been made under C.31e. or the license is to be terminated, each person licensed under C.28d. shall provide, upon request, to the Agency, the NRC, and to any appropriate Agreement State, records of

final disposition required under C.28d.v.(3).

v. Material transfer reports and records. Each person licensed under C.28d. to initially transfer devices to generally licensed persons shall comply with the requirements of C.28d.

(1) The person shall report all transfers of devices to persons for use under the general license in C.22d. and all receipts of devices from persons licensed under C.22d. The report shall be submitted on a quarterly basis on the NRC Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

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

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

(ii) The name, title, and telephone 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;

(iii) The date of transfer;

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

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

(b) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(c) For devices received from a C.22d. general licensee, the report shall include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by a C.22d. general licensee, such that the label shall be changed to update required information, the report shall identify the general licensee, the device,

and the changes to information on the device label.

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

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

(g) If no transfers have been made to or from persons generally licensed under C.22d. during the reporting period, the report shall so indicate.

(2) The person shall report all transfers of devices to persons for use under a general license in an NRC or Agreement State's regulations that are equivalent to C.22d. and all receipts of devices from general licensees in the NRC or Agreement State's jurisdiction to the NRC or responsible Agreement State agency. The report shall be submitted on NRC Form 653--``Transfers of Industrial Devices Report" 10 CFR 32.52a. or in a clear and legible report containing all of the data required by the form.

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

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

(ii) The name, title, and telephone 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;

(iii) The date of transfer;

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

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

(b) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(c) For devices received from a general licensee, the report shall include

the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

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

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

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

(g) If no transfers have been made to or from the NRC or a particular Agreement State during the reporting period, this information shall be reported to the NRC or responsible Agreement State agency upon request of the Agency.

(3) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this C.28d.v. Records required by this C.28d.v. shall be maintained for a period of 3 years following the date of the recorded event.

e. <u>Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft.</u>

i. 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.22f. will be approved if:

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

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

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

(b) Details of construction and design;

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

(d) 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;

(e) Any quality control procedures proposed as alternatives to those prescribed by C.28e.iii.

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

(3) 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.

(4) The Agency determines that:

(a) 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;

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

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

(d) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by C.28e.iv.

ii. Labeling of devices.

(1) A person licensed under C.28e. to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under C.22f. shall, except as provided in C.28e.ii.(2), affix to each device a label containing the radiation symbol prescribed by D.1901 of these regulations, such other information as may be required by the Agency including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement: [8/]

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

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.

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_____

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

(2) If the Agency determines that it is not feasible to affix a label to the device containing all the information called for in C.28e.ii.(1), it may waive the requirements of that paragraph and require in lieu thereof that:

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

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

(ii) The type of radioactive material; and

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

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

(ii) The type and quantity of radioactive material,

(iii) The model number,

(iv) 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 U.S. NRC or of an Agreement State, and

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

iii. Quality assurance; prohibition of transfer.

(1) Each person licensed under C.28e. 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.

(2) Each person licensed under C.28e. shall take a random sample of the size

[*/] *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.*

required by the table in C.28m. 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:

(a) 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.

(b) The immersion test water from the preceding test in C.28e.iii.(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.

(c) 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.

(3) 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.28e.iii.(2), and proposed criteria for acceptance under those procedures. The Agency will approve the proposed alternative procedures if the applicant demonstrates that:

(a) 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

(b) 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.

(4) No person licensed under C.28e. shall transfer to persons generally licensed under C.22f. of this chapter:

(a) 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.28e.iii.(2); or

(b) Any inspection lot which has been rejected as a result of the procedures in C.28m. or alternative procedures in C.28e.iii.(3), 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.28e.iii.(2).

iv. Schedule B--prototype tests for luminous safety devices for use in aircraft. An applicant for a license pursuant to C.28e. shall conduct prototype tests on each of five prototype luminous safety devices for use in aircraft as follows:

(1) 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.

(2) 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

(a) 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.

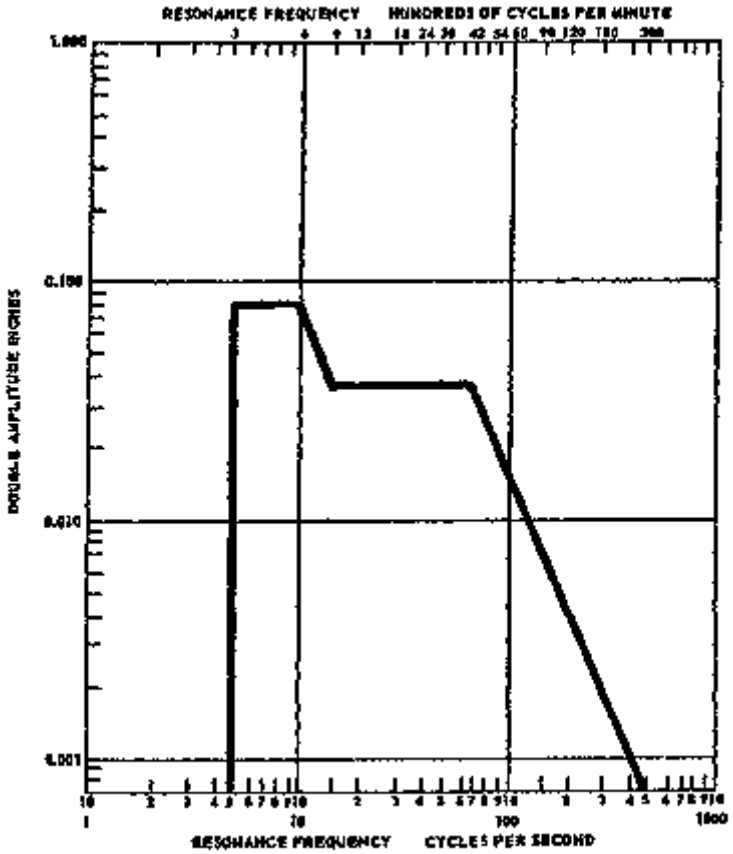

FIGURE 1—Amplitude of vibration at resonance frequency.

(b) 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.

(c) 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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.28e.iv.(5) 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.

v. Material transfer reports. Each person licensed under C.28e. 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.22f. 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 or Initially Transfer Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.22h.

i. An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under C.22h. will be approved if:

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

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

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

(b) Details of construction and design;

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

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

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

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

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

(3) Each source will contain no more than 185 kBq (5 μCi) of americium-241, plutonium or radium-226.

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

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

(b) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by C.28f.ii., Schedule C, of this Part.

ii. Schedule C- prototype tests for calibration or reference sources containing americium-241, plutonium or radium-226. An applicant for a license pursuant to C.28f. 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:

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

(2) 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.

(3) 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.

(4) 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.

(5) Dry wipe test. On completion of the preceding test in this section, the dry wipe test described in C.28f.ii.(2) shall be repeated.

(6) 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 and percent of removal from the total amount of radioactive material deposited on the source.

iii. Labeling of devices. Each person licensed under C.28f. 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:[9/]

> The receipt, possession, use and transfer of this source, Model __, 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 [PLUTONIUM OR RADIUM-226].
> DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
>
> _____
> Name of manufacturer or initial transferor

iv. Leak testing of each source. Each person licensed under C.28f. shall perform a dry wipe test upon each source containing more than 3.7 kBq (0.1 μCi) of americium-241, plutonium or radium 226 prior to transferring the source to a general licensee under C.22h. 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-241, plutonium, or 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, plutonium or radium-226 and shall not be transferred to a general licensee under C.22h. 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.22i. will be approved if:

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

ii. The radioactive material is to be prepared for distribution in prepackaged units of:

(1) Carbon-14 in units not exceeding 370 kBq (10 μCi) each.

(2) Cobalt-57 in units not exceeding 370 kBq (10 μCi) each.

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

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

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

(5) 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.

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

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

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

iii. Each prepackaged unit bears a durable, clearly visible label:

(1) 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 µCi) of americium-241 each; and

(2) Displaying the radiation caution symbol described in D.1901a. and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

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

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

_____

Name of manufacturer

v. 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 shall also contain directions to the licensee regarding the waste disposal requirements set out in Part D.2001a. of these regulations.

i. Licensing the Manufacture or Initial Transfer of Ice Detection Devices Containing Strontium-90.

i. An application for a specific license to manufacture or intially transfer ice detection devices to persons generally licensed under C.22j. will be approved if:

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

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

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

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

(c) Radiation profile of a prototype device;

(d) 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;

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

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

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

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

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

(4) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by D.1901a. 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;

(5) The Agency determines that:

(a) 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;

(b) 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;

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

(d) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by C.28i.iii.; and

(e) Quality control procedures have been established to satisfy the requirements of C.28i.ii.

ii. Quality assurance; prohibition of transfer.

(1) Each person licensed under C.28.i shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(2) Each person licensed under C.28i. 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.

(3) Each person licensed under C.28i. shall take a random sample of the size required by the table in C.28m. 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:

(a) 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.

(b) The immersion test water from the preceding test in C.28i.ii.(3)(a) 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.

(4) 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.28i.ii.(3), and proposed criteria for acceptance under those procedures. The Agency will approve the proposed alternative procedures if the applicant demonstrates that:

(a) 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

(b) 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.

(5) No person licensed under C.28i.ii. shall transfer to persons generally licensed under C.22j.:

(a) Any device which has been tested and found defective under the criteria and procedures specified in this C.28i. unless the defective units have been repaired or reworked and then met the tests set out in C.28i.ii.(3); or

(b) Any inspection lot which has been rejected as a result of the procedures in C.28m. or alternative procedures in C.28i.ii.(4), 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.28i.ii.(3).

iii. Schedule D--prototype tests for ice detection devices containing strontium-90. An applicant for a license pursuant to C.28i. shall conduct prototype tests on each of five prototype ice detection devices as follows:

(1) 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.28e.iv.(1)

(2) Vibration tests. The device shall be subjected to vibration tests as set forth in C.28e.iv.(2).

(3) Shock test. The device shall be subjected to shock test as set forth in C.28e.iv.(4).

(4) 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.

(5) 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.28.i.ii.(4) 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 Radioactive Drugs Containing Radioactive Material for Medical Use Under Part G of these regulations.

i. 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 of these regulations will be approved if:

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

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

(a) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 10 CFR21 CFR 207.20(a);

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

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

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

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

(3) 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

(4) The applicant satisfies the following labeling requirements:

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

(b) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall 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.

ii. A licensee described by C.28j.i.(2)(c) or (d):

(1) May prepare radioactive drugs for medical use, as defined in G.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph C28j.ii.(2) or C.28j.ii.(4), or an individual under the supervision of an authorized nuclear pharmacist as specified in G.21b.

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

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

(b) This individual meets the requirements specified in G27 and G30 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with C28j.ii.(4).

(3) The actions authorized in C.28j.ii.(1) and C.28j.ii.(2) are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in G.2) as an authorized nuclear pharmacist if:

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

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

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

(a) Certification by a specialty board whose certification process has been recognized by the NRC or an Agreement State as specified in G27 of these regulations with the written attestation signed by a preceptor as required by G27 of these regulations; or

(b) The NRC or Agreement State license; or

(c) NRC master materials licensee permit, or

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

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

(f) A 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.28j.ii.(2)(a) and C.28j.ii.(2)(b).

iii. 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:

(1) 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

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

iv. 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 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 G.59, G.69, G.71, and G.89 of these regulations will be approved if:

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

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

(1) The radioactive material contained, its chemical and physical form, and amount,

(2) Details of design and construction of the source or device,

(3) 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,

(4) For devices containing radioactive material, the radiation profile of a prototype device,

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

(6) Procedures and standards for calibrating sources and devices,

(7) Legend and methods for labeling sources and devices as to their radioactive content, and

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

iii. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the Agency has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in Part G.35, G.59, G.69, G.71 and G.89 as appropriate, and to persons who hold an equivalent license issued by an Agreement State.

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

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

(1) Primary containment or source capsule;

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

vi. If an application is filed in accordance with C.28k. on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Agency issues the license or notifies the applicant otherwise

l. <u>Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.</u>

i. An application for a specific license to manufacture industrial products and devices

containing depleted uranium for use pursuant to C.21e. or equivalent regulations of the NRC or an Agreement State will be approved if:

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

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in Part D.1201a. of these regulations; and

(3) 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.

ii. 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.28l. 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.

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

iv. Each person licensed pursuant to C.28l.i. shall:

(1) 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;

(2) Label or mark each unit to:

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

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

(3) 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";

(4) (a) Furnish a copy of the general license contained in C.21e. and a copy of Agency Form W to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in C.21e., or

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

(5) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in C.21e. 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.21e. during the reporting period, the report shall so indicate;

(6) (a) Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in C.21e.,

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

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

(d) If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC, and

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

of that Agency; and

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

m. Acceptance sampling procedures under certain specific licenses.

i. A random sample shall be taken from each inspection lot of devices licensed under 10 CFR 32.14, C.28e., or C.28i. for which testing is required in accordance with the appropriate Sampling Table in this section determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table in this section, the lot shall be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table in this section, the entire inspection lot shall be rejected.

ii. Single sampling tables for Lot Tolerance Percent Defective:

(1) Lot Tolerance Percent Defective 0.5 percent:

Lot size	Sample Size	Acceptance No.
1 to 180	All	0
181 to 210	180	0
211 to 250	210	0
251 to 300	240	0
301 to 400	275	0
401 to 500	300	0
501 to 600	320	0
601 to 800	350	0
801 to 1,000	365	0
1,001 to 2,000	410	0
2,001 to 3,000	430	0
3,001 to 4,000	440	0
4,001 to 5,000	445	0
5,001 to 7,000	450	0
7,001 to 10,000	455	0
10,001 to 20,000	460	0
20,001 to 50,000	775	1
50,001 to 100,000	780	1

(2) Lot Tolerance Percent Defective 1.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 120	All	0
121 to 150	120	0
151 to 200	140	0
201 to 300	165	0
300 to 400	175	0
401 to 500	180	0
501 to 600	190	0
601 to 800	200	0
801 to 1,000	205	0
1,000 to 3,000	220	0
3,001 to 5,000	225	0
5,001 to 10,000	230	0
10,001 to 100,000	390	1

(3) Lot Tolerance Percent Defective 2.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 75	All	0
76 to 100	70	0
101 to 200	85	0
201 to 300	95	0
301 to 400	100	0
401 to 600	105	0
601 to 800	110	0
801 to 4,000	115	0
4,001 to 10,000	195	1
10,001 to 100,000	200	1

(4) Lot Tolerance Percent Defective 3.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 40	All	0
41 to 55	40	0
56 to 100	55	0
101 to 200	65	0
201 to 500	70	0
501 to 3,000	75	0
3,001 to 100,000	130	1

(5) Lot Tolerance Percent Defective 4.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 35	All	0
36 to 50	34	0
51 to 100	44	0
101 to 200	50	0
201 to 2,000	55	0
2,001 to 100,000	95	1

(6) Lot Tolerance Percent Defective 5.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2,001 to 100,000	75	1

(7) Lot Tolerance Percent Defective 7.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 25	All	0
26 to 50	24	0
51 to 100	28	0
101 to 200	30	0
201 to 300	31	0
301 to 800	32	0
801 to 1,000	33	0
1,001 to 100,000	55	1

(8) Lot Tolerance Percent Defective 10.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	1

Sec. C.29 - Reserved.

Sec. C.30 - Issuance of Specific Licenses.

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

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

i. Minimize danger to public health and safety or property;

ii. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

iii. Prevent loss or theft of material subject to Part C.

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

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

b. No license issued or granted under Part C 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 Part C shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

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

e. Each general licensee that is required to register by C.22d.iii.(13) and each specific licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.) by or against:

i. The licensee;

ii. 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

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

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

g. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

h. 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 G.48 of these regulations. The licensee shall record the results of each test and retain each record for 3 years after the record

is made.

i. i. Authorization under C.24h. 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 Agreement State requirements governing radioactive drugs.

ii. Each licensee authorized under C.24h. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(1) Satisfy the labeling requirements in C.28j.i.(4) 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.

(2) 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.28j.iii.

iii. A licensee that is a pharmacy authorized under C.24h. 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:

(1) An authorized nuclear pharmacist that meets the requirements in C.28j.ii.(2), or

(2) An individual under the supervision of an authorized nuclear pharmacist as specified in G.21 of these regulations.

iv. A pharmacy, authorized under C.24h. 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.28j.ii.(5).

Sec. C.32 - Expiration and Termination of Licenses.

[a. Except as provided in O.5. of these regulations, each specific license shall expire at the end of the specified day in the month and year stated therein. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

i. Limit actions involving radioactive material to those related to decommissioning; and

ii. Continue to control entry to restricted areas until they are suitable for release in accordance with Part O of these regulations.]

b. Each licensee shall notify the Agency [immediately], in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license shall include the reports and information specified in C.32d.i.(4) and (5).

c. No less than 30 days before the expiration date specified in the license, the licensee shall either:

i. Submit an application for license renewal under C.33; or

ii. Notify the Agency, in writing, if the licensee decides not to renew the license.

d. i. If a licensee does not submit an application for license renewal under C.33, the licensee shall, on or before the expiration date specified in the license:

(1) Terminate use of radioactive material;

(2) Remove radioactive contamination to the extent practicable;

(3) Properly dispose of radioactive material;

(4) Submit a completed Agency Form T; and

(5) Submit a radiation survey report to confirm the absence of radioactive material 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:

(a) Report levels of radioactivity, including alpha and beta, in units of MBq (disintegrations per minute or µCi) per 100 cm^2--removable and fixed--for surfaces, MBq (µCi) per milliliter for water, and Bq (pCi) per gram for solids such as soils or concrete; and report levels of gamma radiation in units of mSv (microroentgen) per hour at one meter from surfaces; and

(b) Specify the instrumentation used and certify that each instrument was properly calibrated and tested.

ii. 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. The Agency will notify the licensee, in writing, of the termination of the license.

iii. (1) If detectable levels of residual radioactive contamination attributable to activities conducted under the 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 C.32e.

(2) In addition to the information submitted under C.32d.i.(4) and (5), the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

e. Each licensee who possesses residual radioactive material under C.32d.iii., following the expiration date specified in the license shall:

i. Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

ii. 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.

Sec. C.33 - Renewal of Licenses.

a. Applications for renewal of specific licenses shall be filed in accordance with C.24.

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

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

Sec. C.35 - Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in C.25, C.27, and C.28 and in Parts A,C, D, E, G, [I], J, [M], N, O, P, Q, S, T or W of these regulations, as applicable.

Licenses Held at the Time of the Effective Date of These Regulations

Sec. C.36 - Persons Possessing a License for Radioactive Material to include Source, and/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 radioactive material, to include source and/or special nuclear material in quantities not sufficient to form a critical mass, issued by the NRC, shall be deemed to possess an equivalent license issued under Part C 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 or expiration specified in the NRC license, whichever is earlier.

Sec. C.37 - Reserved.

[*/] *Upon subsequent revision of the State's regulations, these sections may be deleted.*

Transfer of Material

Sec. C.40 - Transfer of Material.

a. No licensee shall transfer radioactive material except as authorized pursuant to C.40.

b. Except as otherwise provided in the license and subject to the provisions of C.40c. and C.40d., any licensee may transfer radioactive material:

   i. To the Agency only after receiving prior approval from the Agency;

   ii. To the U.S. Department of Energy;

   iii. To any person exempt from these regulations to the extent permitted under such exemption;

   iv. 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 NRC, 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 an Agreement State; or

   v. As otherwise authorized by the Agency in writing.

c. Before transferring radioactive material to a specific licensee of the Agency, the NRC, or an Agreement State, or to a general licensee who is required to register with the Agency, the NRC, 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. Any of the following methods for the verification required by C.40c. is acceptable:

   i. The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

   ii. The transferor may possess a written certification by the transferee that the transferee 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.

   iii. For emergency shipments, the transferor may accept oral certification by the transferee that the transferee 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.

iv. The transferor may obtain other information compiled by a reporting service from official records of the Agency, the NRC, or an Agreement State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

v. When none of the methods of verification described in C.40d.i. through C.40d.iv. are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the NRC, or an Agreement State that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of Part T of these regulations.

Modification and Revocation of Licenses

Sec. C.50 - Modification and Revocation 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 or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

Reciprocity

Sec. C.90 - Reciprocal Recognition of Licenses.

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

i. Subject to these regulations, any person who holds a specific license from the NRC or an 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 for a period not in excess of 180 days in any calendar year provided that:

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

(2) The out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.90a.i.;

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

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

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90a.i. except by transfer to a person:

(a) Specifically licensed by the Agency or by the NRC to receive such material, or

(b) Exempt from the requirements for a license for such material under C.4a.

ii. Notwithstanding the provisions of C.90a.i., any person who holds a specific license issued by the NRC or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in C.21, C.22d.i., C.22e., and C.22g. 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:

(1) Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

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

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

(4) The holder of the specific license shall furnish to each general licensee to whom the licensee transfers such device or on whose premises the licensee installs such device a copy of the general license contained in C.22d. or in equivalent regulations of the Agency having jurisdiction over the manufacture and distribution of the device.

iii. The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or an Agreement State, 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.

b. Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.

i. Subject to these regulations and Part N of these regulations, any person who holds a specific license from a Licensing State, and issued by the Agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

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

(2) The out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.90b.i.;

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

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

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90b.i. except by transfer to a person:

(a) Specifically licensed by the Agency or by another Licensing State to receive such material, or

(b) Exempt from the requirements for a license for such material under C.4.

ii. Notwithstanding the provisions of C.90b.i., any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in C.21, C.22d.i., C.22e., and C.22g. 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:

(1) Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

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

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

(4) The holder of the specific license shall furnish to each general licensee to whom the licensee transfers such device or on whose premises the licensee installs such device a copy of the general license contained in C.22d. or in equivalent regulations of the Agency having jurisdiction over the manufacture and distribution of the device.

iii. The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, 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.

c. <u>Recognition of Agreement State Licenses.</u>

i. Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site shall be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.

(1) In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the NRC, and

(2) Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction shall be obtained from the NRC by either:

(a) Filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or

(b) By applying for a specific NRC license.

ii. Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained for the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

Sec. C.95 - 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 radioactive material as follows:

i. 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.

ii. 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.

iii. 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, [I], [M], N and Q 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 Agreement State terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

c. i. Records which must be maintained pursuant to this Part and Parts E, G, [I], [M], N and Q 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.

ii. If there is a conflict between the Agency's regulations in this Part and Parts E, G, [I], [M], N and Q 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, [I], [M], N and Q of these regulations for such records shall apply unless the Agency, pursuant to A.3a. or C.4, has granted a specific exemption from the record retention requirements specified in the regulations in this Part or Parts E, G, [I], [M], N and Q 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:

i. Records of disposal of licensed material made under D.2001 (including burials authorized before January 28, 1981 [11/]), D.2003, D.2004, D.2005; and

ii. Records required by D.2103b.iv. of these regulations

e. If licensed activities are transferred or assigned in accordance with C.31b., 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:

i. Records of disposal of licensed material made under D.2001 (including burials authorized before January 28, 1981 [11/]), D.2003, D.2004, D.2005; and

ii. Records required by D.2103b.iv. of these regulations.

f. Prior to license termination, each licensee shall forward the records required by S.5 of these regulations to the Agency.

[Sec. C.100 - 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

[11/] *A previous 10 CFR 20.304, or equivalent state regulation, permitted burial of small quantatities of licensed materials in soil before January 28, 1981, without specific Commission, or Agency, authorization.*

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 Part C, may not:

i. 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

ii. 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 C.100a.i. or C100a.ii. may be subject to enforcement action in accordance with Agency procedures.

c. For the purposes of C.100a.i., deliberate misconduct by a person means an intentional act or omission that the person knows:

i. 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

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

Sec. C.101 - Reserved.

Sec. C.102 - Reserved.

Sec. C.103 - Reserved.

Sec. C.104 - Reserved.

Part C

APPENDIX A

EXEMPT CONCENTRATIONS

		Column I Gas concentration		Column II Liquid and solid concentration	
Element (atomic number)	Radionuclide	GBq/m^3	µCi/ml	GBq/m^3	µCi/ml
Antimony (51)	Sb-122			1.1×10^{-2}	3×10^{-4}
	Sb-124			7.4×10^{-3}	2×10^{-4}
	Sb-125			3.7×10^{-2}	1×10^{-3}
Argon (18)	Ar-37	3.7×10^{-2}	1×10^{-3}		
	Ar-41	1.5×10^{-5}	4×10^{-7}		
Arsenic (33)	As-73			1.9×10^{-1}	5×10^{-3}
	As-74			1.9×10^{-2}	5×10^{-4}
	As-76			7.4×10^{-3}	2×10^{-4}
	As-77			3.0×10^{-2}	8×10^{-4}
Barium (56)	Ba-131			7.4×10^{-2}	2×10^{-3}
	Ba-140			1.1×10^{-2}	3×10^{-4}
Beryllium (4)	Be-7			7.4×10^{-1}	2×10^{-2}
Bismuth (83)	Bi-206			1.5×10^{-2}	4×10^{-4}
Bromine (35)	Br-82	1.5×10^{-5}	4×10^{-7}	1.1×10^{-1}	3×10^{-3}
Cadmium (48)	Cd-109			7.4×10^{-2}	2×10^{-3}
	Cd-115m			1.1×10^{-2}	3×10^{-4}
	Cd-115			1.1×10^{-2}	3×10^{-4}
Calcium (20)	Ca-45			3.3×10^{-3}	9×10^{-5}
	Ca-47			1.9×10^{-2}	5×10^{-4}
Carbon (6)	C-14	3.7×10^{-5}	1×10^{-6}	3.0×10^{-1}	8×10^{-3}
Cerium (58)	Ce-141			3.3×10^{-2}	9×10^{-4}
	Ce-143			1.5×10^{-2}	4×10^{-4}
	Ce-144			3.7×10^{-3}	1×10^{-4}
Cesium (55)	Cs-131			7.4×10^{-1}	2×10^{-2}
	Cs-134m			$2.2\times10^{+0}$	6×10^{-2}
	Cs-134			3.3×10^{-3}	9×10^{-5}
Chlorine (17)	Cl-38	3.3×10^{-5}	9×10^{-7}	1.5×10^{-1}	4×10^{-3}
Chromium (24)	Cr-51			7.4×10^{-1}	2×10^{-2}
Cobalt (27)	Co-57			1.9×10^{-1}	5×10^{-3}
	Co-58			3.7×10^{-2}	1×10^{-3}
	Co-60			1.9×10^{-2}	5×10^{-4}
Copper (29)	Cu-64			1.1×10^{-1}	3×10^{-3}
Dysprosium (66)	Dy-165			1.5×10^{-1}	4×10^{-3}
	Dy-166			1.5×10^{-2}	4×10^{-4}
Erbium (68)	Er-169			3.3×10^{-2}	9×10^{-4}
	Er-171			3.7×10^{-2}	1×10^{-3}
Europium (63)	Eu-152(9.2 h)			2.2×10^{-2}	6×10^{-4}
	Eu-155			7.4×10^{-2}	2×10^{-3}
Fluorine (9)	F-18	7.4×10^{-5}	2×10^{-6}	3.0×10^{-1}	8×10^{-3}
Gadolinium (64)	Gd-153			7.4×10^{-2}	2×10^{-3}
Gadolinium (64)	Gd-159			3.0×10^{-2}	8×10^{-4}
Gallium (31)	Ga-72			1.5×10^{-2}	4×10^{-4}

Column I		Column II			
		Gas concentration		Liquid and solid concentration	
Element (atomic number)	Radionuclide	GBq/m^3	µCi/ml	GBq/m^3	µCi/ml
Germanium (32)	Ge-71			$7.4x10^{-1}$	$2x10^{-2}$
Gold (79)	Au-196			$7.4x10^{-2}$	$2x10^{-3}$
	Au-198			$1.9x10^{-2}$	$5x10^{-4}$
	Au-199			$7.4x10^{-2}$	$2x10^{-3}$
Hafnium (72)	Hf-181			$2.6x10^{-2}$	$7x10^{-4}$
Hydrogen (1)	H-3	$1.9x10^{-4}$	$5x10^{-6}$	$1.1x10^{+0}$	$3x10^{-2}$
Indium (49)	In-113m			$3.7x10^{-1}$	$1x10^{-2}$
	In-114m			$7.4x10^{-3}$	$2x10^{-4}$
Iodine (53)	I-126	$1.1x10^{-7}$	$3x10^{-9}$	$7.4x10^{-4}$	$2x10^{-5}$
	I-131	$1.1x10^{-7}$	$3x10^{-9}$	$7.4x10^{-4}$	$2x10^{-5}$
	I-132	$3.0x10^{-6}$	$8x10^{-8}$	$2.2x10^{-2}$	$6x10^{-4}$
	I-133	$3.7x10^{-7}$	$1x10^{-8}$	$2.6x10^{-3}$	$7x10^{-5}$
	I-134	$7.4x10^{-6}$	$2x10^{-7}$	$3.7x10^{-2}$	$1x10^{-3}$
Iridium (77)	Ir-190			$7.4x10^{-2}$	$2x10^{-3}$
	Ir-192			$1.5x10^{-2}$	$4x10^{-4}$
	Ir-194			$1.1x10^{-2}$	$3x10^{-4}$
Iron (26)	Fe-55			$3.0x10^{-1}$	$8x10^{-3}$
	Fe-59			$2.2x10^{-2}$	$6x10^{-4}$
Krypton (36)	Kr-85m	$3.7x10^{-5}$	$1x10^{-6}$		
	Kr-85	$1.1x10^{-4}$	$3x10^{-6}$		
Lanthanum (57)	La-140			$7.4x10^{-3}$	$2x10^{-4}$
Lead (82)	Pb-203			$1.5x10^{-1}$	$4x10^{-3}$
Lutetium (71)	Lu-177			$3.7x10^{-2}$	$1x10^{-3}$
Manganese (25)	Mn-52			$1.1x10^{-2}$	$3x10^{-4}$
	Mn-54			$3.7x10^{-2}$	$1x10^{-3}$
	Mn-56			$3.7x10^{-2}$	$1x10^{-3}$
Mercury (80)	Hg-197m			$7.4x10^{-2}$	$2x10^{-3}$
	Hg-197			$1.1x10^{-1}$	$3x10^{-3}$
	Hg-203			$7.4x10^{-3}$	$2x10^{-4}$
Molybdenum (42)	Mo-99			$2.2x10^{-2}$	$2x10^{-3}$
Neodymium (60)	Nd-147			$2.2x10^{-2}$	$6x10^{-4}$
	Nd-149			$1.1x10^{-1}$	$3x10^{-3}$
Nickel (28)	Ni-65			$3.7x10^{-2}$	$1x10^{-3}$
Niobium (Columbium) (41)	Nb-95			$3.7x10^{-2}$	$1x10^{-3}$
	Nb-97			$3.3x10^{-1}$	$9x10^{-3}$
Osmium (76)	Os-185			$2.6x10^{-2}$	$7x10^{-4}$
	Os-191m			$1.1x10^{+0}$	$3x10^{-2}$
	Os-191			$7.4x10^{-2}$	$2x10^{-3}$
	Os-193			$2.2x10^{-2}$	$6x10^{-4}$
Palladium (46)	Pd-103			$1.1x10^{-1}$	$3x10^{-3}$
	Pd-109			$3.3x10^{-2}$	$9x10^{-4}$
Phosphorus (15)	P-32			$7.4x10^{-3}$	$2x10^{-4}$
Platinum (78)	Pt-191			$3.7x10^{-2}$	$1x10^{-3}$
	Pt-193m			$3.7x10^{-1}$	$1x10^{-2}$
	Pt-197m			$3.7x10^{-1}$	$1x10^{-2}$
Platinum (78)	Pt-197			$3.7x10^{-2}$	$1x10^{-3}$
Potassium (19)	K-42			$1.1x10^{-1}$	$3x10^{-3}$
Praseodymium (59)	Pr-142			$1.1x10^{-2}$	$3x10^{-4}$
	Pr-143			$1.9x10^{-2}$	$5x10^{-4}$
Promethium (61)	Pm-147			$7.4x10^{-2}$	$2x10^{-3}$

Element (atomic number)	Radionuclide	Column I Gas concentration GBq/m^3	Column I Gas concentration µCi/ml	Column II Liquid and solid concentration GBq/m^3	Column II Liquid and solid concentration µCi/ml
	Pm-149			$1.5x10^{-2}$	$4x10^{-4}$
Rhenium (75)	Re-183			$2.2x10^{-1}$	$6x10^{-3}$
	Re-186			$3.3x10^{-2}$	$9x10^{-4}$
	Re-188			$2.2x10^{-2}$	$6x10^{-4}$
Rhodium (45)	Rh-103m			$3.7x10^{+0}$	$1x10^{-1}$
	Rh-105			$3.7x10^{-2}$	$1x10^{-3}$
Rubidium (37)	Rb-86			$2.6x10^{-2}$	$7x10^{-4}$
Ruthenium (44)	Ru-97			$1.5x10^{-1}$	$4x10^{-3}$
	Ru-103			$3.0x10^{-2}$	$8x10^{-4}$
	Ru-105			$3.7x10^{-2}$	$1x10^{-3}$
	Ru-106			$3.7x10^{-3}$	$1x10^{-4}$
Samarium (62)	Sm-153			$3.0x10^{-2}$	$8x10^{-4}$
Scandium (21)	Sc-46			$1.5x10^{-2}$	$4x10^{-4}$
	Sc-47			$3.3x10^{-2}$	$9x10^{-4}$
	Sc-48			$1.1x10^{-2}$	$3x10^{-4}$
Selenium (34)	Se-75			$1.1x10^{-1}$	$3x10^{-3}$
Silicon (14)	Si-31			$3.3x10^{-1}$	$9x10^{-3}$
Silver (47)	Ag-105			$3.7x10^{-2}$	$1x10^{-3}$
	Ag-110m			$1.1x10^{-2}$	$3x10^{-4}$
	Ag-111			$1.5x10^{-2}$	$4x10^{-4}$
Sodium (11)	Na-24			$7.4x10^{-2}$	$2x10^{-3}$
Strontium (38)	Sr-85			$3.7x10^{-2}$	$1x10^{-3}$
	Sr-89			$3.7x10^{-3}$	$1x10^{-4}$
	Sr-91			$2.6x10^{-2}$	$7x10^{-4}$
	Sr-92			$2.6x10^{-2}$	$7x10^{-4}$
Sulfur (16)	S-35	$3.3x10^{-6}$	$9x10^{-8}$	$2.2x10^{-2}$	$6x10^{-4}$
Tantalum (73)	Ta-182			$1.5x10^{-2}$	$4x10^{-4}$
Technetium (43)	Tc-96m			$3.7x10^{+0}$	$1x10^{-1}$
	Tc-96			$3.7x10^{-2}$	$1x10^{-3}$
Tellurium (52)	Te-125m			$7.4x10^{-2}$	$2x10^{-3}$
	Te-127m			$2.2x10^{-2}$	$6x10^{-4}$
	Te-127			$1.1x10^{-1}$	$3x10^{-3}$
	Te-129m			$1.1x10^{-2}$	$3x10^{-4}$
	Te-131m			$2.2x10^{-2}$	$6x10^{-4}$
	Te-132			$1.1x10^{-2}$	$3x10^{-4}$
Terbium (65)	Tb-160			$1.5x10^{-2}$	$4x10^{-4}$
Thallium (81)	Tl-200			$1.5x10^{-1}$	$4x10^{-3}$
	Tl-201			$1.1x10^{-1}$	$3x10^{-3}$
	Tl-202			$3.7x10^{-2}$	$1x10^{-3}$
	Tl-204			$3.7x10^{-2}$	$1x10^{-3}$
Thulium (69)	Tm-170			$1.9x10^{-2}$	$5x10^{-4}$
	Tm-171			$1.9x10^{-1}$	$5x10^{-3}$
Tin (50)	Sn-113			$3.3x10^{-2}$	$9x10^{-4}$
	Sn-125			$7.4x10^{-3}$	$2x10^{-4}$
Tungsten (Wolfram) (74)	W-181			$1.5x10^{-1}$	$4x10^{-3}$
	W-187			$2.6x10^{-2}$	$7x10^{-4}$
Vanadium (23)	V-48			$1.1x10^{-2}$	$3x10^{-4}$
Xenon (54)	Xe-131m	$1.5x10^{-4}$	$4x10^{-6}$		
	Xe-133	$1.1x10^{-4}$	$3x10^{-6}$		
	Xe-135	$3.7x10^{-5}$	$1x10^{-6}$		
Ytterbium (70)	Yb-175			$3.7x10^{-2}$	$1x10^{-3}$

Column I		Column II			
		Gas concentration		Liquid and solid concentration	
Element (atomic number)	Radionuclide	GBq/m^3	µCi/ml	GBq/m^3	µCi/ml
Yttrium (39)	Y-90			$7.4x10^{-3}$	$2x10^{-4}$
	Y-91m			$1.1x10^{+0}$	$3x10^{-2}$
	Y-91			$1.1x10^{-2}$	$3x10^{-4}$
	Y-92			$2.2x10^{-2}$	$6x10^{-4}$
	Y-93			$1.1x10^{-2}$	$3x10^{-4}$
Zinc (30)	Zn-65			$3.7x10^{-2}$	$1x10^{-3}$
	Zn-69m			$2.6x10^{-2}$	$7x10^{-4}$
	Zn-69			$7.4x10^{-1}$	$2x10^{-2}$
Zirconium (40)	Zr-95			$2.2x10^{-2}$	$6x10^{-4}$
	Zr-97			$7.4x10^{-3}$	$2x10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life of less than 3 years.		$3.7x10^{-9}$	$1x10^{-1}0$	$3.7x10^{-5}$	$1x10^{-6}$

Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

Note 2: For purposes of C.4 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1".

Example: $\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} + \frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} < 1$

Part C

APPENDIX B

EXEMPT QUANTITIES OF RADIONUCLIDES

Radionuclide		Exmpt Quantity	
		kBq	µCi
Antimony-122	Sb 122	3,700	100
Antimony-124	Sb 124	370	10
Antimony-125	Sb 125	370	10
Arsenic-73	As 73	3,700	100
Arsenic-74	As 74	370	10
Arsenic-76	As 76	370	10
Arsenic-77	As 77	3,700	100
Barium-131	Ba 131	370	10
Barium-133	Ba 133	370	10
Barium-140	Ba 140	370	10
Bismuth-210	Bi 210	37	1
Bromine-82	Br 82	370	10
Cadmium-109	Cd 109	370	10
Cadmium-115m	Cd 115m	370	10
Cadmium-115	Cd 115	3,700	100
Calcium-45	Ca 45	370	10
Calcium-47	Ca 47	370	10
Carbon-14	C 14	3,700	100
Cerium-141	Ce 141	3,700	100
Cerium-143	Ce 143	3,700	100
Cerium-144	Ce 144	37	1
Cesium-129	Cs 129	3,700	100
Cesium-131	Cs 131	37,000	1,000
Cesium-134m	Cs 134m	3,700	100
Cesium-134	Cs 134	37	1
Cesium-135	Cs 135	370	10
Cesium-136	Cs 136	370	10
Cesium-137	Cs 137	370	10
Chlorine-36	Cl 36	370	10
Chlorine-38	Cl 38	370	10
Chromium-51	Cr 51	37,000	1,000
Cobalt-57	Co 57	3,700	100
Cobalt-58m	Co 58m	370	10
Cobalt-58	Co 58	370	10
Cobalt-60	Co 60	37	1
Copper-64	Cu 64	3,700	100
Dysprosium-165	Dy 165	370	10
Dysprosium-166	Dy 166	3,700	100
Erbium-169	Er 169	3,700	100
Erbium-171	Er 171	3,700	100
Europium-152	Eu 152 9.2h	3,700	100
Europium-152	Eu 152 13 yr	37	1
Europium-154	Eu 154	37	1
Europium-155	Eu 155	370	10
Fluorine-18	F 18	37,000	1,000
Gadolinium-153	Gd 153	370	10

Radionuclide		Exempt Quantity	
		kBq	µCi
Gadolinium-159	Gd 159	3,700	100
Gallium-67	Ga 67	3,700	100
Gallium-72	Ga 72	370	10
Germanium-68	Ge 68	370	10
Germanium-71	Ge 71	3,700	100
Gold-195	Au 195	370	10
Gold-198	Au 198	3,700	100
Gold-199	Au 199	3,700	100
Hafnium-181	Hf 181	370	10
Holmium-166	Ho 166	3,700	100
Hydrogen-3	H 3	37,000	1,000
Indium-111	In 111	3,700	100
Indium-113m	In 113m	3,700	100
Indium-114m	In 114m	370	10
Indium-115m	In 115m	3,700	100
Indium-115	In 115	370	10
Iodine-123	I 123	3,700	100
Iodine-125	I 125	37	1
Iodine-126	I 126	37	1
Iodine-129	I 129	3.7	0.1
Iodine-131	I 131	37	1
Iodine-132	I 132	370	10
Iodine-133	I 133	37	1
Iodine-134	I 134	370	10
Iodine-135	I 135	370	10
Iridium-192	Ir 192	370	10
Iridium-194	Ir 194	3,700	100
Iron-52	Fe 52	370	10
Iron-55	Fe 55	3,700	100
Iron-59	Fe 59	370	10
Krypton-85	Kr 85	3,700	100
Krypton-87	Kr 87	370	10
Lanthanum-140	La 140	370	10
Lutetium-177	Lu 177	3,700	100
Manganese-52	Mn 52	37	10
Manganese-54	Mn 54	370	10
Manganese-56	Mn 56	370	10
Mercury-197m	Hg 197m	3,700	100
Mercury-197	Hg 197	3,700	100
Mercury-203	Hg 203	370	10
Molybdenum-99	Mo 99	3,700	100
Neodymium-147	Nd 147	3,700	100
Neodymium-149	Nd 149	3,700	100
Nickel-59	Ni 59	3,700	100
Nickel-63	Ni 63	370	10
Nickel-65	Ni 65	3,700	100
Niobium-93m	Nb 93m	370	10
Niobium-95	Nb 95	370	10
Niobium-97	Nb 97	370	10
Osmium-185	Os 185	370	10
Osmium-191m	Os 191m	3,700	100
Osmium-191	Os 191	3,700	100
Osmium-193	Os 193	3,700	100
Palladium-103	Pd 103	3,700	100

Radionuclide		Exempt Quantity	
		kBq	µCi
Palladium-109	Pd 109	3,700	100
Phosphorus-32	P 32	370	10
Platinum-191	Pt 191	3,700	100
Platinum-193m	Pt 193m	3,700	100
Platinum-193	Pt 193	3,700	100
Platinum-197m	Pt 197m	3,700	100
Platinum-197	Pt 197	3,700	100
Polonium-210	Po 210	3.7	0.1
Potassium-42	K 42	370	10
Potassium-43	K 43	370	10
Praseodymium-142	Pr 142	3,700	100
Praseodymium-143	Pr 143	3,700	100
Promethium-147	Pm 147	370	10
Promethium-149	Pm 149	370	10
Rhenium-186	Re 186	3,700	100
Rhenium-188	Re 188	3,700	100
Rhodium-103m	Rh 103m	3,700	100
Rhodium-105	Rh 105	3,700	100
Rubidium-81	Rb 81	370	10
Rubidium-86	Rb 86	370	10
Rubidium-87	Rb 87	370	10
Ruthenium-97	Ru 97	3,700	100
Ruthenium-103	Ru 103	370	10
Ruthenium-105	Ru 105	370	10
Ruthenium-106	Ru 106	37	1
Samarium-151	Sm 151	370	10
Samarium-153	Sm 153	3,700	100
Scandium-46	Sc 46	370	10
Scandium-47	Sc 47	3,700	100
Scandium-48	Sc 48	370	10
Selenium-75	Se 75	370	10
Silicon-31	Si 31	3,700	100
Silver-105	Ag 105	370	10
Silver-110m	Ag 110m	37	1
Silver-111	Ag 111	3,700	100
Sodium-22	Na 22	370	10
Sodium-24	Na 24	370	10
Strontium-85	Sr 85	370	10
Strontium-89	Sr 89	37	1
Strontium-90	Sr 90	3.7	0.1
Strontium-91	Sr 91	370	10
Strontium-92	Sr 92	370	10
Sulphur-35	S 35	3,700	100
Tantalum-182	Ta 182	370	10
Technetium-96	Tc 96	370	10
Technetium-97m	Tc 97m	3,700	100
Technetium-97	Tc 97	3,700	100
Technetium-99m	Tc 99m	3,700	100
Technetium-99	Tc 99	370	10
Tellurium-125m	Te 125m	370	10
Tellurium-127m	Te 127m	370	10
Tellurium-127	Te 127	3,700	100
Tellurium-129m	Te 129m	370	10
Tellurium-129	Te 129	3,700	100

Radionuclide		Exempt Quantity	
		kBq	µCi
Tellurium-131m	Te 131m	370	10
Tellurium-132	Te 132	370	10
Terbium-160	Tb 160	370	10
Thallium-200	Tl 200	3,700	100
Thallium-201	Tl 201	3,700	100
Thallium-202	Tl 202	3,700	100
Thallium-204	Tl 204	370	10
Thulium-170	Tm 170	370	10
Thulium-171	Tm 171	370	10
Tin-113	Sn 113	370	10
Tin-125	Sn 125	370	10
Tungsten-181	W 181	370	10
Tungsten-185	W 185	370	10
Tungsten-187	W 187	3,700	100
Vanadium-48	V 48	370	10
Xenon-131m	Xe 131m	37,000	1,000
Xenon-133	Xe 133	3,700	100
Xenon-135	Xe 135	3,700	100
Ytterbium-175	Yb 175	3,700	100
Yttrium-87	Y 87	370	10
Yttrium-88	Y 88	370	10
Yttrium-90	Y 90	370	10
Yttrium-91	Y 91	370	10
Yttrium-92	Y 92	3,700	100
Yttrium-93	Y 93	3,700	100
Zinc-65	Zn 65	370	10
Zinc-69m	Zn 69m	3,700	100
Zinc-69	Zn 69	37,000	1,000
Zirconium-93	Zr 93	370	10
Zirconium-95	Zr 95	370	10
Zirconium-97	Zr 97	370	10
Any radioactive material not listed above other than alpha-emitting radioactive material		3.7	0.1

Part C

APPENDIX C

Reserved

Part C

APPENDIX D

LIMITS FOR BROAD LICENSES (C.27)

Radionuclide	Column I		Column II	
	GBq	Ci	GBq	Ci
Antimony-122	37	1	0.37	0.01
Antimony-124	37	1	0.37	0.01
Antimony-125	37	1	0.37	0.01
Arsenic-73	370	10	3.7	0.1
Arsenic-74	37	1	0.37	0.01
Arsenic-76	37	1	0.37	0.01
Arsenic-77	370	10	3.7	0.1
Barium-131	370	10	3.7	0.1
Barium-140	37	1	0.37	0.01
Beryllium-7	370	10	3.7	0.1
Bismuth-210	3.7	0.1	0.037	0.001
Bromine-82	370	10	3.7	0.1
Cadmium-109	37	1	0.37	0.01
Cadmium-115m	37	1	0.37	0.01
Cadmium-115	370	10	3.7	0.1
Calcium-45	37	1	0.37	0.01
Calcium-47	370	10	3.7	0.1
Carbon-14	3,700	100	37.	1.
Cerium-141	370	10	3.7	0.1
Cerium-143	370	10	3.7	0.1
Cerium-144	3.7	0.1	0.037	0.001
Cesium-131	3,700	100	37.	1.
Cesium-134m	3,700	100	37.	1.
Cesium-134	3.7	0.1	0.037	0.001
Cesium-135	37	1	0.37	0.01
Cesium-136	370	10	3.7	0.1
Cesium-137	3.7	0.1	0.037	0.001
Chlorine-36	37	1	0.37	0.01
Chlorine-38	3,700	100	37.	1.
Chromium-51	3,700	100	37.	1.
Cobalt-57	370	10	3.7	0.1
Cobalt-58m	3,700	100	37.	1.
Cobalt-58	37	1	0.37	0.01
Cobalt-60	3.7	0.1	0.037	0.001
Copper-64	370	10	3.7	0.1
Dysprosium-165	3,700	100	37.	1.
Dysprosium-166	370	10	3.7	0.1

Radionuclide	Column I		Column II	
	GBq	Ci	GBq	Ci
Erbium-169	370	10	3.7	0.1
Erbium-171	370	10	3.7	0.1
Europium-152 (9.2 h)	370	10	3.7	0.1
Europium-152 (13 y)	3.7	0.1	0.037	0.001
Europium-154	3.7	0.1	0.037	0.001
Europium-155	37	1	0.37	0.01
Fluorine-18	3,700	100	37.	1.
Gadolinium-153	37	1	0.37	0.01
Gadolinium-159	370	10	3.7	0.1
Gallium-72	370	10	3.7	0.1
Germanium-71	3,700	100	37.	1.
Gold-198	370	10	3.7	0.1
Gold-199	370	10	3.7	0.1
Hafnium-181	37	1	0.37	0.01
Holmium-166	370	10	3.7	0.1
Hydrogen-3	3,700	100	37.	1.
Indium-113m	3,700	100	37.	1.
Indium-114m	37	1	0.37	0.01
Indium-115m	3,700	100	37.	1.
Indium-115	37	1	0.37	0.01
Iodine-125	3.7	0.1	0.037	0.001
Iodine-126	3.7	0.1	0.037	0.001
Iodine-129	3.7	0.1	0.037	0.001
Iodine-131	37.	1	0.37	0.01
Iodine-132	370	10	3.7	0.1
Iodine-133	37	1	0.37	0.01
Iodine-134	370	10	3.7	0.1
Iodine-135	37	1	0.37	0.01
Iridium-192	37	1	0.37	0.01
Iridium-194	370	10	3.7	0.1
Iron-55	370	10	3.7	0.1
Iron-59	37	1	0.37	0.01
Krypton-85	3,700	100	37.	1.
Krypton-87	370	10	3.7	0.1
Lanthanum-140	37	1	0.37	0.01
Lutetium-177	370	10	3.7	0.1
Manganese-52	37	1	0.37	0.01
Manganese-54	37	1	0.37	0.01
Manganese-56	370	10	3.7	0.1
Mercury-197m	370	10	3.7	0.1
Mercury-197	370	10	3.7	0.1
Mercury-203	37	1	0.37	0.01
Molybdenum-99	370	10	3.7	0.1
Neodymium-147	370	10	3.7	0.1
Neodymium-149	370	10	3.7	0.1

Radionuclide	Column I		Column II	
	GBq	Ci	GBq	Ci
Nickel-59	370	10	3.7	0.1
Nickel-63	37	1	0.37	0.01
Nickel-65	370	10	3.7	0.1
Niobium-93m	37	1	0.37	0.01
Niobium-95	37	1	0.37	0.01
Niobium-97	3,700	100	37.	1.
Osmium-185	37	1	0.37	0.01
Osmium-191m	3,700	100	37.	1.
Osmium-191	370	10	3.7	0.1
Osmium-193	370	10	3.7	0.1
Palladium-103	370	10	3.7	0.1
Palladium-109	370	10	3.7	0.1
Phosphorus-32	37	1	0.37	0.01
Platinum-191	370	10	3.7	0.1
Platinum-193m	3,700	100	37.	1.
Platinum-193	370	10	3.7	0.1
Platinum-197m	3,700	100	37.	1.
Platinum-197	370	10	3.7	0.1
Polonium-210	0.4	0.01	0.0037	0.0001
Potassium-42	37	1	0.37	0.01
Praseodymium-142	370	10	3.7	0.1
Praseodymium-143	370	10	3.7	0.1
Promethium-147	37	1	0.37	0.01
Promethium-149	370	10	3.7	0.1
Radium-226	0.4	0.01	0.0037	0.0001
Rhenium-186	370	10	3.7	0.1
Rhenium-188	370	10	3.7	0.1
Rhodium-103m	37,000	1,000	370.	10.
Rhodium-105	370	10	3.7	0.1
Rubidium-86	37	1	0.37	0.01
Rubidium-87	37	1	0.37	0.01
Ruthenium-97	3,700	100	37.	1.
Ruthenium-103	37	1	0.37	0.01
Ruthenium-105	370	10	3.7	0.1
Ruthenium-106	3.7	0.1	0.037	0.001
Samarium-151	37	1	0.37	0.01
Samarium-153	370	10	3.7	0.1
Scandium-46	37	1	0.37	0.01
Scandium-47	370	10	3.7	0.1
Scandium-48	37	1	0.37	0.01
Selenium-75	37	1	0.37	0.01
Silicon-31	370	10	3.7	0.1
Silver-105	37	1	0.37	0.01
Silver-110m	3.7	0.1	0.037	0.001
Silver-111	370	10	3.7	0.1

Radionuclide	Column I		Column II	
	GBq	Ci	GBq	Ci
Sodium-22	3.7	0.1	0.037	0.001
Sodium-24	37	1	0.37	0.01
Strontium-85m	37,000	1,000	370.	10.
Strontium-85	37	1	0.37	0.01
Strontium-89	37	1	0.37	0.01
Strontium-90	0.4	0.01	0.0037	0.0001
Strontium-91	370	10	3.7	0.1
Strontium-92	370	10	3.7	0.1
Sulphur-35	370	10	3.7	0.1
Tantalum-182	37	1	0.37	0.01
Technetium-96	370	10	3.7	0.1
Technetium-97m	370	10	3.7	0.1
Technetium-97	370	10	3.7	0.1
Technetium-99m	3,700	100	37.	1.
Technetium-99	37	1	0.37	0.01
Tellurium-125m	37	1	0.37	0.01
Tellurium-127m	37	1	0.37	0.01
Tellurium-127	370	10	3.7	0.1
Tellurium-129m	37	1	0.37	0.01
Tellurium-129	3,700	100	37.	1.
Tellurium-131m	370	10	3.7	0.1
Tellurium-132	37	1	0.37	0.01
Terbium-160	37	1	0.37	0.01
Thallium-200	370	10	3.7	0.1
Thallium-201	370	10	3.7	0.1
Thallium-202	370	10	3.7	0.1
Thallium-204	37	1	0.37	0.01
Thulium-170	37	1	0.37	0.01
Thulium-171	37	1	0.37	0.01
Tin-113	37	1	0.37	0.01
Tin-125	37	1	0.37	0.01
Tungsten-181	37	1	0.37	0.01
Tungsten-185	37	1	0.37	0.01
Tungsten-187	370	10	3.7	0.1
Vanadium-48	37	1	0.37	0.01
Xenon-131m	37,000	1,000	370.	10.
Xenon-133	3,700	100	37.	1.
Xenon-135	3,700	100	37.	1.
Ytterbium-175	370	10	3.7	0.1
Yttrium-90	37	1	0.37	0.01
Yttrium-91	37	1	0.37	0.01
Yttrium-92	370	10	3.7	0.1
Yttrium-93	37	1	0.37	0.01
Zinc-65	37	1	0.37	0.01
Zinc-69m	370	10	3.7	0.1

Radionuclide	Column I		Column II	
	GBq	Ci	GBq	Ci
Zinc-69	3,700	100	37.	1.
Zirconium-93	37	1	0.37	0.01
Zirconium-95	37	1	0.37	0.01
Zirconium-97	37	1	0.37	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	3.7	0.1	0.037	0.001