Title 15 – Mississippi State Department of Health

Part III – Office of Health Protection

Subpart 78 – Division of Radiological Health

CHAPTER 01 REGULATIONS FOR CONTROL OF RADIATION IN MISSISSIPPI

300 Licensing of Radioactive Material

300.01 Purpose and Scope.

1. This section of these regulations provides for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this section or as otherwise provided in this section.

2. In addition to the requirements of this section, all licensees are subject to the requirements of Sections 100, 400, 1000, and 1300 of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Section 500 of these regulations, licensees using radionuclides in the healing arts are subject to the requirements of Section 700 of these regulations, licensees engaged in the extraction, mining, beneficiating, processing, use, transfer, transport, storage, and/or disposal of naturally occurring radioactive materials (NORM) are subject to the requirements of Section 1100 of these regulations, licensees authorizing the use of sealed sources containing radioactive materials in irradiators are subject to the requirements of Section 1200 of these regulations, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Section 1400 of these regulations.

Exemptions from the Regulatory Requirements

300.02 Source Material.

1. Any person is exempt from this section 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.

2. Any person is exempt from this section 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.

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

   a. any quantities of thorium contained in

      i. incandescent gas mantles,

      ii. vacuum tubes,

      iii. welding rods,

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

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

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

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

   b. source material contained in the following products:

      i. glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

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

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

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

   c. photographic film, negatives, and prints containing uranium or thorium;

   d. 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;

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

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

   ii. each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",[1]

   iii. each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",[1] and

   iv. 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;

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

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

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

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

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

[1] The requirements specified in 300.02(e)(ii) and (iii) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend. "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the regulations.

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

h. uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

i. thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

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

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

4. The exemptions in 300.02(3) do not authorize the manufacture of any of the products described.

300.03 Radioactive Material Other Than Source Material.

1. Exempt Concentrations.

a. Except as provided in 300.03(1)(c) and (d), any person is exempt from this section 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 this section.

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

c. 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 300.03(1)(a) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or Licensing State, except in accordance with a specific license issued pursuant to 10 CFR 32.11.

d. A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in the Act and from these regulations to the extent that the person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Appendix A of Section 300 and introduced into the product or material by a licensee holding a specific license issued by the Nuclear Regulatory Commission 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.

2. Exempt Quantities.

a. Except as provided in 300.03(2)(c) through (e), 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 radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of this section.

b. Any person who possesses radioactive material received or acquired under the general license formerly provided in 300.06(2) is exempt from the requirements for a license set forth in this section to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium-226.

c. Section 300.03(2) 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.

d. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this section, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 300.03(2) or equivalent regulations of the Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR 32.18 or by the Agency pursuant to 300.12(2) which license states that the radioactive material may be transferred by the persons exempt under 300.03(2) or the equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or Licensing State.

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

3. Exempt Items.

a. Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who desire to initially transfer for sale or distribute such products containing radioactive material, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[2]

i. 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 millicuries) of tritium per timepiece.

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

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

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

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

vi. 2.22 MBq (60 microcuries) of promethium-147 per watch dial or 4.44 MBq (120 microcuries) 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 milligrams per square centimeter of absorber:

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

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

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

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

viii. 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in timepieces acquired prior to May 9, 1986.

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

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

iv. 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 millicuries) of tritium per micro-wave receiver protector tube or 370 MBq (10 millicuries) of tritium per any other electron tube.

ii. 37 kBq (1 microcurie) of cobalt-60.

iii. 185 kBq (5 microcuries) of nickel-63.

iv. 1.11 MBq (30 microcuries) of krypton-85.

v. 185 kBq (5 microcuries) of cesium-137.

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

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 10 μGy (1 millirad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. [3]

[3] For purposes of 300.03(3)(a)(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.

v. 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 this section, 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 this section, provided that the sum of such fractions shall not exceed unity.

iii. For americium-241, 1.85 kBq (0.05 microcurie) is considered an exempt quantity under 300.03(3)(a)(viii).

vi. 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.

b. Self-Luminous Products Containing Radioactive Material.

i. 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 Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 300.03(3)(b) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

ii. Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq (0.1 microcurie) of radium-226 which were acquired prior to May 9, 1986.

iii. Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-

147, or to transfer such products for use pursuant to 300.03(3)(b)(i), 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 300.03(3)(b)(i), or equivalent regulations of an Agreement State.

c. Gas and Aerosol Detectors Containing Radioactive Material.

i. 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 these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission[4] pursuant to 10 CFR 32.26; or an Agreement State or a Licensing State pursuant to 300.12(3) 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 300.12(3). authorizing distribution to persons exempt from regulatory requirements.

ii. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State or a Licensing State shall be considered exempt under 300.03(3)(c)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 300.12(3).

iii. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use in accordance with 300.03(3)(c)(i), 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 300.03(3)(c)(i), or equivalent regulations of an Agreement State.

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

iv. Radioactive Drug: Capsules Containing Carbon-14 Urea for "in vivo" Diagnostic Use for Humans.

d. Except as provided in 300.03(4)(b) and (c) of this section, any person is exempt from the requirements for a license set forth in these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μCi) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process), for "in vivo" diagnostic use for humans.

e. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license as specified in these regulations.

f. 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 as specified in 10 CFR Part 32, Sec.32.21.

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

Licenses

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

1. General licenses provided in this section 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.[5] The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

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

General Licenses

300.05 General Licenses - Source Material.

[5] Certificate of registration for General Licenses shall be accompanied by the fee as provided in Section 45-14-31 of the Act. Fees are not required for registrations issued to local, city, county, or state government for general licensed devices associated with Homeland Security.

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

2. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 300.05(1) are exempt from the provisions of Sections 400 and 1000 of these regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this section.

3. Persons who receive, possess, use, or transfer source material pursuant to the general license in 300.05(1) are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

4. 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.

5. Depleted Uranium in Industrial Products and Devices.

    a. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 300.05(5)(b), (c), (d), and (e), 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.

    b. The general license in 300.05(5)(a) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 300.12(13) or in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the. Nuclear Regulatory Commission or an Agreement State.

    c. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 300.05(5)(a) shall file Agency Form "Registration 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 the Agency Form the following information and such other information as may be required by that form:

i. name and address of the general licensee;

ii. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 300.05(5)(a) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

iii. name, 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 300.05(5)(c)(ii).

iv. The general licensee possessing or using depleted uranium under the general license established by 300.05(5)(a) shall report in writing to the Agency any changes in information furnished by him in Agency Form "Registration Certificate - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

d. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 300.05(5)(a):

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

ii. shall not abandon such depleted uranium;

iii. shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 300.24 In the case where the transferee receives the depleted uranium pursuant to the general license established by 300.05(5)(a), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form, "Registration Certificate - Use of Depleted Uranium Under General License,". In the case where the transferee receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 300.05(5)(a), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form "Registration Certificate - Use of Depleted Uranium Under General License," accompanied by a note explaining that use of the

product or device is regulated by the Agency, the Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in this regulation;

iv. within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

v. shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

e. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 300.05(5)(a) is exempt from the requirements of Sections 400 and 1000 of these regulations with respect to the depleted uranium covered by that general license.

300.06 General Licenses - Radioactive Material Other Than Source Material.

1. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission or an Agreement State for use pursuant to 10 CFR Part 31.3. This general license is subject to the provisions of 100.04 through 100.10, 300.03(1)(b), 300.15, 300.24, 300.20, 300.25, and Sections 400,[6] 1000 and 1300 of these regulations, as applicable.

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

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

2. Reserved.

3. Reserved.

[6] Attention is directed particularly to the provisions of Section 400 of these regulations which relate to the labeling of containers.

4. Certain Measuring, Gauging or Controlling Devices.

a. 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 300.06(4)(b), (c), (d) and (e), 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.

b. The general license in 300.06(4)(a) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to 300.12(4) or an equivalent specific license issued by the Nuclear Regulatory Commission, an Agreement State or a Licensing State with provisions comparable to 300.12(4).[7]

i. The devices shall have been received from one of the specific licensees described in 300.06(4)(b); or

ii. Through a transfer made under 300.06(4)(c)(ix).

c. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 300.06(4)(a):

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

ii. Shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however,

i. Devices containing only krypton need not be tested for leakage of radioactive material, and

[7] 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.

ii. Devices containing only tritium or not more than 3.7 MBq (100 microcuries) of other beta- and/or gamma-emitting material or 0.37 MBq (10 microcuries) 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;

iii. Shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

i. In accordance with the instructions provided by the labels, or

ii. By a person holding an applicable specific license from the Agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

iv. Shall maintain records showing compliance with the requirements of 300.06(4)(c)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance 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 300.06(4)(c)(ii) 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 300.06(4)(c)(ii) 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 300.06(4)(c)(iii) 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;

v. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 1.85 Bq (0.005 microcurie) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable

specific license to receive the radioactive material contained in the device or as otherwise approved by the Agency. 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 furnish to the Agency within 30 days.

vi. Shall not abandon the device containing radioactive material;

vii. Shall not export the device containing radioactive material except in accordance with 10 CFR Part 110.

viii. Shall transfer or dispose of the device containing radioactive material:

i. Only by export as provided by 300.06(4)(c)(vii), by transfer to another general licensee as authorized in 300.06(4)(c)(ix), or to a person authorized to receive the device by a specific license under Section 300 or a specific license that authorizes waste collection under Section 300, or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under 300.06(4)(c)(viii)(iii).

ii. Shall 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.

iii. Shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in 300.06(4)(c)(viii)(i); 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 300.06(4)(c)(i) of this section so that the device is labeled in compliance with 400.32 of these regulations; however the manufacturer, model number, and serial number must be retained;

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

iv. Reports the transfer under 300.06(4)(c)(xiii)(ii) of this section.

ix. Shall transfer the device to another general licensee only:

i. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of Sections 100.04 through 100.10, 300.06., 400.54, 400.55 of these regulations and any safety documents identified in the label on the device. Within 30 days of the transfer, report to the Agency;

i. The manufacturer's or initial transferor's name

ii. The model number and serial number of 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 300.06(4)(c)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

ii. Where 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.

x. Shall comply with the provisions of 400.54 and 400.55 of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other reporting requirements of Sections 400 and 1000 of these regulations.

xi. Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within 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.

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

xiii. Shall register general license devices:

i. In accordance with 300.06(4)(c)(xiii)(ii) and (iii). Each address for a location of use, as described in 300.06(4)(c)(xiii)(iii)(iv), represents a separate general licensee and requires a separate registration and fee.

ii. 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 is subject to the bankruptcy notification requirement in 300.15(5).

iii. 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 300.06(4)(c)(xii);

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.

xiv. 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.

xv. 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 300.06(4)(c)(ii) 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.

d. The general license in 300.06(4)(a) does not authorize the manufacture or import of devices containing radioactive material.

e. The general license provided in 300.06(4)(a) is subject to the provisions of 100.04 through 100.10, 300.15, 300.24 300.25, and Section 1300 of these regulations.

5. Luminous Safety Devices for Aircraft.

a. 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:

i. each device contains not more than 370 GBq (10 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147; and

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

b. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 300.06(5)(a) are exempt from the requirements of Sections 400 and 1000 of these regulations except that they shall comply with the provisions of 400.54 and 400.55.

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

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

e. This general license is subject to the provisions of 100.04 through 100.10, 300.15, 300.24, 300.25, and Section 1300 of these regulations.

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

6. 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.

7. Calibration and Reference Sources.

   a. 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 300.06(7)(d) and (e), americium-241 in the form of calibration or reference sources:

      i. any person who holds a specific license issued by the Agency which authorizes the licensee to receive, possess, use, and transfer radioactive material; and

      ii. any person who holds a specific license issued by the Nuclear Regulatory Commission which authorizes the licensee to receive, possess, use, and transfer special nuclear material.

   b. 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 300.06(7)(d) and (e) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

   c. 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 300.06(7)(d) and (e) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

   d. The general licenses in 300.06(7)(a), (b) and (c) 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 Nuclear Regulatory Commission 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, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in 300.12(6), 10 CFR 32.57 or of 10 CFR 70.39.

   e. The general licenses provided in 300.06(7)(a), (b), and (c) are subject to the provisions of 100.04 through 100.10, 300.15, 300.24, 300.25, and Sections 400, 1000, and 1300 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:

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

ii. shall 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 called for in one of the following statements, as appropriate:

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

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)[8] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or initial transferor

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

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

_____

[8] Showing only the name of the appropriate material.

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

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

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

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

8. Reserved.

9. General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing. [9]

a. 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 300.06(9)(b), (c), (d), (e), and (f), 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:

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

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

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

[9] 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.

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

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

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

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

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

b. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 300.06(9)(a) until that person has filed Agency Form, "Registration Certificate - *In Vitro* Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of the Agency Form with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on the Agency Form the following information and such other information as may be required by that form:

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

ii. the location of use; and

iii. a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized under the general license in 300.06(9)(a) 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.

c. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 300.06(9)(a) shall comply with the following:

i. The general licensee shall not possess at any one time, pursuant to the general license in 300.06(9)(a), 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 microcuries).

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

iii. The general licensee shall use the radioactive material only for the uses authorized by 300.06(9)(a).

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

v. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 300.06(9)(a)(v) as required by 400.35(1) of these regulations.

d. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 300.06(9)(a):

i. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 300.12(8) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, any Agreement State or Licensing 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 300.06(9) or its equivalent, and

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

i. This radioactive material 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 Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

ii. This radioactive material 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 a Licensing State.

_____

Name of manufacturer

e. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 300.06(9)(a) shall report in writing to the Agency, any changes in the information furnished by him in the "Registration Certificate - *In Vitro* Testing with Radioactive Material Under General License". The report shall be furnished within 30 days after the effective date of such change.

f. Any person using radioactive material pursuant to the general license of 300.06(9)(a) is exempt from the requirements of Sections 400 and 1000 of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 300.03(9)(a)(v) shall comply with the provisions of 400.35(1), 400.54, and 400.55 of these regulations.

10. Ice Detection Devices.

a. 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 microcuries) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission 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 300.12(9) or equivalent to those in 10 CFR 32.61.

b. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 300.06(10)(a):

i. shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 400.35(1) of these regulations;

ii. 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

iii. are exempt from the requirements of Sections 400 and 1000 of these regulations except that such persons shall comply with the provisions of 400.35(1), 400.54, and 400.55.

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

d. This general license is subject to the provisions of 100.04 through 100.10, 300.15, 300.24, 300.25, and Section 1300 of these regulations.

11. Self-Luminous Products Containing Radium-226.

a. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of 300.06(11)(b) through (d), radium-226 contained in the following products manufactured prior to November 30, 2007.

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

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

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

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

v. Small radium sources containing no more than 0.037 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 Nuclear Regulatory Commission educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Nuclear Regulatory Commission.

b. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in 300.06(11)(a) are exempt from the provisions of Sections 400 and 1000, and 100.07 and 300.20 of these regulations, to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under Section 300 of these regulations.

c. Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in 300.06(11)(a) shall:

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

ii. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 400.42 of these regulations or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Agency.

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

iv. 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 Section, or equivalent regulations of the Nuclear Regulatory Commission or an

Agreement State, or as otherwise approved by the Nuclear Regulatory Commission or an Agreement State.

v. Respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Agency, a written justification for the request.

d. The general license in 300.06(11)(a) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

300.07 Reserved.

SPECIFIC LICENSES

300.08 Filing Application for Specific Licenses.

1. Applications for specific licenses shall be filed on a form prescribed by the Agency and shall be accompanied by the fee as provided in Section 45-14-31 of the Act.

2. 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.

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

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

5. 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.

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

7. 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:

a. identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission 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

b. Contain the information identified in 10 CFR 32.210(c); or

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

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

ii. 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.

8. Certain applications for specific licenses submitted under this section and Sections 500, 700, 1100, 1200, and 1400 must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning, as provided by 300.09(7),

a. Each application submitted after April 7, 1993, to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix C, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," of this section must contain either:

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

ii. An emergency plan for responding to a release of radioactive material.

b. One or more of the following factors may be used to support an evaluation submitted under 300.08(8)(a)(i) of this section:

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

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

iii. The release fraction in the respirable size range would be lower than the release fraction shown in Appendix C of this section due to the chemical or physical form of the material;

iv. The solubility of the radioactive material would reduce the dose received;

v. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix C of this section;

vi. Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix C of this section; or

vii. Other factors appropriate for the specific facility.

c. An emergency plan for responding to a release of radioactive material submitted under 300.08(8)(a)(ii) must include the following information:

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

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

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

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

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

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

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

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

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

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

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

xii. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the

scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

xiii. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

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

9. An application from a medical facility, or educational institution, to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Section 700 of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements shall include:

a. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Section 300 of these regulations or Nuclear Regulatory Commission or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

b. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 300.12(10)(a)(ii) of this section.

c. 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 300.12(10)(b)(ii) of this section.

d. Information identified in 300.12(10)(a)(iii) of this section on the PET drugs to be noncommercially transferred to members of its consortium.

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

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

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

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

4. the applicant satisfies any applicable special requirements in 300.11, 300.12, or Section 500, Section 700, Section 1100, Section 1200, or Section 1400 of these regulations.

5. 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.

6. Reserved.

7. Financial Assurance and Recordkeeping for Decommissioning.

   a.

      i. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix F to Section 400 of these regulations shall submit a decommissioning funding plan as described in 300.09(7)(e). The decommissioning funding plan must also be submitted when a combination of isotopes is involved

if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F to Section 400 of these regulations.

ii. Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix F to Section 400 (or when a combination of isotopes is involved if R, as defined in 300.09(7)(a)(i), divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in 300.09(7)(e) of this section. The decommissioning funding plan must be submitted to the Agency by July 1, 2009.

b. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 300.09(7)(d) shall either:

i. Submit a decommissioning funding plan as described in 300.09(7)(e); or

ii. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 300.09(7)(d) using one of the methods described in 300.09(7)(f). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of 300.07(7)(f) must be submitted to the Agency before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 300.09(7)(f).

c. Each holder of a specific license issued on or after November 15, 1992, which is of a type described in 300.09(7)(a) or (b), shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

i. Each holder of a specific license issued before November 15, 1992, and of a type described in 300.09(7)(a) shall submit on or before January 1, 1993, a decommissioning funding plan as described in 300.09(7)(e) or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in

accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

ii. Each holder of a specific license issued before November 15, 1992, and of a type described in 300.09(7)(b) shall submit, on or before January 1, 1993, a decommissioning funding plan as described in 300.09(7)(e) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

iii. Any licensee who has submitted an application before November 15, 1992, for renewal of license in accordance with 300.17 shall provide financial assurance for decommissioning in accordance with 300.09(7)(a) and (b) of this section. This assurance must be submitted within 180 days of the effective date of these regulations.

iv. Waste collectors and waste processors, as defined in Section 400, Appendix D, must provide financial assurance in an amount based on a decommissioning funding plan as described in 300.09(7)(e) of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of Section 400. The decommissioning funding plan must be submitted by July 1, 2009.

d. Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by July 1, 2009. Licensees required to submit the $113,000 or $225,000 amount must do so by September 1, 2009. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F to Section 400 of these regulations in unsealed form. (For a combination of radionuclides, if R, as defined in 300.09(7)(a), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1).....$1,125,000

greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F to Section 400 of these regulations in unsealed form. (For a combination of radionuclides, if R, as defined in 300.09(7)(a), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1).....$225,000

greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix F to Section 400 of these regulations in sealed sources or plated foils. (For a combination of radionuclides, if R, as defined in 300.09(7)(a), divided by 10^{10} is greater than 1 but R divided by 10^{12} is less than or equal to 1).....$113,000

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 300.09(7)(f), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of 300.09(7)(f).

f. Financial assurance for decommissioning must be provided by one or more of the following methods:

i. Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

ii. A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix D of this section. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix E of this section. For commercial companies that do not issue bonds, a guarantee of

funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix F to this section. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

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

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

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

iii. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 300.09(7)(f)(ii).

iv. In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 300.09(7)(d) and indicating that funds for decommissioning will be obtained when necessary.

g. Each person licensed under this section and Sections 500, 700, 1100, 1200, and 1400 of these regulations shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 300.15(2), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

i. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms and concentrations.

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

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

i. All areas designated and formerly designated restricted areas as defined in 100.02 of these regulations.

ii. All areas outside of restricted areas that require documentation under 300.09(g)(i).

iii. All areas outside of restricted areas where current and previous wastes have been buried as documented under 400.51 of these regulations.

iv. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 400.36 of these regulations.

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

300.10 Reserved

300.11 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.[10]

1. Reserved.

2. An application for a specific license of broad scope will be approved if:

   a. the applicant satisfies the general requirements specified in 300.09;

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

   c. 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:

      i. 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;

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

ii. 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

iii. the establishment of appropriate administrative procedures to assure:

i. control of procurement and use of radioactive material;

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

iii. review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 300.11(2)(c)(iii)(ii) prior to use of the radioactive material.

3. Reserved.

4. Reserved.

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

a. Unless specifically authorized, persons licensed pursuant to 300.11 shall not:

i. conduct tracer studies in the environment involving direct release of radioactive material;

ii. receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

iii. conduct activities for which a specific license issued by the Agency under 300.12, Sections 500, 700, 1100, 1200 or 1400 is required; or

iv. 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.

b. Each specific license of broad scope issued under this section 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.

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

1. Licensing Introduction of Radioactive Material into Products in Exempt Concentrations.

a. In addition to the requirements set forth in 300.09, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 300.03(1)(a) will be issued if:

i. the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

ii. the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A of Section 300, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

b. Each person licensed under 300.12(1) shall file an annual report with the Agency which shall identify:

i. The type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

ii. Name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;

iii. The type and quantity of radionuclide introduced into each such product or material; and

iv. The initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

c. If no transfers of radioactive material have been made pursuant to 300.12(1) during the reporting period, the report shall so indicate. The report shall cover the year ending December 31, and shall be filed within 30 days thereafter.

2. Licensing the Distribution of Radioactive Material in Exempt Quantities.[11]

a. An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to 300.03(2) will be approved if:

i. 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;

ii. 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

iii. the applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

b. The license issued under 300.12(2)(a) is subject to the following conditions:

i. 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.

ii. Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall

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

be contained in any outer package for transfer to persons exempt pursuant to 300.03(2). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 μSv) per hour.

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

i. identifies the radionuclide and the quantity of radioactivity, and

ii. bears the words "Radioactive Material".

iv. In addition to the labeling information required by 300.12(2)(b)(iii), the label affixed to the immediate container, or an accompanying brochure, shall:

i. state that the contents are exempt from Licensing State requirements,

ii. 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

iii. set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

c. Each person licensed under 300.12(2) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 300.03(2) or the equivalent regulations of a Licensing 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 December 31, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 300.12(2) during the reporting period, the report shall so indicate.

3. 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

300.03(3)(c) 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 microcurie).

4. Licensing the Manufacture or Initial Transfer of Devices to Persons Generally Licensed Under 300.06(4).

   a. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 300.06(4) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

      i. The applicant satisfies the general requirements of 300.09;

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

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

         ii. under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive, in 1 year, a dose in excess of 10 percent of the annual limits specified in the table in 400.06(1) of these regulations, and

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

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

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

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

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

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

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

iii. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

i. The receipt, possession, use, and transfer of this device, Model _____, Serial No._____[12], are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or a State with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or initial transferor

ii. The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[13], are subject to a general license

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

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

or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or initial transferor

iv. 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 Section 400.29 of these regulations, and the name of the manufacturer or initial distributor.

v. Each device meeting the criteria of 300.06(4)(c)(xiii)(i), 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 Section 400.29 of these regulations.

b. 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:

i. primary containment or source capsule;

ii. protection of primary containment;

iii. method of sealing containment;

iv. containment construction materials;

v. form of contained radioactive material;

vi. maximum temperature withstood during prototype tests;

vii. maximum pressure withstood during prototype test;

viii. maximum quantity of contained radioactive material;

ix. radiotoxicity of contained radioactive material; and

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

c. In the event the applicant desires that the general licensee under 300.06(4), or under equivalent regulations of the Nuclear Regulatory Commission, and Agreement State, or a Licensing 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 bases for such estimates. The submitted information shall demonstrate the 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 dose in excess of 10 percent of the annual limits specified in the table in 400.06(1) of these regulations.

d. Conditions of Transferring a Device for Use Under a General License in 300.06(4).

i. If a device containing radioactive material is to be transferred for use under the general license in 300.06(4), each person that is licensed under 300.12(4). shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of the general license contained in 300.06(4); if sections 300.06(4)(c)(ii) through (iv) or 300.06(4)(c)(xiii) do not apply to the particular device, those sections may be omitted.

ii. A copy of 100.04, 400.54 and 400.55 of these regulations;

iii. A list of the services that can only be performed by a specific licensee; and

iv. Information on acceptable disposal options including estimated costs of disposal.

ii. If radioactive material is to be transferred in a device for use under an equivalent general license of the Nuclear Regulatory Commission or an Agreement State, each person that is licensed under 300.12(4) shall provide the information specified in this section to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of 300.06(1), 300.06(4), 300.20, 400.54, and 400.55 of these regulations, or a copy of equivalent Nuclear Regulatory Commission or Agreement State's regulations. If a copy of the Nuclear Regulatory Commission's regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State; if certain parts of the regulations do not apply to the particular device, those parts may be omitted.

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

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

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

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

iv. Each device that is transferred shall meet the labeling requirements in 300.12(4)(a)(iii) through 300.12(4)(a)(v).

v. If a notification of bankruptcy has been made under 300.15(5) or the license is to be terminated, each person licensed under 300.12(4) shall provide, upon request, to the Agency, the Nuclear Regulatory Commission, and to any appropriate Agreement State, records of final disposition required under 300.12(4)(e)(iii).

e. Material Transfer Reports and Records. Each person licensed under 300.12(4) to initially transfer devices to generally licensed persons shall comply with the following requirements:

i. The person shall report to the Agency all transfers of devices to persons for use under the general license in 300.06(4) and all receipts of devices from persons licensed under 300.06(4). 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.

i. 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.

ii. 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).

iii. 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.

iv. 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.

v. 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.

vi. The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

vii. If no transfers have been made to or from persons generally licensed under 300.06(4) during the reporting period, the report shall so indicate.

ii. The person shall report all transfers of devices to persons for use under a general license in an Nuclear Regulatory Commission’s or Agreement State's regulations that are equivalent to 300.06(4) and all receipts of devices from general licensees in the Nuclear Regulatory Commission’s or Agreement State's jurisdiction to the Nuclear Regulatory Commission or responsible Agreement State agency. The report shall be submitted on NRC Form 653--``Transfers of Industrial Devices Report" 10 CFR 32.52(a) or in a clear and legible report containing all of the data required by the form.

i. 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.

ii. 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).

iii. 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.

iv. 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.

v. 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.

vi. The report shall clearly identify the specific licensee submitting the report and shall include the license number of the specific licensee.

vii. If no transfers have been made to or from the Nuclear Regulatory Commission or a particular Agreement State during the reporting period, this information shall be reported to the Nuclear Regulatory Commission or responsible Agreement State agency upon request of the agency.

iii. The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by 300.06(4)(e) shall be maintained for a period of 3 years following the date of the recorded event.

5. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 300.06(5) will be approved if:

   a. the applicant satisfies the general requirements specified in 300.09; and

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

6. 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 300.06(7). An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 300.06(7) will be approved if:

   a. the applicant satisfies the general requirement of 300.09; and

   b. the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

7. Reserved.

8. 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 300.06(9) will be approved if:

   a. the applicant satisfies the general requirements specified in 300.09.

b. the radioactive material is to be prepared for distribution in prepackaged units of:

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

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

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

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

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

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

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

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

c. each prepackaged unit bears a durable, clearly visible label:

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

ii. displaying the radiation caution symbol described in 400.29(1) and the words, "CAUTION, RADIOACTIVE MATERIAL" and "Not for Internal or External Use in Humans or Animals".

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

i. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *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 Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

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

_____

Name of manufacturer

e. the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 400.35 of these regulations.

9. Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium-90. An application for a specific license to manufacture and initially transfer ice detection devises to persons generally licenses under 300.06(10) will be approved if:

   a. the applicant satisfies the general requirements of 300.09; and

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

10. Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Pursuant to Section 700 of These Regulations.

   a. 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 Section 700 of these regulations will be approved if:

i. the applicant satisfies the general requirements specified in 300.09 of this section;

ii. the applicant submits evidence that the applicant is at least one of the following:

i. 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 21 CFR 207.20(a);

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

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

iv. Operating as a nuclear pharmacy within a Federal medical institution; or

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

iii. the applicant submits information on the radionuclide, 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 safe handling and storage of the radioactive drugs by medical use licensees; and

iv. the applicant satisfies the following labeling requirements:

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

ii. a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label

must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

b. A licensee described by 300.12(10)(a)(ii)(iii) or (iv) of this section:

i. may prepare radioactive drugs for medical use, as defined in 700.02 of these regulations provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 300.12(10)(b)(ii) or 300.12(10)(b)(iv) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in Section 700.15 of these regulations.

ii. may allow a pharmacist to work as an authorized nuclear pharmacist if:

i. this individual qualifies as an authorized nuclear pharmacist as defined in 700.02 ; or

ii. this individual meets the requirements specified in 700.21(2) and 700.23 of these regulations and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

iii. this individual is designated as an authorized nuclear pharmacist in accordance with 300.12(10)(b)(iv).

iii. The actions authorized in 300.12(10)(b)(i) and 300.12(10)(b)(ii) are permitted in spite of more restrictive language in license conditions.

iv. May designate a pharmacist (as defined in 700.02) as an authorized nuclear pharmacist if:

i. the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

ii. 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 Nuclear Regulatory Commission.

v. Shall provide to the Agency:

i. a copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State as specified in 700.21(1) of these regulations with the written attestation signed by a preceptor as required by 700.21(2)(b); or

ii. the Agency, Nuclear Regulatory Commission or Agreement State license; or

iii. Nuclear Regulatory Commission master materials licensee permit; or

iv. the permit issued by a licensee or Nuclear Regulatory Commission master materials permittee of broad scope; or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

v. 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 Nuclear Regulatory Commission Nuclear Regulatory Commission; and

vi. a copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 300.12(10)(b)(ii)(i) and (b)(ii)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

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

i. Perform tests before initial use periodically, and following repair, on each instrument for accuracy, linearity, and geometry

dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

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

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

11. Reserved

12. 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 Section 700 for use as a calibration, transmission, or reference source or for the uses listed in 700.52, 700.62, 700.64, and 700.82 of these regulations will be approved if:

a. the applicant satisfies the general requirements in 300.09 of this section;

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

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

ii. details of design and construction of the source or device,

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

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

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

vi. procedures and standards for calibrating sources and devices,

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

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

c. 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 named source or device is approved by the Agency for distribution to persons licensed to use radioactive material identified in Sections 700.28, 700.52, 700.62, and 700.64 of these regulations, as appropriate, or under equivalent licenses of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State;

d. 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

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

i. primary containment or source capsule,

ii. protection of primary containment,

iii. method of sealing containment,

iv. containment construction materials,

v. form of contained radioactive material,

vi. maximum temperature withstood during prototype tests,

vii. maximum pressure withstood during prototype tests,

viii. maximum quantity of contained radioactive material,

ix. radiotoxicity of contained radioactive material, and

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

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

a. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 300.05(4) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State will be approved if:

i. the applicant satisfies the general requirements specified in 300.09;

ii. the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive, in 1 year, a radiation dose in excess of 10 percent of the annual limits specified in 400.06(1) of these regulations; and

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

b. 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 300.12(13) 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.

c. The Agency may deny any application for a specific license under 300.12(13) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

d. Each person licensed pursuant to 300.12(13)(a) shall:

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

ii. label or mark each unit to:

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

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

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

i. furnish a copy of the general license contained in 300.05(4) and a copy of the Agency Form, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in 300.05(4), or

ii. furnish a copy of the general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 300.05(4) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in 300.05(4) and a copy of Agency Form, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 300.05(4);

iv. report to the Agency all transfers of industrial products or devices to persons for use under the general license in 300.05(4). 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 300.05(4) during the reporting period, the report shall so indicate.

i. report to the Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the general license in 300.05(5) of these regulations;

ii. report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 300.12(13) for use under a general license in that State's regulations equivalent to 300.05(4);

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

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

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

v. 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 300.05(5) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State. The

records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

300.13 Reserved.

300.14 Issuance of Specific Licenses.

1. 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.

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

   a. minimize danger to public health and safety or property;

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

   c. prevent loss or theft of material subject to this section.

300.15 Specific Terms and Conditions of License.

1. Each license issued pursuant to the regulations in this section and the regulations in Sections 500, 700, 1100, 1200, and 1400 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.

2. No license issued or granted pursuant to the regulations in this section and Sections 500, 700, 1100, 1200, and 1400 nor any right to possess or utilize radioactive material granted by any license 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.

3. Each person licensed by the Agency pursuant to the regulations in this section and Sections 500, 700, 1100, 1200, and 1400 shall confine use and

possession of the material licensed to the locations and purposes authorized in the license.

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

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

        i. the licensee;

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

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

    b. The notification shall indicate:

        i. the bankruptcy court in which the petition for bankruptcy was filed; and

        ii. the date of the filing of the petition.

5. Licensees required to submit emergency plans by 300.07(8) shall follow the emergency plan approved by the Agency. The licensee may change the approved emergency plan without Agency approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Agency and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Agency.

6. Security Requirements for Portable Gauges. 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.

7. 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

8. 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 700.41 of these regulations. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

9.

a. Authorization under 300.08(9) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

b. Each licensee authorized under 300.08(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

i. Satisfy the labeling requirements in 300.12(10)(a)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

ii. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 300.12(10)(c) .

c. A licensee that is a pharmacy authorized under 300.08(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

i. an authorized nuclear pharmacist that meets the requirements in 300.12(10)(b)(ii), or

ii. an individual under the supervision of an authorized nuclear pharmacist as specified in 700.15 of these regulations.

d. A pharmacy, authorized under 300.08(9) 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 300.12(10)(b)(v).

300.16 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

1. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 300.17 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

2. Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

3. 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:

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

    b. Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

4. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 300.16(6)(a), and begin decommissioning upon approval of that plan if:

    a. The license has expired pursuant to 300.16(1) or (2); or

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

    c. No principal activities under the license have been conducted for a period of 24 months; or

    d. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual

radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

5. Coincident with the notification required by 300.16(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 300.09(7) in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 300.16(6)(d)(v).

    a. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so within 180 days of the effective date of these regulations.

    b. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

6. The Agency may grant a request to extend the time periods established in 300.16(4) if the Agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 300.16(4). The schedule for decommissioning set forth in 300.16(4) may not commence until the Agency has made a determination on the request.

    a. A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

        i. Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

        ii. Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

        iii. Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

iv. Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

b. The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 300.16(4) if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

c. Procedures such as those listed in 300.16(6)(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

d. The proposed decommissioning plan for the site or separate building or outdoor area must include:

i. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

ii. A description of planned decommissioning activities;

iii. A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.

iv. A description of the planned final radiation survey; and

v. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

vi. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 300.16(7).

e. The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

i. Except as provided in 300.16(7), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

ii. Except as provided in 300.16(7), when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

7. The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:

   a. Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

   b. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

   c. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

   d. Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

   e. Other site-specific factors which the Agency may consider appropriate on a case-by-base basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

8. As the final step in decommissioning, the licensee shall:

   a. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Agency Form, "Certification of Disposition of Materials" or equivalent information; and

   b. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 400.64, 400.65 or 400.66. The licensee shall, as appropriate:

      i. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of disintegrations per minute or megabecquerels (microcuries) per 100 square centimeters-removable and fixed-for surfaces, megabecquerels (microcuries) per milliliter for water, and

becquerels (picocuries) per gram for solids such as soils or concrete; and

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

9. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

a. Radioactive material has been properly disposed;

b. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

i. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 400.64, 400.65, or 400.66.; or

ii. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 400.64, 400.65, or 400.66.

300.17 Renewal of Licenses.

1. Applications for renewal of specific licenses shall be filed in accordance with 300.08.

2. 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.

300.18 Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with 300.08 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

300.19 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 300.09, and 300.11, and in Sections 100, 400, 500, 700, 1000, 1300, 1100, 1200, or 1400 of these regulations as applicable.

300.20 Records.

1. Each person who receives radioactive material pursuant to a license issued pursuant to these regulations shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

    a. 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.

    b. The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another section of the regulations dictates otherwise.

    c. 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.

2. The licensee shall retain each record that is required by these regulations or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

3. Records which must be maintained pursuant to 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.

4. If licensed activities are transferred or assigned in accordance with 300.15(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

    a. Records of disposal of licensed material made under 400.36 (including burials authorized before May 9, 1986), 400.37, 400.38, 400.39; and

    b. Records required by 400.37(2).

300.21 Reserved.

300.22 Reserved.

300.23 Reserved.

300.24 Transfer of Material.

1. No licensee shall transfer radioactive material except as authorized pursuant to 300.24.

2. Except as otherwise provided in the license and subject to the provisions of 300.24(3) and (4), any licensee may transfer radioactive material:

   a. to the Agency;[14]

   b. to the U.S. Department of Energy;

   c. to any person exempt from the regulations in the section to the extent permitted under such exemption;

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

   e. as otherwise authorized by the Agency in writing.

3. Before transferring radioactive material to a specific licensee of the Agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing 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.

4. Any of the following methods for the verification required by 300.24(3) is acceptable:

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

   b. The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to

[14] A licensee may transfer material to the Agency only after receiving prior approval from the Agency.

receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

c. 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.

d. The transferor may obtain other information compiled by a reporting service from official records of the Agency, the Nuclear Regulatory Commission, the licensing agency of an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

e. When none of the methods of verification described in 300.24(4)(a) through (d) 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 Nuclear Regulatory Commission, or the licensing agency of an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

5. Shipment and transport of radioactive material shall be in accordance with the provisions of Section 1300 of these regulations.

300.25 Modification and Revocation of Licenses.

1. 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.

2. 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.

3. 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

300.26 Reciprocal Recognition of Licenses for Byproduct, Source, Naturally Occurring and Accelerator-Produced Radioactive Material and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

1. Subject to these regulations, any person who holds a specific license from the Nuclear Regulatory Commission, an Agreement State, or 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, except for areas of exclusive federal jurisdiction, for a period not in excess of 180 days in any calendar year provided that:

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

   b. the out-of-state licensee notifies the Agency in writing at least 3 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 and an annual fee as provided in Section 45-14-31 of the Act. 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 300.26(1);

   c. 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;

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

   e. the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 300.26(1) except by transfer to a person specifically licensed by the

Agency or by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive such material,

2. Notwithstanding the provisions of 300.26(1), any person who holds a specific license issued by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in 300.06(4)(a) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

   a. 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;

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

   c. 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 the label is prohibited"; and

   d. the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises the licensee installs such device a copy of the general license contained in 300.06(4) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

3. The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the Nuclear Regulatory Commission 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.

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

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APPENDIX A

Exempt Concentrations

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
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			$1.9x10^{-1}$	$5x10^{-3}$

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
	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			$7.4x10^{-2}$	$2x10^{-3}$
	Gd-159			$3.0x10^{-2}$	$8x10^{-4}$
Gallium (31)	Ga-72			$1.5x10^{-2}$	$4x10^{-4}$
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			$2.6x10^{-2}$	$7x10^{-4}$

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
	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			$3.7x10^{-1}$	$1x10^{-2}$
	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			$7.4x10^{-2}$	$2x10^{-3}$
	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			$1.1x10^{-2}$	$3x10^{-4}$

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
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			$3.7x10^{-2}$	$1x10^{-3}$
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 which are also radioactive. 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 Section 300.03 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".

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

Example: Concentration of Radionuclide A in Product + Exempt concentration of Radionuclide A

Concentration of Radionuclide B in Product ≤ 1
Exempt concentration of Radionuclide B

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APPENDIX B

Exempt Quantities of Radionuclides

Radionuclides		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

Radionuclide		kBq	µCi
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
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

Radionuclide		kBq	µCi
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
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

Radionuclide		kBq	µCi
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
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

Note 1: For purposes of 300.09(6)(f)(ii) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

$$\frac{\text{Amt. of radionuclide A possessed}}{1000 \times \text{Appendix B quantity for radionuclide A}} + \frac{\text{Amt. of radionuclide B possessed}}{1000 \times \text{Appendix B quantity for radionuclide B}} \leq 1$$

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Section 300

APPENDIX C

Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.

Radioactive Material	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000

Radioactive Material	Release fraction	Quantity (curies)
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.0001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000

Radioactive Material	Release fraction	Quantity (curies)
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	3,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[1]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha [1]	.0001	20
Combinations of radioactive materials listed above [2]		

[1] Waste packaged in Type B containers does not require an emergency plan.

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

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Section 300

APPENDIX D

Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

I. Introduction

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

II. Financial Test

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

(1) The parent company must have:

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

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

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

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

(2) The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's and

(ii) Tangible net worth at least six times the current decommissioning cost estimate for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

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

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. (1) After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(2) If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Agency's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and Agency of a notice of

cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

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Section 300

APPENDIX E

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial

statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

Subpart 78

Section 300

APPENDIX F

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds.

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee**.**

II. Financial Test

A. To pass the financial test a company must meet the following criteria:

(1) Tangible net worth greater than $10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform Agency within 90

days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the Agency of intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

DRAFT

Title 15 - Mississippi Department of Health

Part III – Office of Health Protection

Subpart 78 – Division of Radiological Health

CHAPTER 01 REGULATIONS FOR CONTROL OF RADIATION IN MISSISSIPPI

Licensing of Radioactive Material 300

300.01 Purpose and Scope.

1. This section of these regulations provides for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this section or as otherwise provided in this section.

2. In addition to the requirements of this section, all licensees are subject to the requirements of Sections 100, 400, 1000, and 1300 of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Section 500 of these regulations, licensees using radionuclides in the healing arts are subject to the requirements of Section 700 of these regulations, licensees engaged in the extraction, mining, beneficiating, processing, use, transfer, transport, storage, and/or disposal of naturally occurring radioactive materials (NORM) are subject to the requirements of Section 1100 of these regulations, licensees authorizing the use of sealed sources containing radioactive materials in irradiators are subject to the requirements of Section 1200 of these regulations, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Section 1400 of these regulations.

Exemptions from the Regulatory Requirements

300.02 Source Material.

1. Any person is exempt from this section 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.

2. Any person is exempt from this section 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.

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

   a. any quantities of thorium contained in

      i. incandescent gas mantles,

      ii. vacuum tubes,

      iii. welding rods,

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

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

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

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

   b. source material contained in the following products:

      i. glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

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

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

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

c. photographic film, negatives, and prints containing uranium or thorium;

d. 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;

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

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

   ii. each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",[1]

   iii. each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",[15] and

   iv. 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;

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

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

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

[15] The requirements specified in 300.02(e)(ii) and (iii) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend. "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the regulations.

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

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

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

h. uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

i. thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

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

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

4. The exemptions in 300.02(3) do not authorize the manufacture of any of the products described.

300.03 Radioactive Material Other Than Source Material.

1. Exempt Concentrations.

a. Except as provided in 300.03(1)(c) and (d), any person is exempt from this section 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 this section.

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

c. 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 300.03(1)(a) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or Licensing State, except in accordance with a specific license issued pursuant to 10 CFR 32.11.

d. A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in the Act and from these regulations to the extent that the person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Appendix A of Section 300 and introduced into the product or material by a licensee holding a specific license issued by the Nuclear Regulatory Commission 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.

2. Exempt Quantities.

a. Except as provided in 300.03(2)(c) through (e), 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 radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of this section.

b. Any person who possesses radioactive material received or acquired under the general license formerly provided in 300.06(2) is exempt from the requirements for a license set forth in this section to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium-226.

c. Section 300.03(2) 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.

d. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this section, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 300.03(2) or equivalent regulations of the Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR 32.18 or by the Agency pursuant to 300.12(2) which license states that the radioactive material may be transferred by the persons exempt under 300.03(2) or the equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or Licensing State.

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

3. Exempt Items.

a. Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who desire to initially transfer for sale or distribute such products containing radioactive material, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[16]

i. 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 millicuries) of tritium per timepiece.

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

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

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

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

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

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

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

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

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

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

viii. 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in timepieces acquired prior to May 9, 1986.

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

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

iv. 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 millicuries) of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) of tritium per any other electron tube.

ii. 37 kBq (1 microcurie) of cobalt-60.

iii. 185 kBq (5 microcuries) of nickel-63.

iv. 1.11 MBq (30 microcuries) of krypton-85.

v. 185 kBq (5 microcuries) of cesium-137.

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

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 10 μGy (1 millirad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[17]

v. 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 this section, 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 this section, provided that the sum of such fractions shall not exceed unity.

iii. For americium-241, 1.85 kBq (0.05 microcurie) is considered an exempt quantity under 300.03(3)(a)(viii).

vi. 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.

b. Self-Luminous Products Containing Radioactive Material.

i. 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 Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which license authorizes the transfer of the product to persons who are

[17] For purposes of 300.03(3)(a)(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.

exempt from regulatory requirements. The exemption in 300.03(3)(b) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

ii. Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq (0.1 microcurie) of radium-226 which were acquired prior to May 9, 1986.

iii. Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to 300.03(3)(b)(i), 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 300.03(3)(b)(i), or equivalent regulations of an Agreement State.

c. Gas and Aerosol Detectors Containing Radioactive Material.

i.

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 these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission[18] pursuant to 10 CFR 32.26; or an Agreement State or a Licensing State pursuant to 300.12(3) 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 300.12(3)., authorizing distribution to persons exempt from regulatory requirements.

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

ii. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State or a Licensing State shall be considered exempt under 300.03(3)(c)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 300.12(3).

iii. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use in accordance with 300.03(3)(c)(i), 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 300.03(3)(c)(i), or equivalent regulations of an Agreement State.

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

a. Except as provided in 300.03(4)(b) and (c) of this section, any person is exempt from the requirements for a license set forth in these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μCi) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process), for Ain vivo@ diagnostic use for humans.

b. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license as specified in these regulations.

c. 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 as specified in 10 CFR Part 32, Sec.32.21.

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

Licenses

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

1. General licenses provided in this section 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.[19] The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

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

General Licenses

300.05 General Licenses - Source Material.

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

2. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 300.05(1) are exempt from the provisions of Sections 400 and 1000 of these regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this section.

3. Persons who receive, possess, use, or transfer source material pursuant to the general license in 300.05(1) are prohibited from administering source material, or the radiation therefrom, either externally or internally, to

[19] Certificate of registration for General Licenses shall be accompanied by the fee as provided in Section 45-14-31 of the Act. Fees are not required for registrations issued to local, city, county, or state government for general licensed devices associated with Homeland Security.

human beings except as may be authorized by the Agency in a specific license.

4. 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.

5. Depleted Uranium in Industrial Products and Devices.

   a. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 300.05(5)(b), (c), (d), and (e), 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.

   b. The general license in 300.05(5)(a) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 300.12(13) or in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the. Nuclear Regulatory Commission or an Agreement State.

   c. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 300.05(5)(a) shall file Agency Form "Registration 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 the Agency Form the following information and such other information as may be required by that form:

      i. name and address of the general licensee;

      ii. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 300.05(5)(a) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

      iii. name, 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 300.05(5)(c)(ii).

iv. The general licensee possessing or using depleted uranium under the general license established by 300.05(5)(a) shall report in writing to the Agency any changes in information furnished by him in Agency Form "Registration Certificate - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

d. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 300.05(5)(a):

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

ii. shall not abandon such depleted uranium;

iii. shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 300.24 In the case where the transferee receives the depleted uranium pursuant to the general license established by 300.05(5)(a), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form, "Registration Certificate - Use of Depleted Uranium Under General License,". In the case where the transferee receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 300.05(5)(a), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form "Registration Certificate - Use of Depleted Uranium Under General License," accompanied by a note explaining that use of the product or device is regulated by the Agency, the Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in this regulation;

iv. within 30 days of any transfer, shall report in writing to the

Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

v. shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

e. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 300.05 (5)(a) is exempt from the requirements of Sections 400 and

1000 of these regulations with respect to the depleted uranium covered by that general license.

300.06 General Licenses - Radioactive Material Other Than Source Material.

1. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission or an Agreement State for use pursuant to 10 CFR Part 31.3. This general license is subject to the provisions of 100.04 through 100.10, 300.03(1)(b), 300.15, 300.24, 300.20, 300.25, and Sections 400,[20]1000 and 1300 of these regulations, as applicable.

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

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

2. Reserved.

3. Reserved.

4. Certain Measuring, Gauging or Controlling Devices.

   a. 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 300.06(4)(b), (c), (d) and (e), 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.

[20] Attention is directed particularly to the provisions of Section 400 of these regulations which relate to the labeling of containers.

b. The general license in 300.06(4)(a) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to 300.12(4) or ~~in accordance with the specifications contained in~~ an equivalent specific license issued by the Nuclear Regulatory Commission, an Agreement State or a Licensing State with provisions comparable to 300.12(4).[21]

   i. The devices shall have been received from one of the specific licensees described in 300.06(4)(b); or

   ii. Through a transfer made under 300.06(4)(c)(ix).

c. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 300.06(4)(a):

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

   ii. Shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however,

      i. Devices containing only krypton need not be tested for leakage of radioactive material, and

      ii. Devices containing only tritium or not more than 3.7 MBq (100 microcuries) of other beta- and/or gamma-emitting material or 0.37 MBq (10 microcuries) 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;

   iii. Shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

[21] 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.

i. In accordance with the instructions provided by the labels, or

ii. By a person holding an applicable specific license from the Agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

iv. Shall maintain records showing compliance with the requirements of 300.06(4)(c)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance 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 300.06(4)(c)(ii) 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 300.06(4)(c)(ii) 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 300.06(4)(c)(iii) 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;

v. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 1.85 Bq (0.005 microcurie) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the Agency. 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 furnish to the Agency within 30 days.

vi. Shall not abandon the device containing radioactive material;

vii. Shall not export the device containing radioactive material except in accordance with 10 CFR Part 110.

viii. Shall transfer or dispose of the device containing radioactive material:

i. Only by export as provided by 300.06(4)(c)(vii), by transfer to another general licensee as authorized in 300.06(4)(c)(ix), or to a person authorized to receive the device by a specific license under Section 300 or a specific license that authorizes waste collection under Section 300, or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under 300.06(4)(c)(viii)(iii).

ii. Shall 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.

iii. Shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in 300.06(4)(c)(viii)(i); 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 300.06(4)(c)(i) of this section so that the device is labeled in

compliance with 400.32 of these regulations; however the manufacturer, model number, and serial number must be retained;

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

iv. Reports the transfer under 300.06(4)(c)(xiii)(ii) of this section.

ix. Shall transfer the device to another general licensee only:

i. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of Sections 100.04 through 100.10, 300.06., 400.54, 400.55 of these regulations and any safety documents identified in the label on the device. Within 30 days of the transfer, report to the Agency;

i. The manufacturer's or initial transferor's name

ii. The model number and serial number of 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 300.06(4)(c)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

ii. Where 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.

x. Shall comply with the provisions of 400.54 and 400.55 of these regulations for reporting radiation incidents, theft, or loss of

licensed material, but shall be exempt from the other reporting requirements of Sections 400 and 1000 of these regulations.

xi. Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within 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.

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

xiii. Shall register general license devices:

i. In accordance with 300.06(4)(c)(xiii)(ii) and (iii). Each address for a location of use, as described in 300.06(4)(c)(xiii)(iii)(iv), represents a separate general licensee and requires a separate registration and fee.

ii. 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 is subject to the bankruptcy notification requirement in 300.15(5).

iii. 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 300.06(4)(c)(xii);

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.

xiv. 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.

xv. 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 300.06(4)(c)(ii) 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.

d. The general license in 300.06(4)(a) does not authorize the manufacture or import of devices containing radioactive material.

e. The general license provided in 300.06(4)(a) is subject to the provisions of 100.04 through 100.10, 300.15, 300.24 300.25, and Section 1300 of these regulations.

5. Luminous Safety Devices for Aircraft.

a. 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:

i. each device contains not more than 370 GBq (10 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147; and

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

b. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 300.06(5)(a) are exempt from the requirements of Sections 400 and 1000 of these regulations except that they shall comply with the provisions of 400.54 and 400.55.

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

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

e. This general license is subject to the provisions of 100.04 through 100.10, 300.15, 300.24, 300.25, and Section 1300 of these regulations.

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

6. 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.

7. Calibration and Reference Sources.

   a. 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 300.06(7)(d) and (e), ~~300.12(6) and~~ americium-241 in the form of calibration or reference sources:

      i. any person who holds a specific license issued by the Agency which authorizes the licensee to receive, possess, use, and transfer radioactive material; and

      ii. any person who holds a specific license issued by the Nuclear Regulatory Commission which authorizes the licensee to receive, possess, use, and transfer special nuclear material.

   b. 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 300.06(7)(d) and (e) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

   c. 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 300.06(7)(d) and (e) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

   d. The general licenses in 300.06(7)(a), (b) and (c) 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 Nuclear Regulatory Commission 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, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in 300.12(6), 10 CFR 32.57 or of 10 CFR 70.39.

   e. The general licenses provided in 300.06(7)(a), (b), and (c) are subject to the provisions of 100.04 through 100.10, 300.15, 300.24, 300.25, and Sections 400, 1000, and 1300 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:

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

ii. shall 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 called for in one of the following statements, as appropriate:

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

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)[22] DO NOT TOUCH RADIO-ACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or initial transferor

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

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

_____

Name of manufacturer or initial transferor

[22] Showing only the name of the appropriate material.

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

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

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

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

8. Reserved.

9. General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing. [23]

a. 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 300.06(9)(b), (c), (d), (e), and (f), 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:

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

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

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

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

[23] 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.

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

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

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

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

b. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 300.06(9)(a) until that person has filed Agency Form, "Registration Certificate - *In Vitro* Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of the Agency Form with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on the Agency Form the following information and such other information as may be required by that form:

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

ii. the location of use; and

iii. a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized under the general license in 300.06(9)(a) 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.

c. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 300.06(9)(a) shall comply with the following:

i. The general licensee shall not possess at any one time, pursuant to the general license in 300.06(9)(a), 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 microcuries).

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

iii. The general licensee shall use the radioactive material only for the uses authorized by 300.06(9)(a).

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

v. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 300.06(9)(a)(v) as required by 400.35(1) of these regulations.

d. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 300.06(9)(a):

i. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 300.12(8) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, any Agreement State or Licensing 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 300.06(9) or its equivalent, and

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

i. This radioactive material 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 Nuclear Regulatory Commission or of a State with which

the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

ii. This radioactive material 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 a Licensing State.

_____

Name of manufacturer

e. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 300.06(9)(a) shall report in writing to the Agency, any changes in the information furnished by him in the "Registration Certificate - *In Vitro*_Testing with Radioactive Material Under General License". The report shall be furnished within 30 days after the effective date of such change.

f. Any person using radioactive material pursuant to the general license of 300.06(9)(a) is exempt from the requirements of Sections 400 and 1000 of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 300.03(9)(a)(v) shall comply with the provisions of 400.35(1), 400.54, and 400.55 of these regulations.

10. Ice Detection Devices.

a. 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 microcuries) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission 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 300.12(9) or equivalent to those in 10 CFR 32.61.

b. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 300.06(10)(a):

i. shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 400.35(1) of these regulations;

ii. 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

iii. are exempt from the requirements of Sections 400 and 1000 of these regulations except that such persons shall comply with the provisions of 400.35(1), 400.54, and 400.55.

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

d. This general license is subject to the provisions of 100.04 through 100.10, 300.15, 300.24, 300.25, and Section 1300 of these regulations.

11. Self-Luminous Products Containing Radium-226.

a. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of 300.06(11)(b) through (d), radium-226 contained in the following products manufactured prior to November 30, 2007.

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

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

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

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

v. Small radium sources containing no more than 0.037 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 Nuclear Regulatory Commission educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Nuclear Regulatory Commission.

b. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in 300.06(11)(a) are exempt from the provisions of Sections 400 and 1000, and 100.07 and 300.20 of these regulations, to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under Section 300 of these regulations.

c. Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in 300.06(11)(a) shall:

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

ii. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 400.42 of these regulations or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Agency.

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

iv. 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 Section, or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State, or as otherwise approved by the Nuclear Regulatory Commission or an Agreement State.

v. Respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Agency, a written justification for the request.

d. The general license in 300.06(11)(a) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

300.07 Reserved.

SPECIFIC LICENSES

300.08 Filing Application for Specific Licenses.

1. Applications for specific licenses shall be filed on a form prescribed by the Agency and shall be accompanied by the fee as provided in Section 45-14-31 of the Act.

2. 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.

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

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

5. 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.

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

7. 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:

   a. identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission 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

   b. Contain the information identified in 10 CFR 32.210(c); or

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

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

      ii. 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.

8. Certain applications for specific licenses submitted under this section and Sections 500, 700, 1100, 1200, and 1400 must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning, as provided by 300.09(7),

   a. Each application submitted after April 7, 1993, to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in

glass in excess of the quantities in Appendix C, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," of this section must contain either:

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

ii. An emergency plan for responding to a release of radioactive material.

b. One or more of the following factors may be used to support an evaluation submitted under 300.08(8)(a)(i) of this section:

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

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

iii. The release fraction in the respirable size range would be lower than the release fraction shown in Appendix C of this section due to the chemical or physical form of the material;

iv. The solubility of the radioactive material would reduce the dose received;

v. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix C of this section;

vi. Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix C of this section; or

vii. Other factors appropriate for the specific facility.

c. An emergency plan for responding to a release of radioactive material submitted under 300.08(8)(a)(ii) must include the following information:

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

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

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

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

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

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

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

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

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

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

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

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

xiii. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

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

9. An application from a medical facility, or educational institution, to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Section 700 of these regulations or equivalent Nuclear Regulatory Commission or Agreement State requirements shall include:

a. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Section 300 of these regulations or Nuclear Regulatory Commission or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

b. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 300.12(10)(a)(ii) of this section.

c. 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 300.12(10)(b)(ii) of this section.

d. Information identified in 300.12(10)(a)(iii) of this section on the PET drugs to be noncommercially transferred to members of its consortium.

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

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

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

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

4. the applicant satisfies any applicable special requirements in 300.11, 300.12, or Section 500, Section 700, Section 1100, Section 1200, or Section 1400 of these regulations.

5. 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.

6. Reserved.

7. Financial Assurance and Recordkeeping for Decommissioning.

a.

i. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix F to Section 400 of these regulations shall submit a decommissioning funding plan as described in 300.09(7)(e). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F to Section 400 of these regulations.

ii. Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix F to Section 400 (or when a combination of isotopes is involved if R, as defined in 300.09(7)(a)(i), divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in 300.09(7)(e) of this section. The decommissioning funding plan must be submitted to the Agency by July 1, 2009.

b. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 300.09(7)(d) shall either:

i. Submit a decommissioning funding plan as described in 300.09(7)(e); or

ii. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 300.09(7)(d) using one of the methods described in 300.09(7)(f). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial

instrument obtained to satisfy the requirements of 300.07(7)(f) must be submitted to the Agency before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 300.09(7)(f).

c. Each holder of a specific license issued on or after November 15, 1992, which is of a type described in 300.09(7)(a) or (b), shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

i. Each holder of a specific license issued before November 15, 1992, and of a type described in 300.09(7)(a) shall submit on or before January 1, 1993, a decommissioning funding plan as described in 300.09(7)(e) or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

ii. Each holder of a specific license issued before November 15, 1992, and of a type described in 300.09(7)(b) shall submit, on or before January 1, 1993, a decommissioning funding plan as described in 300.09(7)(e) or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

iii. Any licensee who has submitted an application before November 15, 1992, for renewal of license in accordance with 300.17 shall provide financial assurance for decommissioning in accordance with 300.09(7)(a) and (b) of this section. This assurance must be submitted within 180 days of the effective date of these regulations.

iv. Waste collectors and waste processors, as defined in Section 400, Appendix D, must provide financial assurance in an amount based on a decommissioning funding plan as described in 300.09(7)(e) of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license

termination criteria of Section 400. The decommissioning funding plan must be submitted by July 1, 2009.

d. Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by July 1, 2009.Licensees required to submit the $113,000 or $225,000 amount must do so by September 1, 2009. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F to Section 400 of these regulations in unsealed form. (For a combination of radionuclides, if R, as defined in 300.09(7)(a), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1).....$1,125,000

greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F to Section 400 of these regulations in unsealed form. (For a combination of radionuclides, if R, as defined in 300.09(7)(a), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1).....$225,000

greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix F to Section 400 of these regulations in sealed sources or plated foils. (For a combination of radionuclides, if R, as defined in 300.09(7)(a), divided by 10^{10} is greater than 1 but R divided by 10^{12} is less than or equal to 1).....$113,000

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 300.09(7)(f), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of 300.09(7)(f).

f. Financial assurance for decommissioning must be provided by one or more of the following methods:

i. Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay

decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

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

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

ii. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust

operations are regulated and examined by a Federal or State agency.

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

iii. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 300.09(7)(f)(ii).

iv. In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 300.09(7)(d) and indicating that funds for decommissioning will be obtained when necessary.

g. Each person licensed under this section and Sections 500, 700, 1100, 1200, and 1400 of these regulations shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 300.15(2), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

i. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms and concentrations.

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

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

i. All areas designated and formerly designated restricted areas as defined in 100.02 of these regulations.

ii. All areas outside of restricted areas that require documentation under 300.09(g)(i).

iii. All areas outside of restricted areas where current and previous wastes have been buried as documented under 400.51 of these regulations.

iv. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 400.36 of these regulations.

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

300.10 Reserved

300.11 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.[24]

[24] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use,

1. Reserved.

2. An application for a specific license of broad scope will be approved if:

   a. the applicant satisfies the general requirements specified in 300.09;

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

   c. 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:

      i. 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;

      ii. 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

      iii. the establishment of appropriate administrative procedures to assure:

         i. control of procurement and use of radioactive material;

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

         iii. review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 300.11(2)(c)(iii)(ii) prior to use of the radioactive material.

3. Reserved.

4. Reserved.

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transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

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

   a. Unless specifically authorized, persons licensed pursuant to 300.11 shall not:

      i. conduct tracer studies in the environment involving direct release of radioactive material;

      ii. receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

      iii. conduct activities for which a specific license issued by the Agency under 300.12, Sections 500, 700, 1100, 1200 or 1400 is required; or

      iv. 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.

   b. Each specific license of broad scope issued under this section 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.

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

1. Licensing Introduction of Radioactive Material into Products in Exempt Concentrations.

   a. In addition to the requirements set forth in 300.09, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 300.03(1)(a) will be issued if:

      i. the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

ii. the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A of Section 300, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

b. Each person licensed under 300.12(1) shall file an annual report with the Agency which shall identify:

i. The type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

ii. Name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;

iii. The type and quantity of radionuclide introduced into each such product or material; and

iv. The initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

c. If no transfers of radioactive material have been made pursuant to 300.12(1) during the reporting period, the report shall so indicate. The report shall cover the year ending December 31, and shall be filed within 30 days thereafter.

2. Licensing the Distribution of Radioactive Material in Exempt Quantities.[25]

a. An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to 300.03(2) will be approved if:

i. 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;

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

ii. 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

iii. the applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

b. The license issued under 300.12(2)(a) is subject to the following conditions:

i. 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.

ii. 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 300.03(2). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 μSv) per hour.

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

i. identifies the radionuclide and the quantity of radioactivity, and

ii. bears the words "Radioactive Material".

iv. In addition to the labeling information required by 300.12(2)(b)(iii), the label affixed to the immediate container, or an accompanying brochure, shall:

i. state that the contents are exempt from Licensing State requirements,

ii. 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

iii. set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

c. Each person licensed under 300.12(2) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 300.03(2) or the equivalent regulations of a Licensing 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 December 31, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 300.12(2) during the reporting period, the report shall so indicate.

3. 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 300.03(3)(c) 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 microcurie).

4. Licensing the Manufacture or Initial Transfer of Devices to Persons Generally Licensed Under 300.06(4).

a. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 300.06(4) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

i. The applicant satisfies the general requirements of 300.09;

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

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

ii. under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive, in 1 year, a dose in excess of 10 percent of the annual limits specified in the table in 400.06(1) of these regulations, and

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

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

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

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

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

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

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

iii. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

i. The receipt, possession, use, and transfer of this device, Model _____, Serial No._____[26], are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission or a State with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or initial transferor

ii. The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[27], are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or initial transferor

iv. 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 Section

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

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

400.29 of these regulations, and the name of the manufacturer or initial distributor.

v. Each device meeting the criteria of 300.06(4)(c)(xiii)(i), 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 Section 400.29 of these regulations.

b. 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:

i. primary containment or source capsule;

ii. protection of primary containment;

iii. method of sealing containment;

iv. containment construction materials;

v. form of contained radioactive material;

vi. maximum temperature withstood during prototype tests;

vii. maximum pressure withstood during prototype test;

viii. maximum quantity of contained radioactive material;

ix. radiotoxicity of contained radioactive material; and

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

c. In the event the applicant desires that the general licensee under 300.06(4), or under equivalent regulations of the Nuclear Regulatory Commission, and Agreement State, or a Licensing 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 bases for such estimates. The submitted information shall demonstrate the 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 dose in excess of 10 percent of the annual limits specified in the table in 400.06(1) of these regulations.

d. Conditions of Transferring a Device for Use Under a General License in 300.06(4).

i. If a device containing radioactive material is to be transferred for use under the general license in 300.06(4), each person that is licensed under 300.12(4). shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of the general license contained in 300.06(4); if sections 300.06(4)(c)(ii) through (iv) or 300.06(4)(c)(xiii) do not apply to the particular device, those sections may be omitted.

ii. A copy of 100.04, 400.54 and 400.55 of these regulations;

iii. A list of the services that can only be performed by a specific licensee; and

iv. Information on acceptable disposal options including estimated costs of disposal.

ii. If radioactive material is to be transferred in a device for use under an equivalent general license of the Nuclear Regulatory Commission or an Agreement State, each person that is licensed under 300.12(4) shall provide the information specified in this section to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the

information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of 300.06(1), 300.06(4), 300.20, 400.54, and 400.55 of these regulations, or a copy of equivalent Nuclear Regulatory Commission or Agreement State's regulations. If a copy of the Nuclear Regulatory Commission's regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State; if certain parts of the regulations do not apply to the particular device, those parts may be omitted.

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

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

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

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

iv. Each device that is transferred shall meet the labeling requirements in 300.12(4)(a)(iii) through 300.12(4)(a)(v).

v. If a notification of bankruptcy has been made under 300.15(5) or the license is to be terminated, each person licensed under 300.12(4) shall provide, upon request, to the Agency, the Nuclear Regulatory Commission, and to any appropriate Agreement State, records of final disposition required under 300.12(4)(e)(iii).

e. Material Transfer Reports and Records. Each person licensed under 300.12(4) to initially transfer devices to generally licensed persons shall comply with the following requirements:

i. The person shall report to the Agency all transfers of devices to persons for use under the general license in 300.06(4) and all receipts of devices from persons licensed under 300.06(4). 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.

i. 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.

ii. 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).

iii. 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.

iv. 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.

v. 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.

vi. The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

vii. If no transfers have been made to or from persons generally licensed under 300.06(4) during the reporting period, the report shall so indicate.

ii. The person shall report all transfers of devices to persons for use under a general license in an Nuclear Regulatory Commission's or Agreement State's regulations that are equivalent to 300.06(4) and all receipts of devices from general licensees in the Nuclear Regulatory Commission's or Agreement State's jurisdiction to the Nuclear Regulatory Commission or responsible Agreement State agency. The report shall be submitted on NRC Form 653--``Transfers of Industrial Devices Report'' 10 CFR 32.52(a) or in a clear and legible report containing all of the data required by the form.

i. 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.

ii. 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).

iii. 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.

iv. 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.

v. 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.

vi. The report shall clearly identify the specific licensee submitting the report and shall include the license number of the specific licensee.

vii. If no transfers have been made to or from the Nuclear Regulatory Commission or a particular Agreement State during the reporting period, this information shall be reported to the Nuclear Regulatory Commission or responsible Agreement State agency upon request of the agency.

iii. The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by 300.06(4)(e) shall be maintained for a period of 3 years following the date of the recorded event.

5. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 300.06(5) will be approved if:

   a. the applicant satisfies the general requirements specified in 300.09; and

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

6. 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 300.06(7). An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 300.06(7) will be approved if:

   a. the applicant satisfies the general requirement of 300.09; and

   b. the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

7. Reserved.

8. 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 300.06(9) will be approved if:

   a. the applicant satisfies the general requirements specified in 300.09.

   b. the radioactive material is to be prepared for distribution in prepackaged units of:

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

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

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

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

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

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

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

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

c. each prepackaged unit bears a durable, clearly visible label:

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

ii. displaying the radiation caution symbol described in 400.29(1) and the words, "CAUTION, RADIOACTIVE MATERIAL" and "Not for Internal or External Use in Humans or Animals".

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

i. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for 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 Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

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

_____

Name of manufacturer

e. the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 400.35 of these regulations.

9. Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium-90. An application for a specific license to manufacture and initially transfer ice detection devises to persons generally licenses under 300.06(10) will be approved if:

a. the applicant satisfies the general requirements of 300.09; and

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

10. Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Pursuant to Section 700 of These Regulations.

a. 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 Section 700 of these regulations will be approved if:

i. the applicant satisfies the general requirements specified in 300.09 of this section;

ii. the applicant submits evidence that the applicant is at least one of the following:

i. Registered ~~or licensed~~ with the U. S. Food and Drug Administration (FDA) as the owner or operator of a

drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

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

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

iv. Operating as a nuclear pharmacy within a Federal medical institution; or

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

iii. the applicant submits information on the radionuclide, 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 safe handling and storage of the radioactive drugs by medical use licensees; and

iv. the applicant satisfies the following labeling requirements:

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

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

b. A licensee described by 300.12(10)(a)(ii)(iii) or (iv) of this section:

i. may prepare radioactive drugs for medical use, as defined in 700.02 of these regulations provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 300.12(10)(b)(ii) or 300.12(10)(b)(iv) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in Section 700.15 of these regulations.

ii. may allow a pharmacist to work as an authorized nuclear pharmacist if:

i. this individual qualifies as an authorized nuclear pharmacist as defined in 700.02 ; or

ii. this individual meets the requirements specified in 700.21(2) and 700.23 of these regulations and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

iii. this individual is designated as an authorized nuclear pharmacist in accordance with 300.12(10)(b)(iv).

iii. The actions authorized in 300.12(10)(b)(i) and 300.12(10)(b)(ii) are permitted in spite of more restrictive language in license conditions.

iv. May designate a pharmacist (as defined in 700.02) as an authorized nuclear pharmacist if:

i. the individual ~~is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Agency under Section 300~~. <u>was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and</u>

ii. <u>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 Nuclear Regulatory Commission.</u>

v. Shall provide to the Agency:

i. a copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State as specified in 700.21(1) of these regulations with the written attestation signed by a preceptor as required by 700.21(2)(b); or

ii. the Agency, Nuclear Regulatory Commission or Agreement State license; or

iii. Nuclear Regulatory Commission master materials licensee permit; or

iv. the permit issued by a licensee or Nuclear Regulatory Commission master materials permittee of broad scope; or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

v. 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 Nuclear Regulatory Commission Nuclear Regulatory Commission; and

vi. a copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 300.12(10)(b)(ii)(i) and (b)(ii)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

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

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

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

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

11. Reserved

12. 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 Section 700 for use as a calibration, transmission, or reference source or for the uses listed in 700.52, 700.62, 700.64, and 700.82 of these regulations will be approved if:

a. the applicant satisfies the general requirements in 300.09 of this section;

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

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

ii. details of design and construction of the source or device,

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

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

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

vi. procedures and standards for calibrating sources and devices,

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

viii. instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included

on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

c. 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 named source or device is approved by the Agency for distribution to persons licensed to use radioactive material identified in Sections 700.28, 700.52, 700.62, and 700.64 of these regulations, as appropriate, or under equivalent licenses of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State;

d. 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

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

i. primary containment or source capsule,

ii. protection of primary containment,

iii. method of sealing containment,

iv. containment construction materials,

v. form of contained radioactive material,

vi. maximum temperature withstood during prototype tests,

vii. maximum pressure withstood during prototype tests,

viii. maximum quantity of contained radioactive material,

ix. radiotoxicity of contained radioactive material, and

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

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

a. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 300.05(4) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State will be approved if:

i. the applicant satisfies the general requirements specified in 300.09;

ii. the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive, in 1 year, a radiation dose in excess of 10 percent of the annual limits specified in 400.06(1) of these regulations; and

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

b. 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 300.12(13) 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.

c. The Agency may deny any application for a specific license under 300.12(13) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

d. Each person licensed pursuant to 300.12(13)(a) shall:

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

ii. label or mark each unit to:

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

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

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

i. furnish a copy of the general license contained in 300.05(4) and a copy of the Agency Form, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in 300.05(4), or

ii. furnish a copy of the general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 300.05(4) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in 300.05(4) and a copy of Agency Form, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 300.05(4);

iv. report to the Agency all transfers of industrial products or devices to persons for use under the general license in 300.05(4). 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 300.05(4) during the reporting period, the report shall so indicate.

i. report to the Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the general license in 300.05(5) of these regulations;

ii. report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 300.12(13) for use under a general license in that State's regulations equivalent to 300.05(4);

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

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

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

v. 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 300.05(5) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

300.13 Reserved.

300.14 Issuance of Specific Licenses.

1. 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.

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

   a. minimize danger to public health and safety or property;

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

   c. prevent loss or theft of material subject to this section.

300.15 Specific Terms and Conditions of License.

1. Each license issued pursuant to the regulations in this section and the regulations in Sections 500, 700, 1100, 1200, and 1400 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.

2. No license issued or granted pursuant to the regulations in this section and Sections 500, 700, 1100, 1200, and 1400 nor any right to possess or utilize radioactive material granted by any license 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.

3. Each person licensed by the Agency pursuant to the regulations in this section and Sections 500, 700, 1100, 1200, and 1400 shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

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

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

        i. the licensee;

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

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

    b. The notification shall indicate:

        i. the bankruptcy court in which the petition for bankruptcy was filed; and

        ii. the date of the filing of the petition.

5. Licensees required to submit emergency plans by 300.07(8) shall follow the emergency plan approved by the Agency. The licensee may change the approved emergency plan without Agency approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Agency and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Agency.

6. Security Requirements for Portable Gauges. 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.

7. 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

8. 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 700.41 of these regulations. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

9.

   a. Authorization under 300.08(9) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

   b. Each licensee authorized under 300.08(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

      i. Satisfy the labeling requirements in 300.12(10)(a)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

      ii. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 300.12(10)(c).

   c. A licensee that is a pharmacy authorized under 300.08(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

      i. an authorized nuclear pharmacist that meets the requirements in 300.12(10)(b)(ii), or

      ii. an individual under the supervision of an authorized nuclear pharmacist as specified in 700.15 of these regulations.

d. A pharmacy, authorized under 300.08(9) 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 300.12(10)(b)(v).

300.16 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

1. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 300.17 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

2. Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

3. 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:

   a. Limit actions involving radioactive material to those related to

      decommissioning; and

   b. Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

4. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 300.16(6)(a), and begin decommissioning upon approval of that plan if:

   a. The license has expired pursuant to 300.16(1) or (2); or

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

c. No principal activities under the license have been conducted for a period of 24 months; or

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

5. Coincident with the notification required by 300.16(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 300.09(7) in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 300.16(6)(d)(v).

   a. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so within 180 days of the effective date of these regulations.

   b. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

6. The Agency may grant a request to extend the time periods established in 300.16(4) if the Agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 300.16(4). The schedule for decommissioning set forth in 300.16(4) may not commence until the Agency has made a determination on the request.

   a. A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

i. Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

ii. Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

iii. Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

iv. Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

b. The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 300.16(4) if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

c. Procedures such as those listed in 300.16(6)(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

d. The proposed decommissioning plan for the site or separate building or outdoor area must include:

i. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

ii. A description of planned decommissioning activities;

iii. A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.

iv. A description of the planned final radiation survey; and

v. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

vi. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan

shall include a justification for the delay based on the criteria in 300.16(7).

e. The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

i. Except as provided in 300.16(7), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

ii. Except as provided in 300.16(7), when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

7. The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:

a. Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

b. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

c. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

d. Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

e. Other site-specific factors which the Agency may consider appropriate on a case-by-base basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

8. As the final step in decommissioning, the licensee shall:

a. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Agency Form, "Certification of Disposition of Materials" or equivalent information; and

b. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 400.64, 400.65 or 400.66. The licensee shall, as appropriate:

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

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

9. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

a. Radioactive material has been properly disposed;

b. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

i. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 400.64, 400.65, or 400.66.; or

ii. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 400.64, 400.65, or 400.66.

300.17 Renewal of Licenses.

1. Applications for renewal of specific licenses shall be filed in accordance with 300.08.

2. 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.

300.18 Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with 300.08 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

300.19 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 300.09, and 300.11, and in Sections 100, 400, 500, 700, 1000, 1300, 1100, 1200, or 1400 of these regulations as applicable.

300.20 Records.

1. Each person who receives radioactive material pursuant to a license issued pursuant to these regulations shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

   a. 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.

   b. The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another section of the regulations dictates otherwise.

   c. 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.

2. The licensee shall retain each record that is required by these regulations or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

3. Records which must be maintained pursuant to 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.

4. If licensed activities are transferred or assigned in accordance with 300.15(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

    a. Records of disposal of licensed material made under 400.36 (including burials authorized before May 9, 1986), 400.37, 400.38, 400.39; and

    b. Records required by 400.37(2).

300.21 Reserved.

300.22 Reserved.

300.23 Reserved.

300.24 Transfer of Material.

1. No licensee shall transfer radioactive material except as authorized pursuant to 300.24.

2. Except as otherwise provided in the license and subject to the provisions of 300.24(3) and (4), any licensee may transfer radioactive material:

    a. to the Agency;[28]

    b. to the U.S. Department of Energy;

    c. to any person exempt from the regulations in the section to the extent permitted under such exemption;

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

    e. as otherwise authorized by the Agency in writing.

3. Before transferring radioactive material to a specific licensee of the Agency, the Nuclear Regulatory Commission, an Agreement State or a

[28] A licensee may transfer material to the Agency only after receiving prior approval from the Agency.

Licensing State, or to a general licensee who is required to register with the Agency, the Nuclear Regulatory Commission, an Agreement State or a Licensing 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.

4. Any of the following methods for the verification required by 300.24(3) is acceptable:

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

   b. 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.

   c. 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.

   d. The transferor may obtain other information compiled by a reporting service from official records of the Agency, the Nuclear Regulatory Commission, the licensing agency of an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

   e. When none of the methods of verification described in 300.24(4)(a) through (d) 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 Nuclear Regulatory Commission, or the licensing agency of an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

5. Shipment and transport of radioactive material shall be in accordance with the provisions of Section 1300 of these regulations.

300.25 Modification and Revocation of Licenses.

1. 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.

2. 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.

3. 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

300.26 Reciprocal Recognition of Licenses for Byproduct, Source, Naturally Occurring and Accelerator-Produced Radioactive Material and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

1. Subject to these regulations, any person who holds a specific license from the Nuclear Regulatory Commission, an Agreement State, or 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, except for areas of exclusive federal jurisdiction, for a period not in excess of 180 days in any calendar year provided that:

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

   b. the out-of-state licensee notifies the Agency in writing at least 3 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 and an annual fee as provided in Section 45-14-31 of the Act. 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 300.26(1);

c. 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;

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

e. the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 300.26(1) except by transfer to a person specifically licensed by the Agency or by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive such material,

2. Notwithstanding the provisions of 300.26(1), any person who holds a specific license issued by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in 300.06(4)(a) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

a. 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;

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

c. 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 the label is prohibited"; and

d. the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises the licensee installs such device a copy of the general license contained in 300.06(4) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

3. The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the Nuclear Regulatory

Commission 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.

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APPENDIX A

Exempt Concentrations

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
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			$1.5x10^{-1}$	$4x10^{-3}$

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
	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			$7.4x10^{-2}$	$2x10^{-3}$
	Gd-159			$3.0x10^{-2}$	$8x10^{-4}$
Gallium (31)	Ga-72			$1.5x10^{-2}$	$4x10^{-4}$
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			$2.2x10^{-2}$	$6x10^{-4}$

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
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			$3.7x10^{-1}$	$1x10^{-2}$
	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			$7.4x10^{-2}$	$2x10^{-3}$
	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			$1.1x10^{-1}$	$3x10^{-3}$

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
	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			$3.7x10^{-2}$	$1x10^{-3}$
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 which are also radioactive. 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 Section 300.03 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".

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

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

$\frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} \leq 1$

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APPENDIX B

Exempt Quantities of Radionuclides

Radionuclides		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

Radionuclide		kBq	µCi
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
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

Radionuclide		kBq	µCi
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
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

Radionuclide		**kBq**	**µCi**
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
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

Note 1: For purposes of 300.09(6)(f)(ii) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

$$\frac{\text{Amt. of radionuclide A possessed}}{1000 \times \text{Appendix B quantity for radionuclide A}} + \frac{\text{Amt. of radionuclide B possessed}}{1000 \times \text{Appendix B quantity for radionuclide B}} \leq 1$$

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APPENDIX C

Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.

Radioactive Material	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000

Radioactive Material	Release fraction	Quantity (curies)
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.0001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000

Radioactive Material	Release fraction	Quantity (curies)
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	3,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[1]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha [1]	.0001	20
Combinations of radioactive materials listed above [2]		

[1] Waste packaged in Type B containers does not require an emergency plan.

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

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Section 300

APPENDIX D

Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

I. Introduction

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

II. Financial Test

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

(1) The parent company must have:

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

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

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

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

(2) The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's and

(ii) Tangible net worth at least six times the current decommissioning cost estimate for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

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

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. (1) After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(2) If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Agency's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

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Section 300

APPENDIX E

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

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Section 300

APPENDIX F

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds.

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee**.**

II. Financial Test

A. To pass the financial test a company must meet the following criteria:

(1) Tangible net worth greater than $10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform Agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the Agency of intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.