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, V 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 the requirements for a license set forth in the [State] Radiation Control Act and from Part C, Part D and Part J of these regulations 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 thorium, 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 manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material,

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

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

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

(3) 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 or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 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 mirrors or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror, or

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

[1/] *The requirements specified in Subdivisions C.3c.v.(1) and (2) need not be met by counterweights manufactured prior to December 31, 1969; provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by 10 CFR 40.13(c)(5)(ii) in effect on June 30, 1969 .*

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

ix. No person may initially transfer for sale or distribution a product containing source material to persons exempt under this paragraph c., or equivalent regulations of an Agreement State, unless authorized by a license issued under 10 CFR 40.52 by the United States Nuclear Regulatory Commission to initially transfer such products for sale or distribution. Persons authorized to manufacture, process, or produce these materials or products containing source material by the Agency, an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 by the United States Nuclear Regulatory Commission for distribution only and are exempt from the requirements of Part D, and C.25a. and C.25b. of these regulations.

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/]

[*/] *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.*

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

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

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

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

(iv) 3.7 MBq (100 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) (i) Static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device.

(ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(iii) Such devices authorized before October 23, 2012 for use under the general license then provided in regulations of the Agency and equivalent regulations of Agreement States or the United States Nuclear Regulatory Commission and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Agency.

(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/]

[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*

(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 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) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, 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 and for a certificate of registration in accordance with 10 CFR 32.210.

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 requirements for a license set forth in Parts A, C, D, E, G, J, O, Q and W of 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 health, safety or property and 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 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 radioactive 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 and for a certificate of registration in accordance with 10 CFR 32.210.

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

[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.*

(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. Certain Industrial Devices.

(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in the Act and these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30; or an Agreement State pursuant to C.28 which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(2) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

vi. 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 receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

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

   ii. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of C.21a.i.; or

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

   iv. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material

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

being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

b. 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, and transfer is within the terms of such general license, except that such person shall comply with the provisions of D.2001 and O.9. to the extent necessary to meet the provisions of C.21c.ii.(4) and C.21f. However, this exemption does not apply to any person who also holds 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.:

i. Is 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.

ii. Shall not abandon such source material. Source material may be disposed of as follows:

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

(2) In accordance with D.2001 of these regulations.

(3) Is subject to the provisions in A.4, A.5, A.6, A.8, C.25, C.31, C.40, C.50, C.95, C.96 and C.100.

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

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. <u>Depleted Uranium in Industrial Products and Devices.</u>

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

f. Any person who receives, possesses, uses, or transfers source material in accordance with C.21a. shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Agency about such contamination and may consult with the Agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in O.9 of these regulations.

g. No person may initially transfer or distribute source material to persons generally licensed under C.21a.i. or C.21a.ii., or equivalent regulations of the NRC or an Agreement State, unless authorized by a specific license issued in accordance with C.28n. or equivalent provisions of the NRC or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

Sec. C.22 - General Licenses[*/] - Radioactive Material Other Than Source Material.

a. Reserved

b. A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of this Part, a general licensee under C.22 is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

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

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.[4/]

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

[4/] *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.*

(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 on the activity indicated on the label. Each address for a location of

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

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)[5/] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor

(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;

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

(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. [6/]

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", 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

[6/] *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.*

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 manufactured prior to October 23, 2012 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.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1) or equivalent Agreement State regulations, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

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. Commencement of construction may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.]

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.

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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.

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

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. Conditions of transferring a device for use under a general license in C.22d.

(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) Quality assurance procedures to be followed that are sufficient to ensure compliance with 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) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by C.28e.i.(4)(e).

(e) The applicant shall subject at least five prototypes of the device to tests as follows:

(i) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(ii) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(3) of this section.

(iii) Device designs are rejected for which the following has been detected for any unit:
A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or
Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or
Any other evidence of physical damage.

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

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: [7/]

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.

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

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

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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:

(a) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(b) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (3) of this section and in the license issued under C.28e, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(3) The licensee shall subject each inspection lot to:

(a) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(b) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;
(ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and
(iii) Any other criteria specified in the license issued under C.28e.

(4) No person licensed under C.28e. shall transfer to persons generally licensed under C.22f. of this chapter, or under an equivalent general license of an Agreement State:

(a) Any luminous safety device tested and found defective under any condition of a license issued under C.28e., unless the defective units have been repaired or reworked, retested and determined by an independent inspector to meet the applicable acceptance criteria); or

(b) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in C.28e., unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under C.28e.; and
(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs C.28e.iii.(2)(b) and C.28e.iii.(4)(b)(i) of this section and any other criteria that may be required as a condition of the license issued under C.28e.

iv. Material transfer reports.

(1) 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. If no transfers have been made to persons generally licensed under C.22f. during the reporting period, the report must so indicate.

(2) Each person licensed under C.28e. shall report annually all transfers of devices to persons for use under a general license in the NRC or an Agreement State's regulations that are equivalent to C.22f. to the NRC or the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, 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. If no transfers have been made during the reporting period, this information must be reported to the NRC or the responsible Agreement State agency upon request of the agency.

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 appropriate tests required by C.28f.ii.

ii. An applicant for a license pursuant to C.28f. shallsubject at least five prototypes of such source that is designed to contain more than 185 Bq (0.005 μCi) of americium-241 or radium-226, to tests as follows:

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

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in C.28f.ii.(4).

(4) Source designs are rejected for which the following has been detected for

any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

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:[8/]

> 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 or radium 226 prior to transferring the source to a general licensee under C.22h. or equivalent regulations of the NRC or an Agreement State. 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 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 or radium-226 and shall not be transferred to a general licensee under C.22h. or equivalent regulations of the NRC or 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:

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

(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 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) Prototypes of the device have been subjected to and have satisfactorily passed the 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:

(a) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(b) Subject inspection lots to acceptance sampling procedures, by procedures specified in C.28i.ii.(4) and in the license issued under C.28i., to provide at least 95 percent confidence that the Lot Tolerance Percent

Defective of 5.0 percent will not be exceeded.

(4) Each person licensed under C.28i shall subject each inspection lot to:

(a) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(b) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under C.28i.

(5) No person licensed under C.28i.ii. shall transfer to persons generally licensed under C.22j. or under an equivalent general license of the NRC or an Agreement State:

(a) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under C.28i. unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(b) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in C.28i.ii.(3)(b), unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under C.28i.; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with C.28i.ii.(3)(b) and C.28i.ii.(5)(b)(i) and any other criteria as may be required as a condition of the license issued under C.28i.

iii. An applicant for a license pursuant to C.28i. shall subject at least five prototype ice detection devices to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of strontium-

90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in C28.i.iii.(3).

(3) Device designs are rejected for which the following has been detected for any unit:

(a) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or
(b) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or
(c) Any other evidence of physical damage.

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

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

vii. The source or device has been registered in the Sealed Source and Device Registry.

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. Registration of Product Information

i. Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

ii. The request for review must be sent to the Agency at (insert Agency address).

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

iv. The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. C.28 includes specific criteria that apply to certain exempt products and includes specific criteria applicable to certain generally licensed devices. C.28 also includes specific provisions that apply to certain specifically licensed items.

v. After completion of the evaluation, the Agency issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

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

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

(2) The provisions of the registration certificate.

vii. Authority to manufacture or initially distribute a sealed source or device to specific

licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(1) Calibration and reference sources containing no more than:

(i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

(ii) 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

(2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) The intended recipients are licensed under C.27 or comparable provisions of the NRC or an Agreement State; or

(ii) The recipients are authorized for research and development; or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

viii. After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in this section. The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

n. An application for a specific license to initially transfer source material for use under C.21, or equivalent regulations of the NRC or an Agreement State, will be approved if:

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

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

o. i. Each person licensed under C.28n. shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

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

iii. Each person licensed under C.28n. shall provide the information specified in this paragraph to each person to whom source material is transferred for use under C.21, or equivalent provisions in NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(1) A copy of C.21 and C.40, or relevant equivalent regulations of the NRC or an Agreement State.

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

iv. Each person licensed under C.28n. shall report transfers as follows:

(1) File a report with the Agency which shall include the following information:

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

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

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

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

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

(b) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent;

and the type, physical form, and quantity of source material transferred.

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

(3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under C.21 or equivalent NRC or Agreement State provisions during the current period, a report shall be submitted to the Agency indicating so. If no transfers have been made to NRC or Agreement State general licensees during the reporting period, this information shall be reported to the NRC and responsible Agreement State agency upon request of the agency.

v. Each person licensed under C.28n. shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Agency or to the NRC or an Agreement State agency.

Sec. C.29 - Inactivation of Certificates of Registration of Sealed Sources and Devices.

a. A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

b. If a distribution license is to be terminated in accordance with C.32, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

c. A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

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. i. 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.

ii. An application for transfer of license must include:

(1) The identity, technical and financial qualifications of the proposed transferee; and

(2) Financial assurance for decommissioning information required by Part S.

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(15)) controlling the licensee or listing the license or licensee as property of the estate; or

iii. An affiliate (as that term is defined in 11 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.

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.

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

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. <u>Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.</u>

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. Recognition of Agreement State Licenses.

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 until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

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.

iv. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out), to make the records that are required by this part account for 100 percent of the material received.

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

[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.*

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.96 - Reports.

a. Immediate report. Each licensee shall notify the Agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

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

i. An unplanned contamination event that:

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

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

(3) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four hours to decay prior to decontamination.

ii. An event in which equipment is disabled or fails to function as designed when:

(1) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(2) The equipment is required to be available and operable when it is disabled or fails to function; and

(3) No redundant equipment is available and operable to perform the required safety function.

iii. An event that requires unplanned medical treatment at a medical facility of an individual with

spreadable radioactive contamination on the individual's clothing or body.

iv. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part D of these regulations for the material; and

(2) The damage affects the integrity of the licensed material or its container.

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

i. Licensees shall make reports required by paragraphs C.96a. and C.96b. by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(1) The caller's name and call back telephone number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

ii. Written report. Each licensee who makes a report required by paragraph C.96a. and C.96b. shall submit a written follow-up report within thirty days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Agency by an appropriate method listed in Section A.12 of these regulations. The reports must include the following:

(1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of the event;

(5) Corrective actions taken or planned and the results of any evaluations or assessments; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

[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 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			$1.1x10^{-2}$	$3x10^{-4}$
	Sb-124			$7.4x10^{-3}$	$2x10^{-4}$
	Sb-125			$3.7x10^{-2}$	$1x10^{-3}$
Argon (18)	Ar-37	$3.7x10^{-2}$	$1x10^{-3}$		
	Ar-41	$1.5x10^{-5}$	$4x10^{-7}$		
Arsenic (33)	As-73			$1.9x10^{-1}$	$5x10^{-3}$
	As-74			$1.9x10^{-2}$	$5x10^{-4}$
	As-76			$7.4x10^{-3}$	$2x10^{-4}$
	As-77			$3.0x10^{-2}$	$8x10^{-4}$
Barium (56)	Ba-131			$7.4x10^{-2}$	$2x10^{-3}$
	Ba-140			$1.1x10^{-2}$	$3x10^{-4}$
Beryllium (4)	Be-7			$7.4x10^{-1}$	$2x10^{-2}$
Bismuth (83)	Bi-206			$1.5x10^{-2}$	$4x10^{-4}$
Bromine (35)	Br-82	$1.5x10^{-5}$	$4x10^{-7}$	$1.1x10^{-1}$	$3x10^{-3}$
Cadmium (48)	Cd-109			$7.4x10^{-2}$	$2x10^{-3}$
	Cd-115m			$1.1x10^{-2}$	$3x10^{-4}$
	Cd-115			$1.1x10^{-2}$	$3x10^{-4}$
Calcium (20)	Ca-45			$3.3x10^{-3}$	$9x10^{-5}$
	Ca-47			$1.9x10^{-2}$	$5x10^{-4}$
Carbon (6)	C-14	$3.7x10^{-5}$	$1x10^{-6}$	$3.0x10^{-1}$	$8x10^{-3}$
Cerium (58)	Ce-141			$3.3x10^{-2}$	$9x10^{-4}$
	Ce-143			$1.5x10^{-2}$	$4x10^{-4}$
	Ce-144			$3.7x10^{-3}$	$1x10^{-4}$
Cesium (55)	Cs-131			$7.4x10^{-1}$	$2x10^{-2}$
	Cs-134m			$2.2x10^{+0}$	$6x10^{-2}$
	Cs-134			$3.3x10^{-3}$	$9x10^{-5}$
Chlorine (17)	Cl-38	$3.3x10^{-5}$	$9x10^{-7}$	$1.5x10^{-1}$	$4x10^{-3}$
Chromium (24)	Cr-51			$7.4x10^{-1}$	$2x10^{-2}$
Cobalt (27)	Co-57			$1.9x10^{-1}$	$5x10^{-3}$
	Co-58			$3.7x10^{-2}$	$1x10^{-3}$
	Co-60			$1.9x10^{-2}$	$5x10^{-4}$
Copper (29)	Cu-64			$1.1x10^{-1}$	$3x10^{-3}$
Dysprosium (66)	Dy-165			$1.5x10^{-1}$	$4x10^{-3}$
	Dy-166			$1.5x10^{-2}$	$4x10^{-4}$
Erbium (68)	Er-169			$3.3x10^{-2}$	$9x10^{-4}$
	Er-171			$3.7x10^{-2}$	$1x10^{-3}$
Europium (63)	Eu-152(9.2 h)			$2.2x10^{-2}$	$6x10^{-4}$
	Eu-155			$7.4x10^{-2}$	$2x10^{-3}$
Fluorine (9)	F-18	$7.4x10^{-5}$	$2x10^{-6}$	$3.0x10^{-1}$	$8x10^{-3}$
Gadolinium (64)	Gd-153			$7.4x10^{-2}$	$2x10^{-3}$
Gadolinium (64)	Gd-159			$3.0x10^{-2}$	$8x10^{-4}$
Gallium (31)	Ga-72			$1.5x10^{-2}$	$4x10^{-4}$

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.		$3.7x10^{-9}$	$1x10^{-10}$	$3.7x10^{-5}$	$1x10^{-6}$

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

2018
RATIONALE FOR REVISIONS

PART C
LICENSING OF RADIOACTIVE MATERIAL

Introduction

The proposed revisions to Part C were made to make Part C compatible with federal regulations. Since Part C was last revised in 2008 a number of amendments to federal regulations have been made. A summary of these amendments can be found at https://scp.nrc.gov/rss_regamendents.html The federal regulations amendments are specified in U.S. Nuclear Regulatory Commission Regulation Amendment Tracking System Identification Numbers (RATS ID) 2011-1, 2011-2, 2012-3, 2012-4, 2013-1 and 2013-2. Other federal regulation amendment that were made since 2008 (see RATS ID 2012-1, 2012-2, 2015-1, 2015-2, 2015-3, 2015-4 and 2015-5) did not affect Part C.

Specific Provisions

C.2 - Carriers.

C.2. Reference was added to Part V to be consistent with 10 CFR 30.13 (RATS 2013-1).

C.3 - Source Material.
C.3 was changed as follows to be consistent with 10 CFR 40.13 (RATS 2013-2).

C.3c. Part D added to regulations that a person is exempt from. Spelling of thorium corrected in c.i.(6).

C.3c.ii. Manufacture before date of August 27, 2013 added to (1) and (2). Percentage by weight of source material added to (2).

C.3c.v. Paragraph (1) deleted and remaining paragraphs renumbered. Footnote revised.

C.3c.vii. Uranium added to thorium and mirror added to lens. Manufacture before date of August 27, 2013 added. Percentage by weight of source material added.

C.3c.viii. Deleted paragraph and renumbered remaining paragraphs.

C.3c.ix. Added new paragraph concerning transfer or distribution of source material to persons exempt.

C.4 - Radioactive Material Other Than Source Material.

C.4c. was changed as follows to be consistent with 10 CFR 30.15, 30.19, 30.20, 30.22 (RATS 2012-4).

C.4c.i(b). Added paragraph concerning static elimination devices and ion generating tubes.

C.4c.ii.(2) Deleted Ra-226 exemption.

C.4c.ii.(3) Renumbered to C.4.ii.(2). Added "initial transfer for sale or distribution" and added requirement for a certificate of registration.

C.4c.iii.(1) Reworded to change "life" to "health , safety" and deleted fires and airborne hazards phrase.

C.4c.iii.(3) Changed "byproduct material" to "radioactive material" and added requirement for a certificate of registration.

C.4c.v. Added new paragraph "Certain Industrial Devices".

C.21 General Licenses - Source Material.

C.21. was changed as follows to be consistent with 10 CFR 40.22 (RATS 2013-2).

C.21a. Reworded to specify isotopes and forms of source material. Added C.21.a.i, ii., iii., iv. which sets the amount of source material allowed under the general license.

C.21b. Reworded to specify the other regulations that a person must comply with under the general license.

C.21c. Reworded and added C.21.c.i., ii. To state prohibitions on the general license.

C.21f. Added paragraph concerning minimizing contamination.

C.21g. Added paragraph concerning the required license to initially transfer or distribute source material to persons generally licensed.

C.22 General Licenses - Radioactive Material Other Than Source Material.

C.22. was changed as follows to be consistent with 10 CFR 31.3 (RATS 2012-4).

C.22.a. Paragraph was removed and reserved.

Footnote 4 was removed.

C.24 Filing Application for Specific Licenses.

C.24. was changed as follows to be consistent with 10 CFR 30.32 (RATS 2012-4).

C.24g.iii. Removed "containing naturally occurring or accelerator produced radioactive material" and changed manufactured prior to date to October 23, 2012. Added new paragraphs C.24.g.iii.(3) and (4).

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

C.25e. Added to term "commencement of construction".

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

C.28. was changed as follows to be consistent with 10 CFR 32.51, 32.53, 32.55, 32.56, 32.57, 32.59, 32.61, 32.62, 32.74, 32.101, 32.102, 32.103, 32.110, 32.210 (RATS 2012-4) and 10 CFR 40.54 and 40.55 (RATS 2013-2).

C.28d.i.(6) The new language was added.

C.28e.i.(2)(e) The paragraph was reworded.

C.28e.i.(4)(d) The paragraph was reworded.

C.28e.i.(4)(e) The paragraph was added.

C.28e.i.(4)(f) The paragraph was added.

C.28e.iii.(2), (3), (4) were completely rewritten.

C.28e.iv. The section was deleted.

C.28.e.v. The section was renumbered to C.28.e.iv. Statement concerning transfer reports added to paragraph (1). New paragraph (2) added.
C.28f.i.(4) Reference to the deleted Schedule C of this Part was deleted.

C.28f.ii. Schedule C prototype tests were deleted, paragraph was reworded to be consistent with federal regulations.

C.28i.ii.(3), (4), (5) Paragraphs was reworded to be consistent with federal regulations.

C.28i.iii. Information on prototype tests deleted. Paragraph was reworded to be consistent with federal regulations.

C.28k.vii. Added to require SSD registration.

C.28m. Paragraph concerning acceptance sampling procedures and Lot Tolerance Percent Defectives were deleted.

C.28m. New paragraph concerning registration of product information added.

C.28n. New paragraph added.

C.28o. New paragraph added.

C.29 Inactivation of Certificates of Registration of Sealed Sources and Devices.

C.29 was changed as follows to be consistent with 10 CFR 32.211 (RATS 2012-4).

C.29 New paragraph added.

C.31 Specific Terms and Conditions of Licenses.

C.31 was changed as follows to be consistent with 10 CFR 30.34 and 10 CFR 40.46 (RATS 2011-1) and 10 CFR 30.34 (RATS 2012-3).

C.31b.ii. New paragraph added concerning information needed to transfer a license.

C.31e.ii. US Code reference updated.

Matters for Future Consideration

1. Part C will need to be amended to reflect changes to federal regulations outlined in RATS ID 2018-1 "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments" which take effect on January 14, 2019. The required amendments to Part C will need to be made in conjunction with amendments to Part G "Use of Radionuclides in the Healing Arts".

2. In the "Matters for Future Consideration" following the 2008 revision to Part C it was suggested that Part C be restructured to "make it more user friendly and easier to read." This revision does not reflect this needed restructuring. A restructuring of Part C would be a major and resource intensive effort that would also affect other SSR Parts.

2010
RATIONALE FOR REVISIONS

PART C
LICENSING OF RADIOACTIVE MATERIAL

Part C of the Control of Radiation Control Program Directors (CRCPD), Suggested State Regulations (SSR) was last revised in 2008. The Nuclear Regulatory Commission (NRC) performed a review of these regulations and submitted a letter on April 9, 2008 in which they outlined 12 comments.

This revision updates Part C with regards to these comments and brings Part C in line with NRC's 10 CFR corresponding regulations. This revision also brings the regulations up to date in relation to the NRC's Regulation Action Tracking System (RATS) ID numbers: 2006-1, 2006-3, 2007-1, 2007-2 and 2007-3.

We respectfully submit Part C for final review and approval by the CRCPD board.

Specific Provisions

1. Section C.1: added "manufacture, produce"
2. Section C.4.a.i: added "and iv"
3. Section C.4.a.ii: deleted "the NRC and licensing state" and added "10 CFR 32.11"
4. Section C.4.a.iv: deleted "an agreement state" and "or the Atomic Energy Commission"
5. Section C.4.b: added "through v"
6. Section C.4.b.iv: deleted "or Licensing State"
7. Section C.4.v: inserted new section
8. Section C.4.c: renumbered parts of section
9. Section C.4.c.i(1): deleted "the licensee" and added "such person"
10. Section C.4.c.i(1)(b): deleted section
11. Section C.4.c.i(1)(c): added "manufactured before December 17, 2007"
12. Section C.4.c.i(1)(d): deleted section
13. Section C.4.c.i(1)(e): added "manufactured before December 17, 2007"
14. Section C.4.c.i(1)(f): deleted section
15. Section C.4.c.i(1)(i): inserted new section
16. Section C.4.c.ii(3): inserted new section
17. Section C.4.c.iii(1): deleted "or a Licensing State", "of this chapter" and added new verbiage
18. Section C.4.c.iii(2): deleted "or a Licensing State"
19. Section C.4.c.iii(3): inserted new section
20. Section C.4.c.iv: deleted section regarding resin containing scandium-46 and renumbered
21. Section C.20: deleted "Part Q"
22. Section C.21.e.ii: added "or initially transferred"
23. Section C.21.e.iv: added "shall"
24. Section C.21.e.iv(1) through (5): deleted "shall"
25. Section C.22.b: added new section
26. Section C.22.d.ii: deleted "or Licensing State"
27. Section C.22.d.iii(3)(b): deleted "or Licensing State"

28. Section C.22.d.iii(6): deleted “byproduct”
29. Section C.22.d.iii(8): inserted new verbiage
30. Section C.22.d.iii(13): inserted “3.7 MBq (0.1 mCi) of radium-226”
31. Section C.22.g: inserted “manufacture, production, transfer, receipt”
32. Section C.22.h.ii: deleted “him” and added “the licensee”
33. Section C.22.h.iii: deleted “him” and added “the licensee”
34. Section C.22.h.iv: deleted “him” and added “the licensee”
35. Section C.22.h.v: added “shall”
36. Section C.22.h.v(1) through (5): deleted “shall”
37. Section C.22.h.v(2): deleted label information and added new label information
38. Section C.22.h.v(4): deleted “or a Licensing State”
39. Section C.22.i.iii(4): deleted “or a Licensing State”
40. Section C.22.i.iv(1): deleted “or a Licensing State”
41. Section C.22.i.iv(2): deleted verbiage
42. Section C.22.i.v: deleted “by him”
43. Section C.22.k: added section
44. Section C.24.g: added verbiage and new section
45. Section C.24.h: added section
46. Section C.27: deleted “byproduct” and added “radioactive”
47. Section C.28.a: deleted and added new verbiage
48. Section C.28.b.i: deleted “byproduct” and added “radioactive”
49. Section C.28.b.iii(4)(a): deleted “Licensing State”
50. Section C.28.b.iv: deleted “Licensing State”
51. Section C.28.d.i: deleted “Licensing State”
52. Section C.28.d.i(3)(c): deleted and added verbiage
53. Section C.28.d.iii: deleted “or a Licensing State”
54. Section C.28.e.ii: deleted verbiage
55. Section C.28.f.i: added “for distribution”
56. Section C.28.f.iii: deleted and added verbiage
57. Section C.28.g: added section
58. Section C.28.h.iv: deleted and added verbiage
59. Section C.28.j.i: deleted and added verbiage
60. Section C.28.j.ii: deleted and added verbiage
61. Section C.28.k: deleted and added verbiage
62. Section C.31: added sections h and i
63. Section C.32.a: deleted “part”
64. Section C.36: deleted and added verbiage
65. Section C.40: deleted “Licensing State”
66. Section C.95.a: deleted “byproduct”
67. Section C.95.b: deleted “commission” and added “Agreement State”

Matters for future consideration

A petition regarding the generally licensed device rule (10 CFR 31.5 and 31.6) is currently being reviewed. If this petition is approved and the regulations amended, Part C would need to be revised as well. Several comments have been received that Part C is cumbersome and not user friendly. It has also been noticed that regulations in Part C are also contained in other Parts. Once this amendment is finalized the Part C working group would like to begin another review to enhance Part C's usability and ensure that licensing regulations are not also listed in other Parts.

2008
RATIONALE FOR REVISIONS

PART C
LICENSING OF RADIOACTIVE MATERIAL

Introduction

The following is a brief history of the revision process of Part C and reasons for changes made to January 1991 version of Part C.

This Part was originally approved by CRCPD in 1974 and revised in 1978, 1982, 1984, 1988, and 1991 for the purpose of providing States with regulatory guidance regarding licensing of radioactive material.

In 2002 the SR-C committee began drafting revisions:

- Major changes were made to Part C for this edition of the Suggested State Regulations for Control of Radiation (SSRCR) with the revision of Part O, Decommissioning, Part S, Requirements for Financial Assurance, and Part E, Radiation Safety Requirements for Industrial Radiographic Operations. Those provisions in Part C that pertain to these subjects have been deleted from Part C and placed in the appropriate Parts
- The U.S. Nuclear Regulatory Commission made several changes in their regulations regarding Licensing of Radioactive Material that are considered a matter of compatibility for the Agreement States and these changes were incorporated in Part C
- Reviewing drafts of Part C

In 2006 and 2007 the SR-C committee:

- Distributed Draft SR-C for review and comment, to working group members, advisors, and resource individuals
- Met in a face-to-face meeting to review and discuss all comments received
- Distributed Draft SR-C and Rationale with the changes made during the meeting for review and comment, to working group members, advisors, and resource individuals
- Per conference calls on 9/20/06 and 9/28/06, met to review and discuss all comments received
- Distributed Draft SR-C and Rationale with the changes made during the conference call meetings for review and comment, to working group members, advisors, and resource individuals
- Developed a "final" Draft SR-C and Rationale for peer review
- Per conference call on 8/9/07, met to review and discuss all comments received
- Developed a Final Revised SR-C and Rationale for Board Approval - 08/21/07

Specific Provisions

C.1 - Purpose and Scope.

C.1a. References were added regarding Part C, Licensing of Radioactive Material; Part E, Radiation Safety Requirements for Industrial Radiographic Operations; Part I, Radiation Safety Requirements for Particle Accelerators; Part N, Regulation and Licensing of Technologically Enhanced Naturally

Occurring Radioactive Material (TENOR); Part Q, Licensing and Radiation Safety Requirements for Irradiators, and Part T, Transportation of Radioactive Materials to state a complete list of all Suggested State Regulations (SSRs) that address licensing of radioactive material. The word "dispose" was added in brackets to provide this option for those states that have the authority to regulate the disposal of radioactive material. References to Part U were deleted, as this Part has not been formalized as a final SSR. Brackets were added to Part I and M references to indicate that these provisions are either optional or are used to indicate a need for states to add appropriate language or references to local code. In addition, references were added to provide a complete list of the applicable Part C sections that are relevant to the footnote noted in this section.

C.1b. References were added regarding Part O, Decommissioning; Part P, Contingency Planning for Response to Radioactive Material Emergencies; Part S, Requirements for Financial Assurance; Part I, Radiation Safety Requirements for Particle Accelerators; and Part Q, Licensing and Radiation Safety Requirements for Irradiators, to state a complete list of additional SSRs that licensees are possibly subject to, depending on the type of radioactive material that is being licensed. References to Part U were deleted, as this Part has not been formalized as a final SSR. In addition, the word "wireline" was replaced with "well logging" to more accurately state the current terminology used in today's technology. Brackets were added to Part I and Q references to indicate that these provisions are either optional or are used to indicate a need for states to add appropriate language or references to local code. The words "this Part" were replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.2 - Carriers.

C.2. The new section was added to provide exemptions for carriers and to be consistent with 10 CFR 30.13

C.3 - Source Material.

C.3a. - c. The words "this Part" were replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.3c.i.(4) and (7) The term "milligrams" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.3c.vi.2. Parentheses were added for "1/8 inch" to comply with the format prescribed by the SSRCR Style Manual.

C.3c.viii. The equivalent International System of Units (SI) and abbreviations for the stated units were added to comply with the format prescribed by the SSRCR Style Manual.

C.3d. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.4 - Radioactive Material Other Than Source Material.

C.4a.i. and ii. Exempt Concentrations.

C.4a.i. The term "Subdivision" was deleted before the referenced citation and "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.4a.ii. The terms "Subdivision," "Paragraph," and "Section" were deleted before the respective referenced citations to comply with the format prescribed by the SSRCR Style Manual. The reference to “C.22” was added to state the complete list of applicable citations.

C.4a.iii. and iv. These new provisions were added to be consistent with 10 CFR 30.14.

C.4b.i. - iv. Exempt Concentrations.

C.4b.i. The term "Subdivision" was deleted before the referenced citation and "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual. In addition, "the Act and" was added to clarify that any person is also exempt from the requirements of the applicable Regulatory Act relating to exempt quantities.

C.4b.ii. The words "formerly prescribed in Paragraph C.22" were deleted because the referenced citation is invalid due to it being designated as a reserved subsection and "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.4b.iii. The words "This paragraph" were deleted before the respective referenced citation to comply with the format prescribed by the SSRCR Style Manual and the word "transfer" was added in the regulation for exemptions related to commercial distribution to be consistent with 10 CFR 30.18.

C.4b.iv. The term "Paragraph" was deleted before the multiple referenced citations, "Section 32.18 of 10 CFR Part 32" was replaced with "10 CFR 32.18," and "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.4c. Exempt Items.

C.4c.i.(1) - (9) Certain Items Containing Radioactive Material.

C.4c.i. The words ", or persons who desire to initially transfer for sale or distribute such products containing radioactive material" were added after "...following products" to be consistent with 10 CFR 30.15(b). The words "the Act and" were added to clarify that any person is also exempt from the requirements of the applicable Regulatory Act relating to exempt items for certain items containing radioactive material. In addition, "he" was replaced with "the licensee" to comply with the format prescribed by the SSRCR Style Manual. In the footnote noted "2/" related to this paragraph "NRC, Washington, D.C. 20555" was replaced with "Agency" to state the correct entity that grants authority of the transfer stated in this footnote.

C.4c.i.(1)(a) – (f) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "millicuries" and "microcuries" were replaced with the respective abbreviations to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(1)(g) The respective abbreviation for the stated SI unit was added and “per centimeter square” was replaced with the abbreviation “cm^2” to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(1)(g)(i) and (iii) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units, the terms "millirad" and "centimeter(s)" were replaced with the respective abbreviations, and the respective conventional units for centimeter(s) were added to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(1)(h) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "One microcurie" was replaced with "(1 μCi)" to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(2) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "millicuries," "millirad," "centimeters," and "milligrams per square centimeter" were replaced with the respective abbreviations to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(3) and (4) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "millicurie" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(5) and (6) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "millicuries" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(7)(a) - (f) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "millicuries," and "microcurie(s) were replaced with the respective abbreviations to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(7)(g) “And provided further, that” was deleted at the beginning of the sentence for grammatical correctness. The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and " "millirad," "centimeter," "milligrams" and “per square centimenter” were replaced with the respective abbreviations to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(8)(a) and (b) The term "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(8)(c) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units, "microcurie" was replaced with the respective abbreviation, and the term "Subdivision" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.4c.i.(9) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units, "microcurie" was replaced with the respective abbreviation as this term had been spelled out in a previous paragraph, the abbreviation for liters was added as this term had not been spelled out within Part C, and parentheses were added to the conventional unit for liters, to comply with the format prescribed by the SSRCR Style Manual.

<u>C.4c.ii. Self-Luminous Products Containing Radioactive Material.</u>

C.4c.ii.(1) Tritium, Krypton-85, or Promethium-147.

C.4c.ii.(1) The words "initially transferred for sale or distribution" were added after "produce;" the word "imported" was deleted after "produced;" and "initially" was added before "transferred" to be consistent with 10 CFR 30.19a. The words "or equivalent regulations of an Agreement State" were added after "...regulatory requirements" to be consistent with 10 CFR 30.19b. The words "Section 32.22 of 10 CFR Part 32" were replaced with "10 CFR 32.22" and the term “subdivision” was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.4c.ii.(2) Radium-226.

C.4c.ii.(2) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "microcurie" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.4c.iii. Gas and Aerosol Detectors Containing Radioactive Material.

C.4c.iii.(1) The word "or" was deleted after "process," and the words "or initially transfer for sale or distribution" were added after "produce" to be consistent with 10 CFR 30.20(a). The words "the Act and" were added to clarify that any person is also exempt from the requirements of the applicable Regulatory Act relating to gas and aerosol detectors containing radioactive material. The words "imported, or" were deleted after "manufactured," and replaced with "processed, produced, or initially" to be consistent with 10 CFR 30.20. The words "Section 32.26 of 10 CFR Part 32" were replaced with "10 CFR 32.26" and the term “paragraph” was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual. The word "initial" was added before "transfer of the detectors" to be consistent with 10 CFR 30.20.

C.4c.iii.(2) The words "or a Licensing State" were added after "Agreement State" to clarify that a Licensing State also has the authority to issue a specific license. The referenced citation "Subdivision C.4c.iii.(1)" was replaced with "C.4c." and the term "Paragraph" was deleted before "C.28c." to state the correct reference citation and to comply with the format prescribed by the SSRCR Style Manual.

C.4c.iii.(3) This subparagraph was deleted to avoid duplication of information stated in C.4c.iii.(2).

C.4c.iv. Resins Containing Scandium-46 Designed for Sand Consolidation in Oil Wells.

C.4c.iv. The word "imported" was replaced with "initially transferred" and "or initial transfer for sale or distribution" was added to be consistent with 10 CFR 30.16. The referenced citation "Sections 32.16 and 32.17 of 10 CFR Part 32" was replaced with "10 CFR 32.16 and 32.17" to comply with the format prescribed by the SSRCR Style Manual.

C.4c.v. Exemptions for Capsules Containing Carbon-14 Urea for "*in vivo*" Diagnostic Use for Humans.

C.4c.v. The new paragraph was added to provide exemptions for capsules containing carbon-14 urea for "*in vivo*" diagnostic use for humans and to be consistent with 10 CFR 30.21.

C.4c.vi. Additional Exemptions.

C.4c.vi. The new paragraph was added to provide a list of SSRs that address additional exemption requirements specific to the stated Parts.

C.20 Types of Licenses.

C.20a. The former text was deleted and replaced with new language to be consistent with 10 CFR 30.31. The last sentence was added to clarify the specific SSRs that apply to the issuance for a general license.

C.20b. The former text was deleted and replaced with new language to be consistent with 10 CFR 30.31.

C.20c. The new subsection was added to provide terms and conditions for general licenses and to be consistent with 10 CFR 31.2.

C.21 General Licenses - Source Material.

C.21a. The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the term "pounds" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.21b. The terms "Paragraph" and “this Part” were deleted before "C21.a." to comply with the format prescribed by the SSRCR Style Manual.

C.21c. The term "Paragraph" was deleted before "C.21a." to comply with the format prescribed by the SSRCR Style Manual.

C.21e. Depleted Uranium in Industrial Products and Devices.

C.21e.i. The term "Subparagraph" was deleted before "C.21e.ii., iii., iv., and v." to comply with the format prescribed by the SSRCR Style Manual.

C.21e.ii. The term "Subparagraph" was deleted before "C.21e.i." and the term "Paragraph" was deleted before "C.28m." to comply with the format prescribed by the SSRCR Style Manual.

C.21e.iii.(1) The term "Subparagraph" was deleted before "C.21e.i." to comply with the format prescribed by the SSRCR Style Manual.

C.21e.iii.(1)(a) – (c) The first letter in each subpart was capitalized to comply with the format prescribed by the SSRCR Style Manual.

C.21e.iii.(1)(b) The term "Subparagraph" was deleted before "C.21e.i." to comply with the format prescribed by the SSRCR Style Manual.

C.21e.iii.(1)(c) The term "Subdivision" was deleted before "C.21e.iii.(1)(b)" to comply with the format prescribed by the SSRCR Style Manual.

C.21e.iii.(2) The term "Subparagraph" was deleted before "C.21e.i." and replaced "him" with "the licensee" to comply with the format prescribed by the SSRCR Style Manual.

C.21e.iv. The term "Subparagraph" was deleted before "C.21e.i." to comply with the format prescribed by the SSRCR Style Manual.

C.21e.iv.(3) The term "Section" was deleted before "C.40" and the term "Subparagraph" was deleted before "C.21e.i." to comply with the format prescribed by the SSRCR Style Manual. The reference "and D.2001a of these regulations" was added after "C.40" to complete the list of SSRs that provide the applicable provisions.

C.22 General Licenses - Radioactive Material Other Than Source Material.

C.22a. Certain Devices and Equipment.

C.22a. Reference to "or an Agreement State" was added to state that an Agreement State is also authorized to issue a general license for certain devices and equipment. The referenced citation "Section 31.3 of 10 CFR Part 31" was replaced with "10 CFR 31.3," the term "Sections" was replaced with "Parts" before "A.4," the word "Subparagraph" was deleted before "C.4a.ii.," and the word "Sections" was deleted before "C.31, C.40, C.50" to comply with the format prescribed by the SSRCR Style Manual. The words ", as applicable" were added at the end of the sentence to clarify that the general licensee is not subject to all of the listed Parts and sections.

C.22a.i. Static Elimination Device.

C.22a.i. The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the term "microcuries" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.22a.ii Ion Generating Tube.

C.22a.ii. The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the terms "microcuries" and "millicuries" were replaced with the respective abbreviations to comply with the format prescribed by the SSRCR Style Manual.

C.22d. Certain Measuring, Gauging or Controlling Devices.

C.22d.i. The term "Subparagraph" was deleted before the respective referenced citation to comply with the format prescribed by the SSRCR Style Manual. The reference to paragraph "v." was added to provide a concise list of Part C references that specify the applicable provisions.

C.22d.ii. The current language was replaced with new language to be compatible with 10 CFR 31.5.

C.22d.ii.(1) and (2). The new language is added to be consistent with 10 CFR 31.5.

C.22d.iii. The term "Subparagraph" was deleted before the respective referenced citation to comply with the format prescribed by the SSRCR Style Manual. The word "shall" was added at the end of the sentence for grammatical correctness, and as a result of this, the former Subparagraphs (1)-(4), (6), and new (9) and (10), deleted the word "shall" at the beginning of these sentences.

C.22d.iii.(2)(b) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the term "microcuries" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.22d.iii.(4) The term "Subdivision" was deleted before each respective referenced citation to comply with the format prescribed by the SSRCR Style Manual. The word "maintained" was replaced with "retained" throughout the subparagraph and all the record retention time periods were changed to "3 years" to be consistent with 10 CFR 31.5(c).

C.22d.iii.(5) The former text was deleted and replaced with this new language to be consistent with 10 CFR 31.5.

C.22d.iii.(7) The former text was deleted and replaced with this new language to be consistent with 10 CFR 31.5.

C.22d.iii.(8) This new language was added to be consistent with 10 CFR 31.5. Subsequent paragraphs were renumbered as a result of this paragraph being added.

C.22d.iii.(9)(a) This renumbered subsection deleted "this regulation" before "C.22a.," added “Parts” before the referenced citation, and added the words “of these regulations” after "and D.2202" to comply with the format prescribed by the SSRCR Style Manual and deleted the former text after "Agency" to the end of the sentence, to be consistent with 10 CFR 31.5.

C.22d.iii.(9)(a)(i)-(iv) This new language was added to be consistent with 10 CFR 31.5.

C.22d.iii.(9)(b) The former text of this renumbered subsection was deleted and replaced with the new language to be consistent with 10 CFR 31.5.

C.22d.iii.(10) The renumbered section deleted the term "Sections" and added "Part" before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and deleted the former referenced citations and replaced them with the correct reference citations. The word "reporting" was added before "requirements" to clarify that the intent of the subparagraph was to address exemption of reporting requirements of Parts D and J and not all the requirements of Parts D and J.

C.22d.iii.(11)-(15) These new subparagraphs were added to be consistent with 10 CFR 31.5.

C.22d.iv. The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the words "or import" were added to be consistent with 10 CFR 31.5.

C.22d.v. The term "Subparagraph" was deleted before the first referenced citation and "Sections" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual.

<u>C.22e. General License to Install Devices Generally Licensed in C.32d.</u>

C.22e. This subsection was added to be consistent with 10 CFR 31.6. Subsequent subsections were renumbered as a result of this new subsection.

C.22f. Luminous Safety Devices for Aircraft.

C.22f.i.(1) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the terms "curies" and "millicuries" were replaced with the respective abbreviations to comply with the format prescribed by the SSRCR Style Manual.

C.22f.i.(2) The term "imported" was replaced with "initially transferred" and the words "or an Agreement State" were added after "NRC," to be consistent with 10 CFR 31.7. The words "of C.28e. or the" were added after "requirements" to state the Part C requirements that are applicable to this subparagraph. The referenced citation "equivalent to those in Section 32.53" was deleted as C.28e. now includes the text of 10 CFR 32.53.

C.22f.ii. The term "Subparagraph" was deleted before the first referenced citation, "Sections" was replaced with "Part," and the words "of these regulations" were added to comply with the format prescribed by the SSRCR Style Manual. References to other SSR citations were updated.

C.22f.iii. The word "or" was deleted after "assembly," and "or imports" was added after "repair" to be consistent with 10 CFR 31.7.

C.22f.v. The term "Sections" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual.

C.22f.vi. This paragraph was added to be consistent with 10 CFR 31.7(d).

C.22g. Ownership of Radioactive Material.

C.22g. The words "this Part" were replaced with "these regulations" to clarify that the provisions of all the applicable SSRCR's apply to the general license and not just Part C. The last sentence was revised to read "...possession, use, import, or export of radioactive material, except as authorized in a specific license." to be consistent with 10 CFR 31.9

C.22h. Calibration of Reference Sources.

C.22h.i. The term "Subparagraphs" was deleted before the referenced citations to comply with the format prescribed by the SSRCR Style Manual. The referenced citation "C.22g." was updated with "C.28f. and C.22h.iv. and v." to state the complete list of applicable subsections.

C.22h.i.(1) and (2) The term "him" was replaced with "the licensee" to comply with the format prescribed by the SSRCR Style Manual.

C.22h.ii. and iii. The term "Subparagraphs" was deleted before the referenced citations to comply with the format prescribed by the SSRCR Style Manual. The referenced citation “C22g.” was updated to “C22h.”.

C.22h.iv. The term "Subparagraphs" was deleted before the referenced citations and the referenced citations "Section 32.57 of 10 CFR Part 32" and "Section 70.39 of 10 CFR Part 70" were replaced with "10 CFR 32.57" and "10 CFR 70.39" respectively, to comply with the format prescribed by the SSRCR Style Manual. The referenced citation “C22g.” was updated to “C22h.i., ii. and iii.” and

reference to "C.28" was added before the second "10 CFR 32.57" to state the complete list of applicable requirements. The words "or initially transferred" were added after "manufactured" to be consistent with 10 CFR 70.19.

C.22h.v. The term "Subparagraphs" was deleted before the referenced citations and "Sections" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual. The referenced citation “C22g” was updated to “C22h.i., ii., and iii.”.

C.22h.v.(1) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the term "microcuries" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.22h.v.(2)(a) In the signature line for the label "importer" was replaced with "initial transferor" to be consistent with 10 CFR 70.19

C.22h.vi. The sentence was revised to read "...manufacture, import, or export of calibration..." to be consistent with 10 CFR 70.19.

C.22h. The former paragraph, which was listed as “reserved” was deleted.

<u>C.22i. General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.</u>

C.22i.i. The term "Subparagraphs" was deleted before the referenced citations to comply with the format prescribed by the SSRCR Style Manual.

C.22i.i.(1) - (8) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the term "microcurie(s)" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.22i.ii. The term "Subparagraph" was deleted before the referenced citations and "he" was replaced with "the person" to comply with the format prescribed by the SSRCR Style Manual.

C.22i.ii.(3) The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.22i.iii. The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.22i.iii.(1) The term "Subparagraph" was deleted before the referenced citation, the sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and the term "microcuries" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.22i.iii.(3) The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.22i.iii.(5) The term "Subdivision" was deleted before the referenced citation and "Section" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual. The referenced citation “D.301” was updated to “D.2001a”.

C.22i.iv. The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.22i.iv.(1) The term "Paragraph" was deleted before the referenced citations to comply with the format prescribed by the SSRCR Style Manual.

C.22i.v. The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.22i.vi. The terms "Subparagraph" and "Subdivision" were deleted before the referenced citation, "Sections" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual. In addition, the former referenced citations were deleted and replaced with the correct reference citations.

C.22j. Ice Detection Devices.

C.22j.i. The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units, the term “microcuries” was replace with the respective abbreviation, and the referenced citation "Section 32.61 of 10 CFR Part 32" was replaced with "10 CFR 32.61" to comply with the format prescribed by the SSRCR Style Manual. The word "imported" was replaced with "initially transferred" to be consistent with 10 CFR 31.10. The referenced citation “of C.28i. or” was added to state the complete list of applicable requirements.

C.22j.ii. The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.22j.ii.(1) The term "Section" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual and the former referenced citation was deleted and replaced with the correct reference citation.

C.22j.ii.(3) The term "Sections" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual and the former referenced citations were deleted and replaced with the correct reference citations.

C.22j.iii. The word "or" was deleted after "disassembly" and ", or transport" was added to be consistent with 10 CFR 31.10.

C.22j.iv. The term "Sections" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual.

C.24 Filing Application for Specific Licenses.

C.24c. The term "his" was replaced with "their" to comply with the format prescribed by the SSRCR Style Manual.

C.24e. The term "his" was replaced with "the" to comply with the format prescribed by the SSRCR Style Manual.

C.24f. The words ", [in accordance with (State open records law)]" were added in brackets to indicate a need for states to add appropriate references to applicable open record laws.

C.24g. The new subsection was added to be consistent with 10 CFR 30.32.

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

C.25d. The term "Sections" was deleted before the referenced Part C citations and the term "Part" was deleted thereafter each referenced Part citation to comply with the format prescribed by the SSRCR Style Manual. References to Parts I, N, O, P, Q, and S were added to state the complete list of applicable parts. Brackets were added to Part I and M references to indicate that these provisions are either optional or are used to indicate a need for states to add appropriate language or references to local code. The reference to “Part U” was deleted because Part U has not been formalized as a final SSR. Reference to “C.26.” was deleted before "C.27." because that section is designated as "Reserved" and is therefore not applicable.

C.25e. Brackets were added to this subsection to indicate that these provisions are either optional or are used to indicate a need for states to add appropriate language or references to local code. The sentence "Source material milling facilities are addressed in Part U of these regulations" was deleted because Part U has not been formalized as a final SSR.

C.25f. The former language of this subsection was deleted and designated as a "reserved" subsection because this information should be addressed in the applicable Part S that relates to Requirements for Financial Assurance.

C.26 Reserved.

C.26 The former sections were deleted and the section was designated as "reserved" section because the only former subsection of this section that contained requirements was deleted since the section addressed Industrial Radiography requirements that are now provided in Part E relating to Radiation Safety Requirements for Industrial Radiographic Operations.

C.27 Special Requirements for Specific Licenses of Broad Scope.

C.27 The related footnote to this section was deleted as a footnote and the information was moved to be stated within the former text to provide the ease of reading this information within the former text. The term "NRC" was replaced with "Agency" to clarify the responsible entity to determine the authority to transfer.

C.27a.ii. The reference to "Part C" was added after “Appendix D of” to state the relevant part that addresses the stated appendix.

C.27a.iii. The term "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.27b.i. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.27b.iii.(3)(c) The term "Subdivision" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.27c.i. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.27c.ii.(2)(c) The term "Subdivision" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.27d.i. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.27e.i. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.27e.i.(2) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "curies" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.27e.i.(3) The term "Sections" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual. Reference to "Parts E, I, N, or Q" were added accordingly, to state a concise list of the applicable SSRs. Brackets were added to the Part I and M references to indicate that these provisions are either optional or are used to indicate a need for states to add appropriate language or references to local code.

C.27e.ii. and iii. The term "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.27e.iv. The term "this Part" was replaced with "Part C" and "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

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

<u>C.28a. Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.</u>

C.28a.i. The terms "Section" and "Subparagraph" were deleted before the respective referenced citations to comply with the format prescribed by the SSRCR Style Manual.

C.28a.i.(2) The term "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.28a.ii. The former paragraph language was restructured and renumbered to more clearly convey the specific requirements. Changes are reflective in C.28a.ii. - iv. The term "Paragraph" was deleted before the referenced citations to comply with the format prescribed by the SSRCR Style Manual.

In addition, the former last sentence was deleted and replaced with the new language to allow a particular state to set an applicable calendar year for the reporting period.

C.28a.iii. The term "Paragraph" was deleted before the referenced citations to comply with the format prescribed by the SSRCR Style Manual.

C.28a.iv. The paragraph was reworded to allow a variable time period for reporting.

C.28a.v. The new paragraph was added to be consistent with 10 CFR 32.13.

C.28b. Licensing the Distribution of Radioactive Material in Exempt Quantities.

C.28b.i. The relevant footnote to this subsection was deleted as a footnote and the information was moved within this new paragraph to provide the ease of reading this information within the text. Subsequent paragraphs and footnotes were renumbered.

C.28b.ii. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28b.iii. The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citation was replaced with the correct reference citation.

C.28b.iii.(2) The term "Paragraph" was deleted before the referenced citation, the sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units, and "millirem" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.28b.iii.(4) The term "Subdivision" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citation was replaced with the correct referenced citation.

C.28b.iv. The term "Paragraph" was deleted before the respective referenced citations to comply with the format prescribed by the SSRCR Style Manual.

C.28c. Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors.

C.28c. The term "Subparagraph" was deleted before the referenced citation, the citation "Section 32.26 of 10 CFR Part 32" was replaced with "10 CFR 32.26," the sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units, and "microcurie" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.28d. Licensing the Manufacture or Initial Transfer of Devices to Persons Generally Licensed Under C.22.d.

C.28d. The title of this subsection was revised to delete the words "and Distribution" and replace with "or Initial Transfer" to be consistent with 10 CFR 32.51. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28d.i. The word "distribute" was replaced with "initially transfer" to be consistent with 10 CFR 32.51. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28d.i.(1) The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28d.i.(2)(b) The term "Paragraph" was replaced with "Part" before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citation was replaced with the correct referenced citation.

C.28d.i.(2)(c) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units, the term "rems" was replaced with "rem", and “square centimeter” was replaced with “cm^2” to comply with the format prescribed by the SSRCR Style Manual.

C.28d.i.(3)(c)(i) The footnote applicable to this paragraph was renumbered as a result of the previous footnote being deleted. The signature line for the label deleted the word "distributor" and replaced with "initial transferor" to be consistent with 10 CFR 32.51.

C.28d.i.(3)(c)(ii) The "2" was replaced with "ii" to state the correct reference designation as prescribed by the SSRCR Style Manual.

C.28d.i.(4) and (5) The new language was added to be consistent with 10 CFR 32.51.

C.28d.iii. The term "Paragraph" was deleted before the first referenced citation and "Paragraph" was replaced with "Part" before the second referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28d.iv. and v. The former language has been replaced with the new language to be consistent with 10 CFR 32.51.

<u>C.28e. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft.</u>

C.28e. The former language in C.28e. was renumbered and reformatted to incorporate the new language equivalent to 10 CFR 32.53-32.56 and 32.101. Changes are reflective in new C.28e.i.(2) and C.28e.ii. - v.

C.28e.i. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual. The citation "C.22e." was updated with "C.22f."

C.28e.i.(1) The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28f. Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.22h.

C.28f. The former language in C.28f. was renumbered and reformatted to incorporate the new language equivalent to 10 CFR 32.57-32.59, 32.102, and 70.39. Changes are reflective in new C.28f.i. - iv.

C.28f. and C.28f.i. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual. The citation "C.28g." was updated to "C.28h.".

C.28f.i. The sentence was revised to read "...manufacture, or initially transfer calibration...." to be consistent with10 CFR 32.57.

C.28f.i.(1) The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28f.i.(2) The 10 CFR referenced citations were deleted and replaced with the specific requirements to be consistent with 10 CFR 32.57-32.59, 32.102, and 70.39.

C.28h. Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License.

C.28h. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28h.i. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28h.ii.(1) - (8) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "microcuries" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.28h.iii.(1) The sequence of the listed units of measure was restructured to state the SI units first followed by the conventional units and "microcuries" was replaced with the respective abbreviation to comply with the format prescribed by the SSRCR Style Manual.

C.28h.iii.(2) The term "subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citation was replaced with the correct referenced citation.

C.28h.v. The term "must" was replaced with "shall" and "Section" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual and the former citation was replaced with the correct referenced citation.

C.28i. Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium-90.

C.28i. The former language in C.28i. was renumbered and reformatted to incorporate the new language equivalent to 10 CFR 32.61, 32.62, and 32.103. Changes are reflective in new C.28i.i. - iii.

C.28i. The words "Containing Strontium-90" were added to be consistent with 10 CFR 32.61.

C.28i.i The sentence was revised to read "...manufacture, or initially transfer ice detection...." to be consistent with 10 CFR 32.61. The word "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28i.i.(1) The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28i.i.(2) The 10 CFR referenced citations were deleted and replaced with the specific requirements to be consistent with 10 CFR 32.61, 32.62, and 32.103.

<u>C.28j. Manufacture and Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Part G of these Regulations.</u>

C.28j. The word "Radiopharmaceutical" was replaced with "Radioactive Drugs" and "Group Licenses" was replaced with "Part G of these regulations" to be consistent with 10 CFR 32.72.

C.28j.i. - iv. The former language was replaced with the new language to be consistent with 10 CFR 32.72.

<u>C.28k. Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.</u>

C.28k. The former subsection was deleted because the Agency no longer regulates the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material. Subsequent subsections were renumbered, as well as any applicable referenced citations stated throughout Part C.

<u>C.28k. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.</u>

C.28k. The former subsection, "C.28l." was renumbered to "C.28k." In addition, "Sections" was replaced with "Part" to comply with the format prescribed by the SSRCR Style Manual and the former citations were replaced with the correct referenced citations. References to Part "G.35 and G.89" were added to state the concise list of Part G sections that apply to this subsection.

C.28k.i. The term "Section" was deleted before the referenced citation and “of this part” was deleted after the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28k.iii. The former language was deleted and replaced with the new paragraph to be consistent with 10 CFR 32.74.

C.28k.iv. The word "he" was replaced with "the applicant" and "his" was replaced with "the" to comply with the format prescribed by the SSRCR Style Manual.

C.28k.vi. The new paragraph was added to be consistent with 10 CFR 32.74.

C.28l. Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

C.28l. The former subsection "C.28m." was renumbered to "C.28l."

C.28l.i. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citation was replaced with the correct referenced citation.

C.28l.i.(1) The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.28l.i.(2) The term "Paragraph" was replaced with "Part" before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citation was replaced with the correct referenced citation.
C.28l.ii. and iii. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citations were replaced with the correct referenced citations.

C.28l.iv. The term "Subparagraph" was deleted before each referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citations were replaced with the correct referenced citations.

C.28l.iv.(4)(a) The term "Paragraph" was deleted before the referenced citation and "he" was replaced with "the licensee" to comply with the format prescribed by the SSRCR Style Manual. The former citations were replaced with the correct referenced citations.

C.28l.iv.(4)(b) The term "Paragraph" was deleted before each referenced citation and "he" was replaced with "the licensee" to comply with the format prescribed by the SSRCR Style Manual. The former citations were replaced with the correct referenced citations.

C.28l.iv.(5) The term "Paragraph" was deleted before each referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citations were replaced with the correct referenced citations.

C.28l.iv.(6)(a) The NRC referenced citations were replaced with the equivalent Part C references to comply with the format prescribed by the SSRCR Style Manual.

C.28l.iv.(6)(b) The term "Paragraph" was deleted before each referenced citation to comply with the format prescribed by the SSRCR Style Manual and the former citations were replaced with the correct referenced citations.

C.28l.iv.(7) The term "Paragraph" was deleted before the referenced citation and "he" was replaced with "the licensee" to comply with the format prescribed by the SSRCR Style Manual. The former citation was replaced with the correct referenced citation.

C.28m. Acceptance Sampling Procedures Under Certain Specific Licenses.

C.28m The new was added to provide acceptable sampling procedures under certain specific licenses and to be consistent with 10 CFR 32.110.

C.30 Issuance of Specific Licenses.

C.30b. and b.iii. The words "this Part" were replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.31 Specific Terms and Conditions of Licenses.

C.31a., b., and c. The words "this Part" were replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.31e. The words "Each general licensee that is required to register by C.22d.iii(13) and each specific" were added to be consistent with 10 CFR 30.34. The abbreviation for United States Code was added to comply with the format prescribed by the SSRCR Style Manual.

C.31f. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.31g. The new subsection language is added to be consistent with 10 CFR 30.34.

C.32 Expiration and Termination of Licenses.

C.32a. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual. The reference to Part O.5 replaced the reference to "C.33b." to provide the applicable SSR requirements. The equivalent 10 CFR 30.36(c) language was added to provide information that the license remains in effect until final agency action is made. Brackets were added to this subsection to indicate that these provisions are either optional or are used to indicate a need for states to add appropriate language or references to local code.

C.32b. The word "must" was replaced with "shall" and "Subdivisions" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.32c.i. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.32d.i. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.32d.i.(5)(a) The former language was deleted and replaced with equivalent 10 CFR 30.36(j)(2)(i) language.

C.32d.iii.(1) The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.32d.iii.(2) The term "Subdivision" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.32e. The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.33. Renewal of Licenses.

C.33a. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.33b. The word "he" was replaced with "the" to comply with the format prescribed by the SSRCR Style Manual.

C.34. Amendment of Licenses at Request of Licensee.

C.34. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.35. Agency Action on Applications to Renew or Amend.

C.35. The term "Sections" was deleted before the referenced Part C citations to comply with the format prescribed by the SSRCR Style Manual. In addition, Parts "A, C, D, I, J, N, O, P, Q, S, and T" were added to the former referenced Parts to correctly state all the SSRCR's that may be applicable for license renewal or amendment. Reference to "C.26." was deleted because that section is designated as "Reserved" and is therefore not applicable. Reference to Part U was deleted as this Part has not been formalized as a final SSR. Brackets were added to Part I and M references to indicate that these provisions are either optional or are used to indicate a need for states to add appropriate language or references to local code.

C.36. Persons Possessing a License for Radioactive Material to include Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of these Regulations.

C.36. The title added "Radioactive Material to include" for clarification. The words "radioactive materials, to include" were added before "source," the words “byproduct, or” were deleted after “source,” and the word "and" was added after "source" to clarify that this section applies to all radioactive material. The words "this Part" was replaced with "Part C" to comply with the format prescribed by the SSRCR Style Manual.

C.37. Reserved.

C.37. The former section was deleted and designated as "Reserved" because the section addressed requirements for Naturally Occurring and Accelerator-Produced Radioactive Material that are now located in Part N relating to Regulation and Licensing of Technologically Enhanced Naturally Occurring Radioactive Material (TENORM).

C.40. Transfer of Material.

C.40a. The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.40b. The term "his" was replaced with "the," "Paragraphs" was deleted before the referenced citation, and “C.40” was added before “d.” to comply with the format prescribed by the SSRCR Style Manual.

C.40b.i. The former footnote was deleted as a footnote and the language was moved to this paragraph for ease in reading.

C.40d. The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.40d.v. The term "Subparagraphs" was deleted before the referenced citation and “C.40d.” was added before “iv.” to comply with the format prescribed by the SSRCR Style Manual.

C.50. Modification and Revocation of Licenses.

C.50c. The word "therefor" was replaced with "therefore" to provide the correct spelling.

C.90. Reciprocal Recognition of Licenses.

C.90a. Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

C.90a.i.(2) and (5) The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.90a.i.(5)(b) The term "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.90a.ii. The term "Subparagraph" was deleted before each referenced citation to comply with the format prescribed by the SSRCR Style Manual. The references to "C.21., C.22e., and C.22g." were added to state all the applicable sections of Part C that apply to this paragraph.

C.90a.ii.(4) The word "he" was replaced with "the licensee" and "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.90b. Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.

C.90b.i. The words "and Part N of these regulations" are added to clarify that any person who has reciprocal recognition of a license of naturally occurring and accelerator-produced radioactive material is also subject to the requirements of Part N.

C.90b.i.(2) and (5) The term "Subparagraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.90b.i.(5)(b) The term "Section" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.90b.ii. The term "Subparagraph" was deleted before each referenced citation to comply with the format prescribed by the SSRCR Style Manual. The references to "C.21., C.22e, and C.22g." were added to state all the applicable sections of Part C that apply to this paragraph.

C.90b.ii.(4) The word "he" was replaced with "the licensee" and "Paragraph" was deleted before the referenced citation to comply with the format prescribed by the SSRCR Style Manual.

C.90c. This new subsection was added to provide for work done in a facility under exclusive federal jurisdiction and to be consistent with 10 CFR 150.20.

C.95. Records.

C.95. This new subsection was added to provide record requirements equivalent to 10 CFR 30.51.

C.100. Deliberate Misconduct.

C.100. The "Reserved" designation was deleted and this new section was added to be consistent with 10 CFR 30.10.

Appendix A. Exempt Concentrations.

Appendix A. The former appendix was deleted and replaced with an updated table to include SI units.

Appendix B. Exempt Quantities.

Appendix B. The former appendix was deleted and replaced with an updated table to include SI units.

Appendix D. Limits for Broad Licenses.

Appendix D. The former appendix was deleted and replaced with an updated table to include SI units.

Matters for Future Consideration

1. Due to the fact that the update of Part C has been long overdue, the 2008 revision did not address the much requested restructure of the entire document to make it more user friendly and easier to read. Therefore, Part C will be immediately revisited after the 2008 revision is finalized and approved, to allow ample time for soliciting comments on a future reorganization of the entire part and to address those comments received during the peer review that needed more time for a detailed research of the items in question.

2. Future revisions of Part C will address any NRC rules that were not addressed in the 2008 revision concerning: Increased Controls; Expanded Definition of Byproduct Material to include addressing Naturally Occurring or Accelerator Produced Radioactive Material (NARM); National Source Tracking System; and any other applicable revisions relating to licensing of radioactive material.

3. Consider adding requirements for sealed source and device evaluation and registration equivalent to 10 CFR 32.210.

4. Consider adding requirements for reports of large quantity transfer or diversion per 10 CFR 30.55 and 40.64.

1988
Rationale for Revisions

Part C
Licensing of Radioactive Material

Introduction

Major changes have been made to Part C for this edition of the Suggested State Regulations for Control of Radiation (SSRCR) with the revision of Part G, Use of Radionuclides in the Healing Arts, and the addition of two new Parts, Part T, Transportation of Radioactive Material, and Part U, Licensing Requirements for Source Material Milling Facilities. Those provisions in Part C that pertain to these subjects have been deleted from Part C and placed in the appropriate Parts. In addition, the U.S. Nuclear Regulatory Commission (NRC) has made several changes in their regulations that are considered a matter of compatibility for the Agreement States.

Specific Provisions

C.1 Purpose and Scope. Paragraphs C.1(a) and (b) have been changed to reflect the revision to Part G and the addition of Parts M, T, and U to the SSRCR. In C.1(b), the reference to Parts M and U is set off by optional brackets to denote that only those Agreement States with the authority to regulate mill tailings and commercial low-level waste disposal need to include those Parts in their regulations as matters of compatibility.

C.3(c)(2)(ii)-(iv) Source Material. Subdivision C.3(c)(2)(ii) is modified and a new Subdivision C.3(c)(2)(iii) is added to delete an exemption from licensing requirements applicable to the possession and use of glass enamel and glass enamel frit containing small amounts of source material. This change is intended to prevent unnecessary radiation exposure that may be received by artists or consumers who use the material containing these products. On July 25, 1983 (48 FR 33697) the NRC suspended the subject exemption until a rulemaking action was completed. The final rule was published in the Federal Register and became effective on September 11, 1984 (49 FR 35611). The existing Subparagraph (iii) is renumbered to (iv).

C.3(c)(6) Source Material (Labeling of Uranium Shielding). The entire provision on labeling of uranium shielding was reworded in accord with amendments to NRC regulations (46 FR 62396).

C.4(c)(2)(i) Self-Luminous Products Containing Radioactive Material. The last sentence of Subdivision C.4(c)(2)(i) was revised by adding the word "primarily" to now read as follows: "The exemption in Subparagraph C.4(c)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments." The omission of the word "primarily" from this sentence changes the scope of the exemption as established by the NRC which has exclusive authority over commercial distribution.

C.21(c)-(e) General Licenses - Source Material. The existing Paragraphs C.21(c) and (d) are renumbered to C.21(d) and (e), respectively. A new Paragraph C.21(c) on prohibition of a general license for source material in pharmaceuticals is added to the SSRCR for consistency with amendments to NRC regulations (45 FR 55419) and with 10 CFR 40.22(c).

C.22(a) Certain Devices and Equipment. The reference to Section C.100 has been deleted and Part T substituted to indicate the new reference for transportation requirements.

C.22(d)(5) Certain Measuring, Gauging or Controlling Devices. The reference to Section C.100 has been deleted and Part T substituted to indicate the new reference for transportation requirements.

C.22(e)(5) Luminous Safety Devices for Aircraft. The reference to Section C.100 has been deleted and Part T substituted to indicate the new reference for transportation requirements.

C.22(g)(5) Calibration and Reference Sources. The reference to Section C.100 has been deleted and Part T substituted to indicate the new reference for transportation requirements.

C.22(h) Medical Diagnostic Uses (Previous Edition of SSRCR). Paragraph C.22(h) from the previous edition of the SSRCR has been deleted in its entirety. With the revision of Part G, this general license is no longer necessary.

C.22(i)(2) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing. Subparagraph C.22(i)(2) has been revised to eliminate the reference to Subparagraph C.26(c)(3), which has been deleted with the revision to Part G.

C.22(j)(4) Ice Detection Devices. The reference to Section C.100 has been deleted and Part T substituted to indicate the new reference for transportation requirements.

C.25(d) General Requirements for the Issuance of Specific Licenses. The reference to Section C.29 is deleted as the requirements are now included in Part U on Licensing Requirements for Source Material Milling Facilities. Also, paragraph (d) was revised by including specific references to Parts E, G, M, U, and W.

C.25(e) Environmental Report, Commencement of Construction. The phrase "source material milling" is deleted from Paragraph C.25(e) as the topic is now fully addressed in Part U of the SSRCR. The optional language in brackets is provided for the case where a state does not have the potential for uranium recovery operations. Also, the last sentence of Paragraph C.25(e) was revised to read as follows: "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."

C.25(f)(4) and (5) Financial Surety Arrangements for Site Reclamation. Subdivision C.25(f)(4)(iv) was deleted

and Subdivision C.25(f)(4)(v) was renumbered to (iv). In Subdivision C.25(f)(5)(i), "or (iv)" was deleted at the end of that subdivision due to the changes in Subparagraph C.25(f)(4).

C.25(g) Long-Term Care Requirements (Previous Edition of SSRCR). These requirements from the previous edition of the SSRCR are deleted from Part C and are now in Parts M and U.

C.26(a)-(d) (Previous Edition of SSRCR) Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material. Paragraphs (a) through (d) are deleted in their entirety, and the revised requirements are now in Part G.

C.26(e) Use of Sealed Sources in Industrial Radiography. The terminology in Paragraph C.26(e) was revised to be consistent with that of the amended Part E.

C.27(e)(1)(iii) Special Requirements for Specific Licenses of Broad Scope. The reference to Section C.29 has been deleted because of the removal of Section C.29 from Part C. A reference to Parts G, M, and U was substituted to be all-inclusive.

C.28(g) Manufacture and Distribution of Radioactive Material for Medical Use Under General License (Previous Edition of SSRCR). Paragraph C.28(g) has been deleted as a result of the elimination of the general license under Section C.22.

C.28(j) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses. Paragraph C.28(j) has been revised as a result of the elimination of the group license under Section C.26 and the revision of Part G.

C.28(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.. Paragraph C.28(k) has been revised as a result of the elimination of the group license under Sec. C.26 and the revision of Part G.

C.28(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. Paragraph C.28(l) has been revised as a result of the elimination of the group license under Section C.26 and the revision of Part G.

C.29 Special Requirements for Issuance of Specific Licenses for Source Material Milling (Previous Edition of SSRCR). Section C.29 has been deleted in its entirety as a result of the addition of Part U which now contains these requirements.

C.31(b) Specific Terms and Conditions of License. Paragraph C.31(b) was amended to include future amendments to the Act and to all valid rules, regulations, and orders of the Agency.

C.31(e) and (f) Specific Terms and Conditions of License. New paragraphs (e) and (f) have been added that require the licensee to notify the Agency following bankruptcy as a result of amendments to NRC regulations published in the Federal Register on January 12, 1987 (52 FR 1292) and which became effective on February 11, 1987.

C.32 Expiration and Termination of Licenses. Section C.32 from the previous edition of the SSRCR is revised significantly in accord with amendments to NRC regulations (48 FR 32324).

C.35 Agency Action on Applications to Renew or Amend. Section C.35 is revised to delete reference to Section C.29 and to include references to Parts E, G, M, U, and W.

C.40(e) Transfer of Material. The reference to Section C.100 has been deleted and Part T substituted to indicate the new reference for transportation requirements.

C.50 Modification and Revocation of Licenses. The word "termination" is removed from the title of Section C.50. Paragraph (d) of Section C.50 is deleted as "termination" is now addressed in Section C.32.

C.100 Transportation of Radioactive Material (Previous Edition of SSRCR). Section C.100 has been deleted in its entirety as a result of the addition of Part T which now contains these requirements.

C.101 Exemptions (Previous Edition of SSRCR). Section C.101 has been deleted in its entirety as a result of the addition of Part T which now contains these requirements.

C.102 General Licenses for Carriers (Previous Edition of SSRCR). Section C.102 has been deleted in its entirety as a result of the addition of Part T which now contains these requirements.

C.103 General License for Delivery of Radioactive Material to a Carrier for Transport (Previous Edition of SSRCR). Section C.103 has been deleted in its entirety as a result of the addition of Part T which now contains these requirements.

C.104 Advance Notification of Transport of Nuclear Waste (Previous Edition of SSRCR). Section C.104 has been deleted in its entirety as a result of the addition of Part T which now contains these requirements.

Appendix A. Appendix A has been revised to replace the words "isotope" and "radioisotope" with the word "radionuclide".

Appendix C (Previous Edition of SSRCR). Appendix C has been deleted with the elimination of the group license and the revision of Part G.

Agency Form T: Certificate-Disposition of Radioactive Materials. A new form has been included for use in certifying certain licensee actions with regard to the disposition of radioactive material.

Agency Form U: Certificate-Medical Use of Radioactive Material Under General License (Previous Edition of SSRCR). Agency Form U, and references to it, have been deleted due to the removal of Paragraph C.22(h) from the SSRCR.

Matters for Future Consideration

1. It is suggested that Subdivisions C.28(j)(2)(ii) and C.28(k)(2)(ii) be revised for consistency with FDA regulations. This provision should be revised in conjunction with revision of 10 CFR 32.72(a)(2)(ii) and 32.73(a)(2)(ii) and in cooperation with the NRC and the Center for Drug Evaluation and Research, Food and Drud Administration, for compatibility with the regulations of these agencies (e.g., substitute ". . . is to be exclusively intrastate and has been reviewed and approved by the Agency for its acceptability" for ". . . is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act").

2. It is suggested that consideration be given to adding data for a number of NARM nuclides already appearing in Appendix B, Exempt Quantities, to the Appendix A, Exempt Concentrations listing (i.e., gallium-67, indium-111, iodine-123, iron-52, potassium-43, sodium-22, and yttrium-87).

3. Consider the possibility of including data for certain short-lived radionuclides in Appendix B, Exempt Quantities (e.g., carbon-11, nitrogen-13, and oxygen-15).

4. The regulation of NORM is to be accomplished by what mechanism - specific and/or general licenses, exemptions and/or de minimus levels.

5. Accelerator-produced radioactivity in recyclables need an exemption, a general license, or a de minimus level.

6. The inclusion of lead-210 into exempt items in Paragraph C.4(c) and their manufacture and distribution in Section C.28.

7. The NRC has amended its regulations to set forth technical and financial criteria for decommissioning licensed nuclear facilities. These amendments apply to the decommissioning of nonfuel-cycle nuclear facilities and are considered a matter of compatibility for Agreement States. These amendments were published in the Federal Register on June 27, 1988 (53 FR 24018) and became effective on July 27, 1988. However, there is a provision in the regulations for specific licenses presently issued that delays implementation until July 27, 1990. These amendments will be added to the next revision to Part C but should be considered by states amending their regulations presently.

8. In Section C.20 on Types of Licenses, the Suggested State Regulations omit the material covered in NRC's regulations in Section 31.6 (General license to install devices generally licensed in Section 31.5). Should this material be included in the next revision of Part C of the SSRCR?

9. Because of the problems the NRC has had with processing material under the comparable paragraph to Paragraph C.21(b) (General Licenses - Source Material), the states might want to prohibit processing of source material under the general license.

10. In Paragraph C.22(a) (Certain Devices and Equipment), consider deleting the words, "for use" during the next revision of Part C of the SSRCR.

11. In Subdivision C.22(g)(1)(ii) under Calibration and Reference Sources, NRC questions the value of this provision as they believe it would apply to few, if any, licensees.

12. Because licensees are required to notify the Agency of bankruptcy in Paragraph C.31(e) under Specific Terms and Conditions of Licenses, consideration should be given to adding references to state insolvency laws in this section. This would assure that the regulatory agency will be notified of insolvency proceedings under state law as well as bankruptcy proceedings under Federal law.

1984
Added Rationale for Revisions

Part C
Licensing of Radioactive Material

Introduction

The changes made to Part C from the 1982 Edition of the Suggested State Regulations for Control of Radiation (SSRCR) for this revision are based on amendments to U.S. Nuclear Regulatory Commission (NRC) standards in Title 10 of the Code of Federal Regulations (CFR).

Specific Provisions

C.4(c)(1)(viii)(c) Certain Items Containing Radioactive Material. Americium-241 as an exempt quantity of 0.05 microcurie is added under Subdivision C.4(c)(1)(viii) for use in internal calibration or standardization of ionizing radiation measuring instruments. This addition to the SSRCR is based on an amendment to 10 CFR 30.15(a)(9) of NRC regulations which was published as a final rule in the Federal Register on September 23, 1981 (46 FR 46875) and became effective on the same date. A notice of proposed amendment to 10 CFR Part 30 was published in the Federal Register on July 9, 1981 (46 FR 35523).

C.26(a)(1) Human Use of Radioactive Material in Institutions. A Radiation Safety Committee with a simplified membership to focus on the radiation safety of workers and the general public is an amended requirement of Subparagraph C.26(a)(1) to replace the previous requirement for hospitals licensed to use radioactive material for human applications to have a Medical Isotopes Committee to review clinical aspects of the use of radioactive material within the hospital. This change, which includes the hospital management and nursing staff as members of the new Radiation Safety Committee, as well as an authorized user for each type of use permitted by the license and the Radiation Safety Officer, is based on an amendment to 10 CFR 35.11(b) published as a final rule in the Federal Register on September 13, 1982 (47 FR 40149) and became effective on October 12, 1982. The proposed amendment to NRC regulations was published in the Federal Register on April 9, 1979 (44 FR 21023).

C.26(c)(2)(v)-(vii) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material. Subdivision C.26(c)(2)(v) is modified and Subdivision C.26(c)(2)(vi) is added to provide an exception from certain regulatory requirements for the technetium-99m pentetate used for lung function studies. Because in the lung function studies, technetium-99m is used as an aerosol and administered by inhalation, a new Subdivision C.26(c)(2)(vii) is included to provide requirements for the administration of radioactive aerosols. These new or modified subdivisions are based on amendments to NRC regulations reflected in 10 CFR 35.14(b)(6)-(8) which were published as a final rule in the Federal Register on February 4, 1983 (48 FR 5217) and became effective on March 7, 1982. The proposed rule was published by NRC in the Federal Register on April 13, 1982 (47 FR 15798).

C.26(c)(2)(vi) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material. Subdivision C.26(c)(2)(vi)(b)-(e) is added to authorize additional clinical procedures for an exemption from certain regulatory requirements. These additions are based on amendment to 10 CFR 35.14(b)(7) which was published as a final rule in the Federal Register on September 10, 1985 (50 FR 36366) and became effective on the same date.

Appendix C, Group III Use of Generators and Reagent Kits for the Preparation and Use of Radiopharmaceuticals Containing Radioactive Material for Certain Diagnostic Uses

(3)(xiii) Disofenin. A new reagent kit used to prepare the radiopharmaceutical, technetium-99m labeled disofenin, is being added to the list of authorized reagent kits in Group III of Appendix C. This addition is based on an amendment to Section 35.100 of 10 CFR Part 35 published as a final rule in the Federal Register on March 26, 1982 (47 FR 12939).

(3)(xiii) Succimer. A reagent kit for preparation of the renal imaging radiopharmaceutical, technetium-99m labeled succimer (also known as DMSA), is added to Group III, Appendix C. An amendment to NRC's regulations, "Human Uses of Byproduct Material", 10 CFR Part 35, was published as a final rule in the Federal Register on June 29, 1982 (47 FR 28087) and provides the basis for this addition.

(3)(xiv) Albumin Colloid. A new reagent kit to prepare the radiopharmaceutical, technetium-99m labeled albumin colloid, for imaging the liver, spleen, and bone marrow by licensed and appropriately trained physicians is being added to Group III of Appendix C. This addition to Part C of the SSRCR is based on an amendment to 10 CFR 35.100(c)(4) of NRC regulations published as a final rule in the Federal Register on June 22, 1983 (48 FR 28431).

Due to the minor procedural nature of the three above amendments to NRC regulations, the customary notice of proposed rulemaking was not published prior to the final rule. Also, the final rules were effective immediately upon publication as the amendments relieved licensees from restrictions under regulations then in effect.

Appendix C, Group III(6). Appendix C, Group III(6) is modified to allow a drug that has passed all its trials and has been approved for sale to be used in the interim time until the drug is added to the list. This modification will eliminate ambiguity present in Appendix C.

Appendix C, Group IV Use of Prepared Radiopharmaceuticals for Certain Therapeutic Uses That Do Not Normally Require Hospitalization for Purposes of Radiation Safety

Appendix C, Group IV(4). Appendix C, Group IV(4) is modified to reflect the actual practice by FDA. FDA accepts INDs and it approves NDAs.

Appendix C, Group VI Use of Sources and Devices Containing Radioactive Material for Certain Medical Uses. A portable hand-held device using low energy radiation from an iodine-125 sealed source to produce

instantaneous imaging of bones or foreign bodies is added to Group VI of Appendix C. The addition of this device is based on an amendment to 10 CFR 35.100(f) of NRC regulations published as a final rule in the Federal Register on June 28, 1983 (48 FR 29677) and became effective on the same date. The proposed rule was published in the Federal Register on March 30, 1983 (48 FR 13189).

1982
Rationale for Revisions

Part C
Licensing of Radioactive Material

Introduction

Part C of the Suggested State Regulations for Control of radiation (SSRCR) was last revised in October 1978. There have been several discussions by committees of the Conference of Radiation Control Program Directors, Inc. (CRCPD) since then regarding regulatory provisions for the manufacture, assembly, and distribution of Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) and the Licensing State concept (for NARM). The U.S. Nuclear Regulatory Commission (NRC) has made several changes in their regulations regarding byproduct material and uranium milling procedures. Primarily, the major revisions from the 1978 Edition of the SSRCR concern NARM provisions and NRC regulation changes. The specific changes to Part C of this revision and their rationale are as given below. (The headings and other references are to this revision of the SSRCR, except where noted otherwise and for the information in parentheses following the specified revision relating it to the 1978 SSRCR.)

Specific Provisions

C.1(b) Purpose and Scope. Reference to the new Part W has been added (Page C1, line 11 of 1978 SSRCR).

C.4(a) Exempt Concentrations. The term "or materials" has been deleted and "introduced" added as editorial updating to preclude misinterpretation (Page C4, lines 7 and 8 of 1978 SSRCR).

C.4(c)(1)(i),(ii), and (vii) Certain Items Containing Radioactive Material. The term "levels of radiation" has been changed to read "radiation dose rate" for purpose of clarity and editorial updating (Page C5, lines 12 and 24 and page C6, lines 3 and 28 of 1978 SSRCR).

C.4(c)(1)(viii) Certain Items Containing Radioactive Material. This Subdivision has been amended to reflect changes to 10 CFR 30.15(a)(9), 46 FR 26471 (Page C6, lines 35-38 of 1978 SSRCR).

C.21(a) General Licenses - Source Material. Specific reference to "pharmacists" and "physicians" was deleted and the expression for persons in "commercial and industrial firms, research, educational and medical institutions, and state and local government agencies" has been reemphasized effective September 19, 1980 due to changes in NRC regulations, 45 FR 55419 (Page C9, lines 16-26 of 1978 SSRCR).

C.22(d)(3)(iii) Certain Measuring, Gauging or Controlling Devices. The phrase "the tests required by Subdivision C.22(d)(3)(ii) and" has been deleted for reasons of clarity and editorial updating (Page C13, line 28 of 1978 SSRCR).

C.22(i)(1),(2), (2)(i), (2)(iii); (4)(ii)(a) and (b), and (5). The term "Veterinarian" has been inserted in accord with recent changes in NRC regulations, 44 FR 50324 (Pages C20, C21, C22 and C23 of 1978 SSRCR).

C.23 of the 1978 Edition, "Intrastate Transportation of Radioactive Material" has been relocated in the revised Section C.100 on "Transportation of Radioactive Material" as consistent with NRC rule changes effective December 12, 1979. Section C.23 is now reserved (Pages C24 and C25 of 1978 SSRCR).

C.25(e) Environmental Report, Commencement of Construction. "Bonding Requirements" has been included in the new Paragraph C.25(f) and replaced by "Environmental Report, Commencement of Construction" in accordance with implementation of P.L. 95-604 (UMTRCA) (Pages C27 and C28 of 1978 SSRCR).

C.25(f) Financial Surety Arrangements for Site Reclamation. "Perpetual Care Requirements" has been deleted and replaced by "Financial Surety Arrangements for Site Reclamation" in accordance with implementation of P.L. 95-604 (UMTRCA) (Page C28 of 1978 SSRCR).

C.25(g) "Long-Term Care Requirements" has been added to provide regulations for "waste handling licensees" and "source material milling licensees" in accordance with implementation of P.L. 95-604 (UMTRCA) (Page C28 of 1978 SSRCR).

C.26(c)(2)(iv) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material. The first sentence was revised and (a) through (d) added in accordance with recent NRC regulation changes, 45 FR 41393 (Page C31 of 1978 SSRCR).

C.26(c)(2)(v) of the 1978 Edition, Specific Licenses for Certain Groups of Medical Uses of Radioactive Material. Entire Subdivision (v) of the 1978 SSRCR was deleted and moved to Part G in order to locate all medical sealed source aspects within the same part of the model regulations, 44 FR 10358 (Pages C31 and C32 of 1978 SSRCR).

C.26(e)(3) Use of Sealed Sources in Industrial Radiography. This Subparagraph has been amended to include user performance aspects of Agency regulations and record retention in accordance with NRC changes effective March 3, 1980 (Page C35 of 1978 SSRCR).

C.28(c) Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. A sentence was added to limit the maximum quantity of radium-226 in exemptable gas and aerosol detectors that are manufactured in compliance with NARM Guide No. 3 (Page C42 of 1978 SSRCR).

C.28(h)(4)(i) and (ii) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. The term "Veterinarian" has been inserted in accord with recent changes in NRC regulations, 44 FR 50329 (Pages C48 and C49 of 1978 SSRCR).

C.28(j)(2)(i) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses and C.28(k)(2)(i) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. The phrase "a biologic product license issued by FDA" was deleted due to biologic product changes by FDA (Pages C49 and C50 of 1978 SSRCR).

C.29 Special Requirements for Issuance of Specific Licenses for Source Material Milling. A new section, including Paragraphs (a) through (f), has been added for states to maintain equivalency with NRC as required by P.L. 95-604 (UMTRCA) (Page C55 of 1978 SSRCR).

C.31 Specific Terms and Conditions of License. New paragraph (d) has been added that requires the licensee to notify the Agency that all licensed activities are being permanently discontinued (Page C56 of the 1978 SSRCR).

C.32 Expiration of Licenses. The phrase "end of the day" has been amended to read "end of the specified day" in order to preclude misinterpretation (Page C56 of the 1978 SSRCR).

C.100 Transportation of Radioactive Material. Section C.100 was revised and expanded in Sections C.101, C.102, C.103, and C.104 as a result of amendments to NRC regulations published November 2, 1979, 44 FR 63083.

Appendix A. The units of concentration were corrected to read "µCi/ml" in Columns I and II (Page C66 of the 1978 SSRCR). Note 3 was added to convert customary units to SI units and an example for performing a typical conversion was also presented (Page C69 of 1978 SSRCR).

Appendix B. Appendix B was amended to include Ge-68, Y-88, and Au-195, which are accelerator-produced materials, due to their use in the medical and research communities. Note 2 was added to convert customary units to SI units and an example for performing a typical conversion was also presented (Page C74 of 1978 SSRCR).

Appendix D. Note 1 was added to convert customary units to SI units and an example for performing a typical conversion was also presented (Page C85 of 1978 SSRCR).

Matters for Future Consideration

1. It is suggested that Subdivisions C.28(j)(2)(ii) and C.28(k)(2)(ii) be revised for consistency with FDA regulations. This provision should be revised in conjunction with revision of 10 CFR 32.72(a)(2)(ii)

and 32.73(a)(2)(ii) and in cooperation with the NRC and the National Center for Drugs and Biologics (NCDB), Food and Drug Administration (FDA), for compatibility with the regulations of those agencies (e.g., substitute "is to be exclusively intrastate and has been reviewed and approved by the Agency for its acceptability" for "are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act)".

2. In Subparagraph C.28(g)(1), the phrase "or in accordance with a license for a biologic product issued by the Secretary, U.S. Department of Health and Human Services" should be revised for consistency with FDA regulations. This revision should be completed in conjunction with a revision of 10 CFR 32.70(b) and with the cooperation of the NRC and the NCDB, FDA, for compatibility with the regulations of those agencies.

3. It is suggested that consideration be given to adding data for a number of NARM nuclides already appearing in Appendix B, Exempt Quantities, to the Appendix A, Exempt Concentrations listing (i.e., gallium-67, indium-111, iodine-123, iron-52, potassium-43, sodium-22, and yttrium-87).

4. Consider the possibility of including data for certain short-lived radionuclides in Appendix B, Exempt Quantities (e.g., carbon-11, nitrogen-13, and oxygen-15).

5. The regulation of NORM is to be accomplished by what mechanism - specific and/or general licenses, exemptions and/or de minimus levels?

6. Question the 30-day timely renewal period provision of Paragraph C.33(b) for uranium mill and radioactive waste disposal licenses.

7. Accelerator-produced radioactivity in recyclables needs an exemption, a general license, or a de minimus level.

8. Look into the inconsistencies between the calibration sources allowed for medical specific licensees versus other specific licenses (Subdivisions C.26(c)(4)(iv) and C.22(g)) with regard to alpha-emitting sources.

9. Use of the word "radionuclide" instead of "isotope" in the Appendices notes throughout the SSRCR, as appropriate.

10. The inclusion of lead-210 into exempt items in Paragraph C.4(c) and their manufacture and distribution in Section C.28.

1978
Rationale for Revisions

Part C
Licensing of Radioactive Material

Introduction

Part C of the Suggested State Regulations for Control of Radiation (SSRCR) was last revised in October 1974. There have been several discussions by committees of the Conference of Radiation Control Program Directors, Inc. (CRCPD) since then regarding regulatory provisions for the manufacture, assembly, and distribution of Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) and the Licensing State concept (for NARM). Also, the U.S. Atomic Energy Commission (AEC) was reorganized into the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Energy Research and Development Administration (ERDA) by the Energy Reorganization Act of 1974, and ERDA later became part of the U.S. Department of Energy. Primarily, the revisions from the 1974 edition of the SSRCR concern NARM provisions and NRC regulation changes. The specific changes to Part C of this revision and their rationale are as indicated below. (The headings and other references are to this revision of the SSRCR, except for the information in parentheses following the specified revision relating it to the 1974 SSRCR.)

Specific Provisions

Sec. C.3 Source Material

C.3(c)(1)(vii) Source Material. Subdivision (vii) has been added per amendment to NRC regulations (Page C2, line 63 of 1974 SSRCR).

C.3(c)(5)(i) Source Material. Reference to "Agency" and "Agreement State" deleted; "U.S. Atomic Energy Commission" changed to read "U.S. Nuclear Regulatory Commission"; and "10 CFR Part 40" cited to indicate that only the NRC can authorize the manufacture and distribution of uranium in counterweights installed in aircraft, rockets, projectiles, and missiles and does not delegate that authority to the Agreement States (Page C2, lines 95-100 of 1974 SSRCR).

C.3(c)(6) Source Material. Revised for consistency with more recent recodification of Department of Transportation regulations (Page C3, lines 116-122 of 1974 SSRCR).

Sec. C.4 Radioactive Material Other Than Source Material

C.4(a)(2) Exempt Concentrations. "U.S. Atomic Energy Commission" changed to read "U.S. Nuclear Regulatory Commission" due to reorganization of AEC. "Licensing State" was added in recognition of those states licensing NARM (Page C4, lines 172-173 of 1974 SSRCR). Definitions for both "NARM" and "Licensing State" have been included in Part A of the SSRCR.

C.4(b)(2) Exempt Quantities. A statement excepting radium-226 from exemption has been added due to its long physical half-life, radiotoxicity, and other health physics considerations: "Such exemption does not apply for radium-226." When generally licensed quantities were transferred to exempt quantities, radium-226 was included with the exempt quantities; however, the working group did not feel that any long-lived alpha emitters should be considered an exempt quantity, which is consistent with Schedule B of Part C (Page C4, line 191 of 1974 SSRCR).

C.4(b)(4) Exempt Quantities. "U.S. Atomic Energy Commission" changed to read "U.S. Nuclear Regulatory Commission" (Page C4, line 203 and Page C5, lines 204, 205, and 209 of 1974 SSRCR).

C.4(c)(1)(i) Exempt Items. The term, "byproduct material," changed to read "radioactivematerial" because formerly distributed radium watches are exempt and radium is not byproduct material (Page C5, line 224 of 1974 SSRCR).

C.4(c)(1) footnote 2/. "Source material" has been deleted, as "source material" is not contained in any of the "certain items" given. "U.S. Atomic Energy Commission" changed to read "U.S. Nuclear Regulatory Commission." See item on "Part C Footnote Changes" (Page C5 of 1974 SSRCR).

C.4(c)(1)(i)(h) Exempt Items. Subdivision (h) has been added. This exempts radium timepiece dials containing a maximum of 1 microcurie of activity providing the timepiece was acquired before the effective date of the regulation, in recognition that radium dial timepieces are in existence and the need to include a "grandfather" clause rather than issue a specific license to each owner (Page C6, line 259 of 1974 SSRCR).

C.4(c)(1)(iii) Exempt Items - Certain Items Containing Radioactive Material. "Balances of precision" has been changed to read "Precision balances" as the latter was determined to be a preferable term and is the usual terminology for these devices (Page C6, line 268 of 1974 SSRCR).

C.4(c)(1)(viii) Exempt Items - Certain Items Containing Radioactive Material. "Byproduct material" changed to read "radioactive material" as some calibration standards contain radium and Schedule B referred to includes both byproduct material and NARM (Page C7, line 310 of 1974 SSRCR).

C.4(c)(2) Exempt Items - Self-Luminous Products Containing Radioactive Material. The title, "Self-luminous products containing tritium, krypton-85, or promethium-147", was changed to "Self-Luminous Products Containing Radioactive Material" and the subparagraph now consists of two subdivisions (i) and

(ii). Some self-luminous products contain radium-226 and this provision (i.e., Subdivision C.4(c)(2)(ii)) was added to exempt those radium products containing less than 0.1 microcurie of radium and acquired prior to the effective date of the regulations (Page C7, lines 314-326 of 1974 SSRCR).

C.4(c)(3)(i) Exempt Items - Gas and Aerosol Detectors Containing Radioactive Material. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission" and "Agreement State" was deleted. Also, "Licensing State" was inserted and "C.28(c)" substituted for "equivalent." These latter two revisions were made to provide a basis of authorization for Licensing States to better control NARM. This subdivision has been restructured to provide authorization to manufacturers in Licensing States to manufacture gas and aerosol detectors pursuant to Paragraph C.28(c) and to distribute these detectors to persons exempt from regulatory requirements (Page C7, lines 331-344 of 1974 SSRCR).

C.4(c)(3)(iii) Exempt Items - Gas and Aerosol Detectors Containing Radioactive Material. Subdivision (iii) has been added. This provides a basis for recognizing the exemption of previously manufactured gas and aerosol detectors which contain radium-226 - i.e., authorizing possession of detectors manufactured in Licensing States prior to licensure of the manufacturers (Page C7, line 353 of 1974 SSRCR).

C.4(c)(4) Exempt Items - Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission" (Page C8, lines 362 and 366 of 1974 SSRCR).

Sec. C.21 General Licenses - Source Material

C.21(d) Depleted Uranium in Industrial Products and Devices. In September 1971, NL Industries, Inc., of Albany, New York filed a petition for rule making with NRC (then AEC) to amend Part 40, "Licensing of Source Material", to exempt from licensing uranium contained in shielding for medical x-ray units, tool holders for vibration damping, and commercial products for mass volume applications. On January 10, 1975, the NRC published a notice of proposed rule making in the Federal Register. The proposed amendments to Part 40 established a general license for the possession and use of depleted uranium in industrial products for the purpose of providing a concentrated mass in a small volume. The amendments also set out requirements concerning the manufacture of such products.

Because of the fact that in recent times there has been increasing demand for information on the distribution of radioactive material in widely distributed commercial, industrial or consumer products, the NRC proposed to institute a registration program for these general licensees. The objectives of the registration requirement are: (1) to provide a means of identifying the general licensee, (2) to provide the Commission an opportunity to inform the general licensee of the terms and conditions of the general license upon first receipt of depleted uranium, and (3) to facilitate subsequent communication with the general licensee.

In a July 11, 1975 letter to all Agreement States the NRC provided specific details on the registration

program to the states. The NRC felt that for the registration program to be comprehensive, it would be desirable to have the states participate. No adverse comments were received from the states.

The proposed amendments to the SSRCR, Section A.2, Paragraphs C.21(d) and C.28(m) therefore incorporate the equivalent to the NRC effective rule, dated January 3, 1977, including the terms and conditions of the general license, registration requirements, and manufacturing requirements. Because of the previous lack of adverse comments, it is expected that the Agreement States will adopt these amendments in their entirety.

Sec. C.22 General Licenses - Radioactive Material Other Than Source Material

C.22(a) Certain Devices and Equipment. References to "C.28(f)", "Agency", and "Agreement State" have been deleted and "Atomic Energy Commission" changed to "Nuclear Regulatory Commission". Presently only the NRC can authorize the manufacture of these static elimination and ion generating devices containing byproduct material (Page C9, lines 443-447 of 1974 SSRCR).

C.22(d) Certain Measuring, Gauging, or Controlling Devices. Paragraph C.22(d) has been revised to reflect amendments to NRC regulations and the Licensing State concept. Subparagraph (1) specifies to whom the general license applies; Subparagraph (2) specifies what material and devices are relevant to the general license; Subparagraph (3) specifies the responsibilities of persons who possess or transfer radioactive material pursuant to the general license; Subparagraph (4) specifies that Subparagraph C.22(d)(1) does not authorize the manufacture; Subparagraph (5) specifies the other sections that apply to the general license given in Subparagraph C.22(d)(1). These revisions were made to provide Licensing States with regulations for controlling NARM, present the matter in straightforward manner, accommodate limits for record retention as required by the NRC and to change "Atomic Energy Commission" to read "Nuclear Regulatory Commission" (Pages C10, C11, and C12 of 1974 SSRCR).

C.22(e) Luminous Safety Devices for Aircraft. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission" (Page C12, lines 595-596 and lines 601-602 of 1974 SSRCR).

C.22(g) Calibration and Reference Sources. Paragraph C.22(g) has been reorganized. Subparagraph C.22(g)(3) of this revision of the SSRCR has been added to provide a basis for general licensing of radium-226 calibration sources and has been inserted after Subparagraph C.22(g)(2), thereby changing Subparagraphs C.22(g)(3) - (5) in the 1974 SSRCR to Subparagraphs C.22(g)(4) - (6) in this revision. (The old exempt radium sources previously covered under Section C.4 and the radium sources under Paragraph C.22(k) of the 1974 SSRCR that were for calibration and reference sources were included in Paragraph C.22(g) of this revision of the SSRCR along with the americium-241 and plutonium calibration and reference sources, and the general license is applicable only to those who already have a specific license.) In Subdivision C.22(g)(1)(ii), "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission". In Subparagraph C.22(g)(2), "C.22(g)(3) and (4)" has been changed to read

"C.22(g)(4) and (5)." In Subparagraph C.22(g)(4), "(3)" and "Licensing State" have been added and "Atomic Energy Commission" changed to read "Nuclear Regulatory Commission". In Subparagraph C.22(g)(5), "(3)" has been added and subdivision (i) specifies that "...5 microcuries of radium-226..." is the possession limit. Further, in Subparagraph C.22(g)(5), separate labels are specified for reference sources containing americium-241 or plutonium (Subdivision C.22(g)(5)(ii)(a)) and radium-226 (Subdivision C.22(g)(5)(ii)(b)); "Licensing State" has been added in (iii); and the storage conditions in (iv) are also applied to radium-226. In Subparagraph C.22(g)(6), the manufacture of "radium-226" reference sources is not authorized by the general license. These revisions were made to provide Licensing States with regulations for controlling NARM, particularly as radium-226 reference sources are commonly used. Also, "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission" where indicated due to the Energy Reorganization Act of 1974 (Pages C14 - C15 of the 1974 SSRCR).

C.22(h)(1) Medical Diagnostic Uses. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission". "Licensing State" has been included as only a Licensing State can grant a general license for the use of cobalt-57 as given in Subdivision C.22(h)(1)(iv) - cobalt-57 is NARM, i.e., accelerator-produced (Page C16, lines 107-108 of the 1974 SSRCR).

C.22(h)(3)(v) Medical Diagnostic Uses. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission". "Licensing State" has been included for reasons given for Subparagraph C.22(h)(1) above (Page C17, lines 190-191 of the 1974 SSRCR).

C.22(i)(1)(vi) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing. Subdivision "(vi)" has been added to extend the general license to cobalt-57 in vitro kits which are commonly available (Page C19, line 248 of the 1974 SSRCR).

C.22(i)(3)(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing. The radionuclide "cobalt-57" has been added to place a "total amount" storage limit of 200 microcuries on cobalt-57 (Page C19, line 280 of the 1974 SSRCR).

C.22(i)(3)(iv) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission". "Licensing State" has been included as only a Licensing State can authorize the receipt of cobalt-57, i.e., NARM (Page C19, lines 292-293 of the 1974 SSRCR).

C.22(i)(4)(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission". Also, "Licensing State" and "cobalt-57" have been included since a Licensing State can authorize the possession or use of NARM (Page C20, lines 303-305 of the 1974 SSRCR).

C.22(i)(4)(ii) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing. The label in the 1974 SSRCR applies only to byproduct material; in this revision of the SSRCR, it is denoted by "(a)" and "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission". A separate label "(b)" has been added for NARM (e.g., Co-57) which is controlled by a Licensing State (Page C20, lines 309-329 of the 1974 SSRCR).

C.22(j)(1) and (2)(i) Ice Detection Devices. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission" (Page C21, lines 353, 358, and 368-369 of the 1974 SSRCR).

The 1974 SSRCR C.22(k) entitled "General Licensed Quantities for Radium-226" has been eliminated in its entirety. Radium sources should not be exempt nor generally licensed without specific applications and requirements placed upon their use. The only radium products formerly covered by Paragraph C.22(k) were calibration and reference sources and are presently covered in this SSRCR by the reorganized Paragraph C.22(g), particularly Subparagraph C.22(g)(3) (Pages C21-C23, lines 389-456 of the 1974 SSRCR).

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

C.25(e) and (f) Bonding and Perpetual Care Requirements. Paragraphs C.25 "(e)" and "(f)" have been added for "Bonding Requirements" and "Perpetual Care Requirements" respectively. The bonding and perpetual care requirements and definitions Paragraph A.2(p), (y), (ac), and (bi) were developed by the CRCPD's Task Force on Bonding and Perpetual Care of Licensed Nuclear Activities. These proposed changes to the SSRCR appeared as Appendix C of the Task Force Report dated April 5, 1976. (See "Report of the Task Force on Bonding and Perpetual Care of Nuclear Licensed Activities", pages 252-271, especially Appendix C on pages 268-269, of the proceedings of the Seventh Annual National Conference on Radiation Control, held April 27-May 2, 1975 in Hyannis, Massachusetts.) The NRC is currently reevaluating its position with regard to decommissioning of nuclear facilities and radioactive residue disposal, and as part of the reevaluation is considering various bonding proposals. Nothing in these suggested regulations should be interpreted as reflecting current or future NRC policy with regard to bonding and/or decommissioning (Page C24, lines 546 of the 1974 SSRCR).

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

C.26(c) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material. Paragraph C.26(c) "Groups of diagnostic uses" of the 1974 SSRCR has been retitled and has been extensively amended, including an expansion from two to six groups. These revisions have been made to update Part C in accordance with recent changes in NRC regulations (10 CFR Part 35) and provide a regulatory basis for Licensing State control of those NARM products applicable to certain groups of medical uses. An insert has been made in the criteria for Group VI to reflect that the leak test for radium-226 sources is a gas emanation test which must satisfy the criteria of Part G, SSRCR, rather than the standard wipe of 0.005

microcurie (Page C25, lines 598-616 of the 1974 SSRCR).

Sec. C.27 Special Requirements for Specific Licenses of Broad Scope

C.27(e)(1) Specific Licenses of Broad Scope. The words, "Unless specifically authorized," have been added to clarify the statement given in Subparagraph C.27(e)(1) and for consistency with 10 CFR 33.17 (Page C30, line 843 of the 1974 SSRCR).

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

C.28(a) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. As a matter of maintaining consistent format, Paragraph C.28(a) has been recodified into 2 subparagraphs and 2 subdivisions within the new Subparagraph C.28(a)(1) (Page C31, lines 882-922 of the 1974 SSRCR).

C.28(b)(1) Licensing the Distribution of Radioactive Material in Exempt Quantities. The acronym "NARM" has been substituted for "radioactive material other than source or byproduct material" as a point of clarification (Page C32, lines 928-929 of the 1974 SSRCR).

C.28(b)(2)(iv) and (3) Licensing the Distribution of Radioactive Material in Exempt Quantities. "Licensing State" has been substituted for "U.S. Atomic Energy Commission" and/or "Agreement State" as only a Licensing State has authority to permit the distribution of NARM in exempt quantities. Reporting requirements of the manufacturer were expanded to include reporting the distribution of generally licensed devices containing NARM to the appropriate regulatory agency of each individual state to which a device is transferred (Page C33, lines 972-995 of the 1974 SSRCR).

C.28(c) Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. "NARM" or its extended form has been substituted for "radioactive material other than source or byproduct material" as a point of clarification (Page C33, lines 998-1004 of the 1974 SSRCR).

C.28(d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under C.22(d). The heading of Paragraph C.28(d) has been amended and the content of Paragraph C.28(d) has been extensively reorganized and revised in accord with changes in NRC regulations (10 CFR 32.51, 32.51a, and 32.52) on this matter and to provide similar regulatory authority for control by Licensing States and Agreement States. Particularly, dose limits under accident conditions, further labeling information, and record keeping aspects have been added (Page C33-C35, lines 1010-1091 of the 1974 SSRCR).

C.28(f) Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.22(g). "Radium-226"

has been added to provide for the control of calibration sources containing radium-226 (Page C35, lines 1110 and 1115 of the 1974 SSRCR).

C.28(g)(2) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In Subparagraph C.28(g)(2) the words, "The following statement" were changed to "one of the following statements, as appropriate" and labels (i) and (ii) for byproduct material and NARM (e.g., Co-57) respectively have been included. Since derivation of the NARM authority is legally distinct from the original byproduct material authority, different labels need to be applied according to the radioactive content of the drug (Page C36, lines 15-29 of the 1974 SSRCR).

C.28(h)(2)(vi) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. "Cobalt-57" has been added as Subdivision C.28(h)(2)(vi) as it is commonly available in prepackaged units (Page C37, line 52 of the 1974 SSRCR).

C.28(h)(3) and (4) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. "Cobalt-57" has been added to Subdivision C.28(h)(3)(i). In Subparagraph C.28(h)(4), the words, "The following statement" were changed to "One of the following statements, as appropriate". Labels for byproduct material and NARM have been included as Subdivisions C.28(h)(4)(i) and (ii) for similar reasons as those given for Subparagraph C.28(g)(2) above (Pages C37, lines 56-86 of the 1974 SSRCR).

C.28(j) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses

C.28(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material

C.28(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. Paragraphs "(j)", "(k)", and "(l)" of Section C.28 have been added for the manufacture and distribution of radiopharmaceuticals, generators or reagent kits, and medical sources or devices, respectively, and provide consistency with amendments to NRC regulations (10 CFR 32.72, 32.73 and 32.74). These revisions have been made to provide regulatory language for licensing the manufacture and distribution of the products described in "(j)", "(k)", and "(l)" which heretofore had not been incorporated in Part C, but whose possession and use is permitted by Paragraph C.26(c) as presently revised (Page C37, line 98 of the 1974 SSRCR).

Sec. C.36 Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of These Regulations. "Atomic Energy Commission" has been changed to "Nuclear Regulatory Commission" (Page C39, lines 168-169 and 172 of the 1974 SSRCR).

Sec. C.37 Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material on Effective Date of These Regulations. "Naturally Occurring and Accelerator-Produced Radioactive Material" has been substituted for "Radioactive Material other than Source, Byproduct, or Special Nuclear Material" in the title and the acronym "NARM" has been used in the text of Section C.37 as a point of clarification (Page C39, lines 174-175 and line 177 of the 1974 SSRCR).

Sec. C.40 Transfer of Material

C.40(b)(2) Transfer of Material. "Atomic Energy Commission" has been changed to read "U.S. Department of Energy" due to the Energy Reorganization Act of 1974 and the Department of Energy Organization Act (Page C40, line 196 of the 1974 SSRCR).

C.40(b)(4) Transfer of Material. "Atomic Energy Commission" changed to read "Nuclear Regulatory Commission" and "Licensing State" has been included. Some of the transferable radioactive material is NARM, hence is authorized by a Licensing State (Page C40, lines 204 and 207 of the 1974 SSRCR).

C.40(c) Transfer of Material. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission" and "Licensing State" has been included for similar reasons as those given for the preceding Subparagraph C.40(b)(4) (Page C40, lines 212-214 of the 1974 SSRCR).

C.40(d)(4) and (5) Transfer of Material. "Atomic Energy Commission" has been changed to read "Nuclear Regulatory Commission" and "Licensing State" has been included for similar reasons as those given for Subparagraph C.40(b)(4) above (Page C41, lines 240-241 and lines 248-249 of the 1974 SSRCR).

Sec. C.90 Reciprocal Recognition of Licenses. Section C.90 has been reorganized to accommodate the reciprocal recognition of both byproduct material and NARM licenses. Hence, paragraphs (a) and (b) now read "Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass" and "Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material", respectively. The substance of both paragraph (a) and paragraph (b) is essentially the same as the 1974 Edition of the SSRCR and only minor changes regarding "Nuclear Regulatory Commission", "Licensing State", and the elimination of the word "section" have been made. The NRC and Agreement States have jurisdiction for licensing byproduct, source and special nuclear material whereas, Licensing States have jurisdiction for licensing NARM (Page C42-C43 of the 1974 SSRCR).

Part C Footnote Changes: No significant changes have been made to footnotes 1, 3, 4 and 5. Footnote 2 has been revised as noted in the rationale for Subparagraph C.4(c)(1). Former footnote 6 of the 1974 SSRCR has been revised and renumbered 12 in this revision of the SSRCR. Former footnotes 7, 8, 9 and 9a in the 1974 SSRCR have been renumbered 6, 7, 8 and 9 respectively in this SSRCR. A new footnote 10 has been added regarding perpetual care. Former footnote 10 has been renumbered 11 and revised by

deleting "source material". Former footnotes 11 and 12 have been renumbered 13 and 14, respectively, in this revision of the SSRCR.

Schedule A of Part C. Polonium-210, radium-226, and radium-228 have been deleted. These are alpha emitting radionuclides and are not permitted exemption under the intent of Subparagraph C.4(a)(2) (Page C47, lines 130 and 136-137 of the 1974 SSRCR).

Schedule C of Part C. Groups I and II have been amended by several new procedures and new Groups III, IV, V and VI have been added to accommodate new medical uses and procedures using radioactive material. These revisions incorporate changes to NRC regulations and provide a regulatory basis for controlling NARM such as iodine-123, fluorine-18, cobalt-57, radon-222, radium-226, and strontium-87m.

NOTE: Under the wording submitted by NRC, any Investigational New Drug material is automatically covered under the appropriate group. For states where this requires specific action by the State (such as verifying the submission of FDA forms 1571 or 1573), such inclusion in this schedule may be inappropriate and should be deleted.

Matters for Future Consideration

1. In Subdivision C.28(j)(2)(i) and in Subdivision C.28(k)(2)(i), it is suggested that the phrase, "a biologic product license issued by FDA", be deleted for consistency with FDA regulations. This action should be taken in concert with the NRC's deletion of the same phrase from 10 CFR 32.72(a)(2)(i) and 32.73(a)(2)(i) in order to maintain compatibility with those regulations.

2. It is suggested that Subdivisions C.28(j)(2)(ii) and C.28(k)(2)(ii) be revised for consistency with FDA regulations. This provision should be revised in conjunction with revision of 10 CFR 32.72(a)(2)(ii) and 32.73(a)(2)(ii) and in cooperation with the NRC and the Bureau of Drugs, FDA for compatibility with the regulations of those agencies (e.g., substitute "is to be exclusively intrastate and has been reviewed and approved by the Agency for its acceptability" for "are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act)".

3. In Subparagraph C.28(g)(1), the phrase "or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education, and Welfare" should be revised for consistency with FDA regulations. This revision should be completed in conjunction with a revision of 10 CFR 32.70(b) and with the cooperation of the NRC and the Bureau of Drugs, FDA for compatibility with the regulations of those agencies.

4. It is suggested that consideration be given to adding data for a number of NARM nuclides already

appearing in Schedule B, Exempt Quantities, to the Schedule A, Exempt Concentrations listing (i.e., gallium-67, indium-111, iodine-123, iron-52, potassium-43, sodium-22, and yttrium-87).

5. Consider the possibility of including data for certain short-lived radionuclides in Schedule B, Exempt Quantities (e.g., carbon-11, nitrogen-13, and oxygen-15).

6. In Subdivisions C.22(i)(1)(i) - (viii), it is suggested that rather than repeating subdivisions (i) through (viii), which are essentially similar except for radionuclide and quantity, a listing of these radionuclides and their quantities, and a single sentence describing their use, would suffice.

7. It is suggested that consideration be given to revising the definition of "NARM" to clearly exclude "special nuclear material in quantities not sufficient to form a critical mass" similar to the exclusion of "source material" in the present definition of NARM (e.g., "'NARM' means any naturally occurring or accelerator-produced radioactive material except source material and special nuclear material" or "'NARM' means naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material").

8. In Paragraph C.4(c) on Exempt Items of Radioactive Material Other than Source Material, it is suggested that further consideration be given to the following: The quantities of radioactivity on manufactured items should be circumscribed by limits on accessible emitted radiation to insure the integrity of the item, and instructions for disposal or other action of defective items should be incorporated.

9. Paragraph (c) of Section C.28 on Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors raises a question with respect to the relationship between the NARM Guides and Part C of the SSRCR. The NARM Guides for such detectors (NARM Guide 3) contain a requirement providing a limit on the amount of radioactive material in the detector, which is not included in Paragraph C.28(c). This paragraph or NARM Guide 3 should be revised to obtain consi requirements. stency between the guides and the SSRCR.

10. In Schedule C, Groups of Medical Uses of Radioactive Material, it is suggested that the radionuclides within each group (i.e., Groups (1)-(6)) be organized alphabetically for the next revision of the SSRCR (i.e., in a manner consistent with those in Schedules A and B).

11. In C.21(a)(1)-(3), a general license is issued to pharmacists to use source material. The question was raised as to whether it is current practice for pharmacists and physicians to use source material in medicines or whether it is a carry-over from an earlier period. If it is unnecessary, consideration should be given to omitting these provisions.

12. It was suggested that consideration be given to adding to the definition of Licensing State, a statement indicating that the effective program for the regulatory control of NARM has been reviewed and certified by some group - e.g., "...an effective program as reviewed and certified by the Conference of Radiation Control Program Directors, Inc.".

13. It was requested that consideration be given to including something in the SSRCR to accommodate byproduct, source and special nuclear material until a State becomes an Agreement State. The following proposed section was suggested for consideration.

    Sec. C.2 Agency Licensing Activities.

    (a) Until this State becomes an Agreement State, the Agency will not issue licenses authorizing the possession or use of byproduct, source, or special nuclear material. This paragraph shall take precedence over other requirements of this part.

    (b) Persons possessing or using radioactive material in this State, unless exempted by these regulations, are required to be in possession of a current NRC or Agency issued license.

    (c) Persons possessing or using radioactive material in this State under the authority of a NRC issued license shall also register such possession or use of radioactive material with the Agency.

14. In Subdivision C.28(b)(1)(ii) and Paragraph C.28(c), consider aspects for improving language and discuss means of implementing the Nuclear Energy Agency (NEA) standard on ionization chamber smoke detectors, particularly labeling.

1974
Rationale for Revisions

Part C
Licensing of Radioactive Material

I. Reorganization

Two major reorganizations have been made to Part C in order to improve the clarity and to facilitate the location of appropriately relevant material under section or subsection titles. Where substantive changes have been made in the text of sections involved in these reorganizations, they will be covered under the specific topic below.

A. Exempt Radioactive Material

The first reorganization involves Section C.4 where exempt concentrations, quantities and items are now located under subsections of the same title. The revised organization of Section C.4 is as follows with notation of the existing organization in the right-hand margin:

Revised	Present
C.4(a) Exempt Concentrations	C.4(a)
C.4(b) Exempt Quantities	C.4(f)
C.4(c) Exempt Items	
(1) Certain items containing radioactive material	C.4(b)
(2) Self-luminous products containing tritium, krypton-85, or promethium-147	C.4(e)
(3) Gas and aerosol detectors containing radioactive material	C.4(d)
(4) Resins containing scandium-46 and designed for sand consolidation in oil wells	C.4(c)

B. Specific License Requirements

The reorganization of specific license requirements was designed to provide a more logical arrangement and to incorporate material covering the licensure of individuals to manufacture or

to distribute products containing radioactive material. The Technical Review Committee which met in March 1974, recommended the addition of material to cover the uniform control of manufacture and distribution and the creation of a new Section C.28. As noted in the following outline, the new Section C.28 includes several new sections which have been patterned after or refer to requirements of the AEC regulations.

Revised		Present
C.26	Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material	C.26
C.26(a)	Human Use of Radioactive Material in Institutions	C.26(a)
C.26(b)	Licensing of Individual Physicians for Human Use of Radioactive Material	C.26(b)
C.26(c)	Groups of Diagnostic Uses	C.26(c)
C.26(d)	Human Use of Sealed Sources	C.26(d)
C.26(e)	Use of Sealed Sources in Industrial Radiography	C.26(f)
C.27	Special Requirements for Specific Licenses of Broad Scope	C.27
	(unchanged)	
C.28	Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material	new
C.28(a)	Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. This is essentially "present" C.26(g) and relates to C.4(a).	C.26(g)
C.28(b)	Licensing the Distribution of Radioactive Material In Exempt Quantities. This relates to C.4(b).	new
C.28(c)	Licensing the Incorporation of Radioactive Material other than Source or Byproduct Material into Gas and Aerosol Detectors. This relates to C.4(c)(3).	

C.28(d)	Distribution of Devices to Persons Generally Licensed Under C.22(d). This relates to C.22(d).	C.26(e)
C.28(e)	Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. This relates primarily to C.22(e).	new
C.28(f)	Special Requirements for License to Manufacture Calibration Sources Containing Americum-241 or Plutonium for Distribution to Persons Generally Licensed Under C.22(g). This relates primarily to C.22(g).	new
C.28(g)	Manufacture and Distribution of Radioactive Material for for Medical Use Under General License. This is essentially "present" C.26(h) and relates primarily to C.22(h).	C.26(h)
C.28(h)	Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. This relates to C.22(i).	C.26(i)
C.28(i)	Licensing the Manufacture and Distribution of Ice Detection Devices. This relates to C.22(j).	new

II. Part J References

As noted below, Part J has been added to maintain compatibility with the new 10 CFR Part 19 of AEC regulations, the provisions of which are comparable to those provided by the Department of Labor for inspections pursuant to the Occupational Safety and Health Act. In order to fully incorporate Part J into the regulations, it is necessary to transfer some material from Part D and to incorporate a reference to Part J in the following paragraphs of Part C:

C.21(b)		
C.22(a)		
C.22(e)	(2)	
C.22(h)	(5)	
C.22(i)	(6)	
C.22(j)	(2)	(iii)

III. Editorial Updating

Revisions have been made in order to maintain consistent terminology within Part C when referring to applicable provisions. The terms, "of this paragraph, subdivision," etc., have been eliminated and applicable provisions are referenced by the specific numeral designations, e.g., Subparagraph C.28(a)(2).

IV. Specific Changes

C.4(c)(1)

Rationale: C.4(c)(1). The specific reference to radium in the present C.4(b) has been deleted in the new C.4(c)(1). Formerly, the receipt, possession, use, transfer, ownership, or acquisition of radium timepieces were exempt from these regulations. Since neither the kind of timepiece nor the quantity of radium contained on its hands or dial was specified, any kind of timepiece with any quantity of radium was exempt. The Working Group felt that the continuance of this is unacceptable; furthermore, the relative hazards of radium indicate that it is imprudent to specify the kinds of timepieces and quantities of radium on their hands and dials which should be exempt from these regulations.

C.4(c)(3)

Present C.4(d) Gas and aerosol detectors containing byproduct material. Except for persons who manufacture, process, or produce gas and aerosol detectors containing byproduct material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing byproduct material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Atomic Energy Commission pursuant to Section 32.26 of 10 CFR Part 32 which license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

Revised C.4(c)(3) Gas and aerosol detectors containing radioactive material

(i) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from 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, imported, or transferred in accordance with a specific license issued by the U.S. Atomic Energy Commission2/ or an Agreement State, pursuant to Section 32.26 of 10 CFR Part 32, or equivalent, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under Subdivision C.4(c)(3)(i), provided that the

device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and provided further that they meet the requirements of Paragraph C.28(c).

Rationale: C.4(c)(3). Amended to accommodate the receipt, possession, use, transfer, ownership, or acquisition of other radioactive material, in addition to byproduct material which is contained in gas and aerosol detectors. This change, in effect, permits the receipt, possession, use, transfer, ownership, or acquisition of any and all radioactive material contained in gas and aerosol detectors which were manufactured, imported, or transferred in accordance with requirements equivalent to those specified in Section 32.26 of 10 CFR 32. Subdivision (i) provides for all radioactive material and subdivision (ii) provides for the radioactive material contained in devices which have been previously distributed.

C.20

Present Sec. C.20 Types of Licenses. Licenses for radioactive materials are of two types: general and specific. General licenses provided in this Part are effective without the filing of applications with the Agency or the issuance of licensing documents to particular persons. Specific licenses are issued to named persons upon application filed pursuant to this Part.

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

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

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

Rationale: C.20. Reorganized into (a) and (b) and each explanation expanded for clarity.

C.22(i)

Present C.22(i) General License for Use of Iodine-125 or Iodine-131 for In Vitro Clinical or Laboratory Testing9/

Revised C.22(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing9/

C.22(i)(1)

Addition (iii) Carbon-14, in units not exceeding 10 microcuries each 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.

Addition (iv) Hydrogen-3 (tritum), in units not exceeding 50 microcuries each 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.

Addition (v) Iron-59, in units not exceeding 20 microcuries each 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.

Rationale: C.22(i)(1). In vitro procedures for carbon-14, hydrogen-3, and iron-59 are being added within Subparagraph C.22(i)(1) to accommodate recent amendments to Parts 31 and 32 of AEC regulations.

C.22(i)(3)(i)

Present (i). The general licensee shall not possess at any one time pursuant to the general license in subparagraph (1) of this paragraph, at any one location of storage or use a total amount of iodine 125 and/or iodine 131 in excess of 200 microcuries.

Revised (i). The general licensee shall not possess at any one time, pursuant to the general license in Subparagraph C.22(i)(1) at any one location of storage or use a total amount of iodine-125, iodine-131, and/or iron-59 in excess of 200 microcuries.

Rationale: C.22(i)(3)(i). A maximum possession limit for the new addition of iron-59 is specified in keeping with amendment to Parts 31 and 32 of AEC regulations.

C.22(i)(4)(i)

Present (i). Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under Paragraph C.26(i) of this Part or in accordance with the provisions of a specific license issued by the U. S. Atomic Energy Commission, or any Agreement State which authorizes the manufacture of iodine-125 or iodine-131 for distribution to persons generally licensed under Paragraph C.22(i) or its equivalent.

Revised (i) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the U. S. Atomic Energy Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritum), or iron-59 for distribution to persons generally licensed under Paragraph C.22(i) or its equivalent, and

Rationale: C.22(i)(4)(i). Accommodate carbon-14, hydrogen-3, and iron-59 in accordance with recent amendments to Parts 31 and 32 of AEC regulations.

C.22(k)

(k) General Licensed Quantities for Radium-226

Addition See revised Part C (Pages C21-C23).

Rationale: C.22(k). This paragraph provides a general license for radium-226. Previously these regulations did not provide for the adequate control of small quanties of radium-226 which were not specifically licensed nor exempt under these regulations. Inasmuch as these regulations tend to promote the uniform control of radioactive material, the Technical Review Committee recommended that this inadequacy should not be permitted to continue. Consequently, C.22(k) was developed as the measure which provides for the adequate control of these small quantities of radium-226.

C.23

Addition Sec. C.23 Intrastate Transportation of Radioactive Material

(a) A general license is hereby issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations, appropriate

to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Persons who transport and store radioactive material pursuant to the general license in this paragraph are exempt from the requirements of Part D and Part J of these regulations.

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(1) Persons who transport radioactive material pursuant to the general license in Paragraph C.23(b) are exempt from the requirements of Part D and Part J of these regulations to the extent that they transport radioactive material.

(2) Physicians, as defined in Paragraph A.2(aa), are exempt from the requirements of Paragraph C.23(b) to the extent that they transport radioactive material for use in the practice of medicine.

Rationale: On March 26, 1972, the AEC amended 10 CFR 20, 30, 40, 70, and 71 to provide that AEC licensees not subject to DOT, Postal Service, or Agreement State Regulations applicable to shippers and carriers of radioactive materials would be required to follow provisions set forth in the DOT requirements. The rule also clarifies who is exempt from these requirements, and includes in the exemption physicians who carry radioactive materials in their own vehicles for use in the practice of medicine. Section C.23 has been added to the Suggested State Regulations to provide for regulatory control over intrastate transportation of radioactive material.

C.24(a)

Present 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.

Revised Section C.24 Filing Application for Specific Licenses

(a) Applications for specific licenses shall be filed in triplicate on a form prescribed

by the Agency.

Rationale: C.24(a). The bracketing of "in triplicate" is in recognition that it is the State's option as to the number of copies it needs to have filed for its use.

C.26(a)(1)

Present (1). The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioisotopes within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against radiation; and,

Revised (1). The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioactive material within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioactive material and protection against radiation;

Rationale: C.26(a)(1). The Technical Review Committee recommended that the words "radioactive material" be substituted for "radionuclides" or "radioisotopes" as this is more consistent with the remainder of the model regulations.

C.26(d)

Present (d) Human Use of Sealed Sources. In addition to the requirements set forth in Section C.25 above, a specific license for human use of sealed sources will be issued only if the applicant, or if the application is made by an institution, the individual user (1) has specialized training in the therapeutic use of the sealed source considered (teletherapy unit, beta applicator, etc.) or has experience equivalent to such training, and (2) is a physician.

Revised (d) Human Use of Sealed Sources. In addition to the requirements set forth in Section C.25, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user (1) has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and (2) is a physician.

Rationale: C.26(d). The Technical Review Committee recommended that the material in parentheses be deleted as unnecessary since the words "diagnostic or" were added for completeness and accuracy.

C.26(e)(2)

Present C.26(f) Use of Sealed Sources in Industrial Radiography

(2) The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as described in Section E.202 and,

Revised (e) Use of Sealed Sources In Industrial Radiography

(2) The applicant has established and submits to the Agency satisfactory written operating and emergency procedures described in Section E.202;

Rationale: C.26(e)(2). The phrase "described in Section E.202" was placed in brackets for ease in changing the section and paragraph designation, upon revision of Part E.

C.26(e)(6)

Addition (6) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

Rationale: C.26(e)(6). Revised to maintain compatability with amendments to 10 CFR Part 34 of AEC regulations.

C.27(c)(2)(i)

Present (i). The appointment of a radiological safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters; and

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

Rationale: C.27(c)(2)(i). The Technical Review Committee recommended that the word "radiological" read "radiation" as this is more in keeping with "control of radiation" of the

rest of the model.

C.28

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

See revised Part C (Pages C31-C37).

Rationale: C.28. The Technical Review Committee recommended the addition of Section C.28 to the SSRCR on the basis of developing a model which provides for the uniform control of all radioactive material, and to develop a more consistent grouping of the various special requirements for licensing in this Part.

Paragraphs (a), (d), (g), and (h) are essentially paragraphs published previously which existed in different numbered sections of Part C. These paragraphs are now all grouped together within a single section, new Section C.28.

Paragraphs (b), (c), (e), (f), and (i) are new developments within the regulations as regards special requirements for the manufacture and distribution of commodities which contain radioactive material. The contents of Paragraph C.28(c) are patterned after 10 CFR Part 32 requirements, in order to maintain uniformity in the control of radioactive material.

C.37

Present — Sec. C.37 Persons Possessing Radioactive Material Other Than Agreement Material on Effective Date of These Regulations

Revised — Sec. C.37 Persons Possessing Radioactive Material Other Than Source, Byproduct, or Special Nuclear Material on Effective Date of These Regulations

Rationale: C.37. The Technical Review Committee recommended that the words "Agreement Material" be amended to read "Source, Byproduct, or Special Nuclear Material" as this is more in keeping with the rest of model regulations.

C.40

Sec. C.40 Transfer of Material

Present (a) No change

Present (b)(1)-(5) No change

Addition (c) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Atomic Energy Commission, or an Agreement State, or to a general licensee who is required to register with the Agency, the U.S. Atomic Energy Commission, or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

Addition (d) The following methods for the verification required by Paragraph C.40(c) are acceptable:

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

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

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

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

(5) When none of the methods of verification described in Subparagraphs C.40(d)(1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the Agency, the U.S. Atomic Energy Commission, or the licensing Agency of an Agreement State that the transferee is licensed to receive the radioactive material.

Addition (e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section C.100.

Rationale: C.40(c), (d), and (e). Revised to reflect amendments to 10 CFR Part 71 and maintain compatability with AEC regulations.

C.90(b)

Present (b) Notwithstanding the provisions of paragraph (a) of this Section C.90, any person who holds a specific license issued by the U.S. Atomic Energy Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in Subparagraph C.22(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, or service such a device in this State provided that:

Revised (b) Notwithstanding the provisions of Paragraph C.90(a), any person who holds a specific license issued by the U.S. Atomic Energy Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in Subparagraph C.22(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

Rationale: C.90(b). As it is generally understood that a general license is issued to cover the demonstration of a portable gauge, the Working Group recommended that Paragraph C.90(b) be amended to indicate this practice.

C.100

Present Sec. C.100 Intrastate Transportation of Radioactive Materials

Revised As C.23

Addition Sec. C.100 Preparation of Radioactive Material for Transport

(a) No licensee shall deliver any radioactive material to a carrier12/ for transport, unless:

(1) The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the packing of radioactive material, and to the monitoring, marking and labeling of those packages;

(2) The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(3) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to, or have been available to the consignee.

(b) Paragraph (a) of C.100 shall not apply to the transportation of licensed material, or to the delivery of licensed material to a carrier for transport, where such transportation is subject to the regulations of the Department of Transportation or the U.S. Postal Service.

Rationale: C.100. The Working Group recommended that Section C.100 should be reserved pursuant to recent AEC developments pertaining to transportation of radioactive material and revised to maintain compatibility with AEC regulations.

12/ For the purpose of this regulation, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport.

Schedule B. Amended by including the following radioactive materials and quantities:

Cesium-129	100 µCi
Cobalt-57	100 µCi
Gallium-67	100 µCi
Indium-111	100 µCi
Iodine-123	100 µCi
Iron-52	10 µCi
Potassium-43	10 µCi
Rubidium-81	10 µCi
Sodium-22	10 µCi
Yttrium-87	10 µCi

Rationale: Schedule B. The Working Group recommended that since these radioactive materials are receiving greater use in science and industry, they should be included in Schedule B.

Schedule D. Title amended to read Limits for Broad Licenses (C.27). The Working Group recommended that the following values for radium-226 be included in Schedule D: 0.01 Ci and 0.0001 Ci for Columns I and II respectively.

Rationale: Schedule D. This title relates Schedule D to the proper section of Part C. The radium values are the same as the values for polonium-210 and stronium-90 which are also "bone seekers."

Matters for Future Consideration

It was decided that the following items require further Working Group investigation:

1. The proposal to include definitions for "AEC Material" and "Licensing State". This relates to certain labeling problems, e.g., accelerator-produced Co-57.

2. The Proposal that radon concentrations be included in Schedule A.

3. The proposal that carbon-11, nitrogen-13 and oxygen-15, even though short half-lived, be included in Schedule B (Exempt Quantities) of Part C.

4. The Working Group anticipates that Schedule C will be amended as "new diagnostic uses are developed in the future".

5. Subdivisions (i) through (v) of C.22(i)(1). Rather than repeat Subdivisions (i) through (v), which are

essentially similar except for radionuclide and quantity, a listing of these radionuclides and their quantities, and a single sentence describing their use, would suffice.

6. C.4(c) Radioactive Material Other Than Source Material - Exempt Items. The quantities of radioactivity on manufactured items should be circumscribed by limits on accessible emitted radiation to insure the integrity of the item, and instructions for disposal or other action of defective items should be incorporated.

7. Proposal to clarify Subparagraph C.27(e)(1) by addition of introductory sentence as follows: "Unless specifically authorized elsewhere in Part C, persons licensed pursuant to C.27 shall not:".