

Virginia Administrative Code
Title 12. Health
Agency 5. Department of Health
Chapter 481. Virginia Radiation Protection Regulations

12VAC5-481-380. Purpose and Scope.

Part III. Licensing of Radioactive Material

Article 1. Purpose and Scope

A. This part, and Parts V ([12VAC5-481-1170](#) et seq.), VII ([12VAC5-481-1660](#) et seq.), XI ([12VAC5-481-2330](#) et seq.), XIII ([12VAC5-481-2950](#) et seq.), XIV ([12VAC5-481-3140](#) et seq.) and XVI ([12VAC5-481-3460](#) et seq.) of this chapter, provide for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to this part or Parts V ([12VAC5-481-1170](#) et seq.), VII ([12VAC5-481-1660](#) et seq.), XI ([12VAC5-481-2330](#) et seq.), XII ([12VAC5-481-2660](#) et seq.), XIII ([12VAC5-481-2950](#) et seq.), XIV ([12VAC5-481-3140](#) et seq.) and XVI ([12VAC5-481-3460](#) et seq.) of this chapter, or as otherwise provided in these parts.

B. In addition to the requirements of this part, all licensees are subject to the requirements of Parts I ([12VAC5-481-10](#) et seq.), IV ([12VAC5-481-600](#) et seq.), X ([12VAC5-481-2250](#) et seq.), and XIII ([12VAC5-481-2950](#) et seq.) of this chapter. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part V ([12VAC5-481-1170](#) et seq.) of this chapter, licensees using radionuclides in the healing arts are subject to the requirements of Part VII ([12VAC5-481-1660](#) et seq.) of this chapter, licensees engaged in irradiator operations are subject to the requirements of Part XII ([12VAC5-481-2660](#) et seq.) of this chapter, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part XIV ([12VAC5-481-3140](#) et seq.) of this chapter.

12VAC5-481-390. Source Material.

Article 2. Exemptions from the Regulatory Requirements

A. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from this part and the requirements for a license set forth in this chapter to the extent that they transport or store radioactive material in the regular course of the carriage for another or storage incident thereto.

B. Any person is exempt from Part III ([12VAC5-481-380](#) et seq.) of this chapter to the extent that such person receives, possesses, uses, owns, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 0.05% of the mixture, compound, solution or alloy. The exemption contained in this chapter does not apply to Australian-obligated radioactive material, nor does it include byproduct materials as defined in [12VAC5-481-10](#) .

C. Any person is exempt from Part III ([12VAC5-481-380](#) et seq.) of this chapter 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.

D. Any person is exempt from Parts III ([12VAC5-481-380](#) et seq.), IV ([12VAC5-481-600](#) et seq.), and X ([12VAC5-481-2250](#) et seq.) of this chapter to the extent such person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in (i) incandescent gas mantles, (ii), vacuum tubes; (iii) welding rods; (iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium; (v) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium; (vi) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or (vii) personnel neutron dosimeters provided that each dosimeter does not contain more than 50 milligrams of thorium.
2. Source material contained in the following products:
 - a. Glaze ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20% by weight source material;
 - b. Piezoelectric ceramic containing not more than 2.0% by weight source material;
 - c. Glassware containing not more than 2.0% by weight source material or for glassware manufactured before August 27, 2013, 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction; or
 - d. Glass enamel or glass enamel frit containing not more than 10% 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. (On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.)
3. Photographic film, negatives, and prints containing uranium or thorium.
4. Any finished product or part fabricated of, or containing tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4.0% by weight and that the exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.
5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights provided that:
 - a. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";
 - b. Each counterweight is durably and legibly labeled or marked with the identification

of the manufacturer, and the statement: "Unauthorized Alterations Prohibited" (The requirements of this subdivision need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by 10 CFR 40.13(c)(5)(ii) in effect on June 30, 1969); and

c. The counterweights are not manufactured for a military purpose using Australian-obligated source material.

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

a. The shipping container is conspicuously and legibly impressed with the legend: "CAUTION—RADIOACTIVE SHIELDING—URANIUM", and

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

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

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

b. The receipt, possession, use, or transfer of uranium or thorium contained in contact lens, spectacles, or eyepieces in binoculars or other optical instruments.

8. Thorium contained in any finished aircraft engine part contained nickel-thoria alloy, provided that:

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

b. The thorium content in the nickel-thoria alloy does not exceed 4.0% by weight.

9. The exemptions in this subsection do not authorize the manufacture of any products described.

10. No person may initially transfer for sale or distribution a product containing source material to persons exempt under this section or equivalent regulations of the NRC or another agreement state, unless authorized by the NRC with a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

a. Persons initially distributing source material in products covered by the exemptions in this section before August 27, 2013, without specific authorization may continue such distribution for one year beyond adoption of this subdivision. Initial distribution may also be continued until the NRC takes final action on a pending application for

license or license amendment to specifically authorize distribution submitted no later than one year beyond adoption of this chapter.

b. Persons authorized to manufacture, process, or produce these materials or products containing source material, and persons who import finished products or parts, for sale or distribution shall be authorized by an NRC license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of [12VAC5-481-450](#) and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-1170](#) et seq.) of this chapter.

12VAC5-481-400. Radioactive Material Other Than Source Material.

A. Exempt concentrations.

1. Except as provided in subdivisions 3 and 4 of this subsection, any person is exempt from the requirements for a license set forth in this part to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in [12VAC5-481-3720](#).
2. This subsection shall not be deemed to authorize the import of radioactive material or products containing radioactive material.
3. A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in this part to the extent that this person transfers radioactive material (i) contained in a product or material in concentrations not in excess of those specified in [12VAC5-481-3720](#) and (ii) introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by or application to a human being.
4. 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 this subsection or equivalent regulations by the NRC or another agreement state except in accordance with a license issued under [12VAC5-481-480](#).

B. Exempt quantities.

1. Except as provided in subdivisions 3, 4, and 5 of this subsection, any person is exempt from the requirements of this chapter 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 [12VAC5-481-3730](#).
2. Any person who possesses radioactive material received or acquired before September 25, 1971, under the general license provided in [12VAC5-481-430](#) is exempt from the requirements for a license set forth in this part and from the regulations contained therein to the extent that this person possesses, uses, transfers, or owns radioactive material.
3. This subsection does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of radioactive material or the incorporation

of radioactive material into products intended for commercial distribution.

4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in [12VAC5-481-3730](#), knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this part or equivalent regulations of the NRC or another agreement state, except in accordance with a license issued under [12VAC5-481-480](#), which license states that the radioactive material may be transferred by the licensee to persons exempt under this part or the equivalent regulations of the NRC or another agreement state.

5. No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in [12VAC5-481-3730](#), except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by this part.

C. Exempt items.

1. Except for persons who apply radioactive material to or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

a. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified quantities:

(1) 25 mCi (925 MBq) of tritium per timepiece;

(2) 5 mCi (185 MBq) of tritium per hand;

(3) 15 mCi (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);

(4) 100 μ Ci (3.7 MBq) of promethium 147 per watch or 200 μ Ci (7.4 MBq) of promethium 147 per any other timepiece;

(5) 20 μ Ci (0.74 MBq) of promethium 147 per watch hand or 40 μ Ci (1.48 MBq) of promethium 147 per other timepiece hand;

(6) 60 μ Ci (2.22 MBq) of promethium 147 per watch dial or 120 μ Ci (4.44 MBq) of promethium 147 per other timepiece dial (bezels when used shall be considered as part of the dial);

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

(a) For wrist watches, 0.1 millirad per hour (1 microgray per hour) at 10 centimeters from any surface,

(b) For pocket watches, 0.1 millirad per hour (1 microgray per hour) at 1 centimeter from any surface, or

(c) For any other timepiece, 0.2 millirad per hour (1 microgray per hour) at 10 centimeters from any surface; or

(8) 1 μCi (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

b. Other products including:

(1) Static elimination devices that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 μCi (18.5 MBq) of polonium-210 per device;

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

(3) Such devices authorized before October 23, 2012, for use under the general license then provided in [12VAC5-481-430](#) and equivalent regulations of the NRC or another agreement state and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the agency, the NRC, or another agreement state.

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

d. (Reserved.)

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

f. (Reserved.)

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

h. Electron tubes (includes: spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents), provided that each tube does not contain more than one of the following specified quantities:

(1) 150 mCi (5.55 GBq) of tritium per microwave receiver protector tube or 10 mCi (370 MBq) of tritium per any other electron tube;

(2) 1 μCi (37 kBq) of cobalt-60;

(3) 5 μCi (185 kBq) of nickel-63;

(4) 30 μCi (1.11 MBq) of krypton-85;

(5) 5 μCi (185 kBq) of cesium-137; or

(6) 30 μCi (1.11 MBq) of promethium-147; and

(7) Provided further that the levels of radiation dose from each electron tube containing radioactive material do not exceed 1 millirad per hour (10 microgray per hour) at 1 centimeter (0.39 inches) from any surface when measured through 7 milligrams per square centimeter of absorber.

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

(1) Each source contains no more than one exempt quantity set forth in [12VAC5-481-3730](#), and

(2) Each instrument contains no more than 10 exempt quantities. For purposes of this subdivision, an instrument's source or sources may contain either one type 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 [12VAC5-481-3730](#), provided that the sum of such fractions shall not exceed unity.

(3) For purposes of this subdivision, 0.05 μCi (1.85 kBq) of americium-241 is considered an exempt quantity under [12VAC5-481-3730](#).

j. (Reserved.)

2. Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in subdivision 1 of this subsection, or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to [12VAC5-481-480](#) C, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to subdivision 1 of this subsection.

D. Self-luminous products containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, or except as provided in subdivision 3 of this subsection, any person is exempt from the requirements for a license set forth in this part to the extent that such person receives, possesses, uses, transfers, own, 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 pursuant to [12VAC5-481-480](#) D, which license authorizes the initial transfer of the product to persons who are exempt from regulatory requirements.

2. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of

radium-226 acquired prior to September 1, 1980.

3. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under subdivision 1 of this subsection should apply for a license and for a certificate of registration in accordance with [12VAC5-481-480 D](#).

4. The exemption in subdivision 1 of this subsection does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

E. Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property from fires and airborne hazards provided that the detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued under [12VAC5-481-480 E](#), which license authorizes use under this subsection. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by the NRC or another agreement state under provisions comparable to [12VAC5-481-480 C](#) authorizing distribution to persons exempt from regulatory requirements.

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under subdivision 1 of subsection E, should apply to the agency for a license in accordance with [12VAC5-481-480 C](#).

3. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under subdivision 1 of this subsection, 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 [12VAC5-481-480 C](#).

4. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by the NRC or another agreement state shall be considered exempt under subdivision 1 of this subsection, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of [12VAC5-481-480 C](#).

F. Radioactive drug: Capsules containing carbon-14 urea for "in-vivo" diagnostic use for humans.

1. Except as provided in subdivision 2 of this subsection, any person is exempt from the requirements for a license set forth in this part, provided that such person receives,

possess, uses, transfers, owns, or acquires capsules containing 1 μCi (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use for humans.

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part VII ([12VAC5-481-1660](#) et seq.) of this chapter.

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for a license under and a certification of registration in accordance with [12VAC5-481-480](#) I.

4. Nothing in this subsection relieves persons from complying with applicable U.S. Food and Drug Administration (FDA), other federal, and state requirements governing receipt, administration, and use of drugs.

G. Carriers. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from this part to the extent that they transport special nuclear material in the regular course of carriage for another or storage incident thereto. This exemption does not apply to the storage in transit or transport of material by persons covered by a general license issued under [12VAC5-481-430](#) E.

H. Certain industrial devices.

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

2. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under subdivision 1 of this subsection, should apply to the NRC for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

12VAC5-481-410. Types of Licenses.

Article 3. Licenses

A radioactive materials license will be one of the following:

1. A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the agency or the issuance by the agency of licensing documents to the particular person; although, the filing of a certificate with the agency may be required by the particular general license. The general licensee is subject to all applicable parts of this chapter and any limitations of the general license.

2. A specific license requires the submission of an application to the agency and the issuance of a licensing document to a named person by the agency. A licensee is subject to all applicable parts of this chapter as well as any limitations specified in the licensing document.

12VAC5-481-420. General Licenses -- Source Material.

A. Small quantities of source material.

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

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

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

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

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

2. Any person who receives, possesses, uses, or transfers source material in accordance with the general license in subdivision 1 of this subsection:

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

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

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

(2) In accordance with [12VAC5-481-910](#) .

c. Is subject to the provisions in [12VAC5-481-100](#) , [12VAC5-481-110](#) , [12VAC5-481-380](#) , [12VAC5-481-500](#) , [12VAC5-481-570](#) , [12VAC5-481-580](#) , and [12VAC5-481-1110](#) .

d. Shall not export such source material except in accordance with 10 CFR Part 110.

3. Any person who receives, possesses, uses, or transfers source material in accordance with subdivision 1 of this subsection shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the agency about such contamination and may consult with the agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in [12VAC5-481-1161](#) .

4. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in subdivision 1 of this subsection is exempt from the provisions of Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of [12VAC5-481-910](#) and [12VAC5-481-1161](#) to the extent necessary to meet the provisions of subdivisions 2 (b) and 3 of this subsection. However, this exemption does not apply to any person who also holds a specific license issued under this chapter.

5. No person may initially transfer or distribute source material to persons generally licensed under subdivision 1 a or b of this subsection, or equivalent regulations of the NRC or another agreement state, unless authorized by a specific license issued in accordance with subdivision E of this subsection or equivalent provisions of the NRC or another agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

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

C. Depleted uranium in industrial products and devices.

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

2. The general license in subdivision 1 of this subsection applies only to industrial products or devices that have been manufactured or initially transferred in accordance with a specific license issued by the agency, the NRC, or another agreement state, which authorizes manufacture of the products or devices for distribution to persons generally licensed.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license in subdivision 1 of this subsection shall file a registration form with the agency by an appropriate method. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium and the agency shall be notified, in writing, within 30 days, of any change afterwards. The registrant shall furnish the following information and such other information as may be required:

a. Name and address of the registrant;

b. A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in subdivision 1 of this subsection and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

c. Name, title, or both; address; and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in this subdivision.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established in subdivision 1 of this subsection:

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

b. Shall not abandon such depleted uranium.

c. Shall transfer or dispose of such depleted uranium only by transfer in accordance with [12VAC5-481-570](#). In the case where the transferee receives the depleted uranium pursuant to the general license established by subdivision 1 of this subsection, the transferor shall furnish the transferee a copy of this subsection and a copy of the

appropriate agency form. In the case where the transferee receives the depleted uranium pursuant to a general license contained in a NRC or another agreement state's regulation equivalent to this subsection, the transferor shall furnish the transferee with a copy of this subsection and a copy of the appropriate agency form accompanied by a note explaining that use of the product or device is regulated by the NRC or agreement state under requirements substantially the same as those in this subsection.

d. Within 30 days of any transfer, shall report, in writing, to the agency the name and address of the person receiving the source material pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by subdivision 1 of this subsection is exempt from the requirements of Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of [12VAC5-481](#) with respect to the depleted uranium covered by that general license.

12VAC5-481-421. Requirements for License to Initially Transfer Source Material for Use under the Small Quantities of Source Material General License.

A. An application for a specific license to initially transfer source material for use under [12VAC5-481-420](#) A or equivalent regulations of the NRC or another agreement state will be approved if:

1. The applicant satisfies the general requirements specified in [12VAC5-481-450](#); and
2. The applicant submits adequate information on, and the agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

B. Conditions of licenses to initially transfer source material for use under the small quantities of source material general license: quality control, labeling, safety instructions, and records and reports.

1. Each person licensed under subsection A of this section shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."
2. Each person licensed under subsection A of this section shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.
3. Each person licensed under subsection A of this section shall provide the information specified in this paragraph to each person to whom source material is transferred for use under [12VAC5-481-420](#) A or equivalent provisions of the NRC or another agreement state. This information shall be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:
 - a. A copy of [12VAC5-481-420](#) A and [12VAC5-481-570](#) , or relevant equivalent regulations of the NRC or another agreement state.
 - b. Appropriate radiation safety precautions and instructions relating to handling, use,

storage, and disposal of the material.

4. Each person licensed under subsection A of this section shall report transfers as follows:

a. File a report with the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:

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

(2) For each general licensee under 10 CFR 40.22 to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name, position, or both and phone number, of the general licensee to whom the material was sent and the type, physical form, and quantity of source material transferred; and

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

b. File a report with the agency and other agreement state agencies that identifies all persons operating under provisions equivalent to [12VAC5-481-420](#) A to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state to which the report is being made:

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

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

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

c. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under [12VAC5-481-420](#) A or equivalent NRC and other agreement state provisions during the current period, a report shall be submitted to the agency indicating so. If no transfers have been made to general licensees of the NRC or in a particular agreement state during the reporting period, this information shall be reported to the NRC or responsible agreement state agency upon request of the agency.

5. Each person licensed under subsection A of this section shall maintain all information that supports the reports required by this section concerning each transfer to a general

licensee for a period of one year after the event is included in a report to the agency, the NRC, or another agreement state.

12VAC5-481-430. General Licenses -- Radioactive Material Other Than Source Material.

A. Certain devices and equipment.

1. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment that have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the agency or equivalent requirements by the NRC or another agreement state for use pursuant to [12VAC5-481-480](#) B or C.

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

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

2. The general licenses provided in this subsection are subject to the general provisions of this subsection, the provisions of this part, and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

B. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

1. A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state, or local government agencies to acquire, receive, possess, use, or transfer, in accordance with the provisions of subdivisions 2, 3, 4, 5, and 6 of this subsection, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

2. The general license in subdivision 1 of this subsection 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. A specific license issued by the agency; or

b. An equivalent specific license issued by the NRC or another agreement state.

3. The devices shall have been received from one of the specific licensees described in this

subsection or through a transfer made under subdivision 4 of this subsection.

4. Any person who owns, acquires, receives, possesses, uses, or transfers radioactive material in a device pursuant to the general license in subdivision 1 of this subsection:

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

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

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

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

c. Shall assure that the tests required by subdivision 4 of this subsection and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(1) In accordance with the instructions provided by the labels; or

(2) By a person holding a specific license issued by the agency, the NRC, or another agreement state to perform such activities.

d. Shall maintain records showing compliance with the requirements of subdivision 4 of this subsection. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(1) Each record of a test for leakage of radioactive material required by subdivision 4 of this subsection shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(2) Each record of a test of the on-off mechanism and indicator required by subdivision 4 of this subsection shall be retained for three 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.

(3) Each record that is required by subdivision 4 of this subsection shall be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

e. Shall immediately suspend operation of the device if there is a failure of, 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 0.005 μCi (185 Bq) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by the agency, NRC, or another agreement state. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the agency. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 μCi (185 Bq) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, shall be furnished to the agency within 30 days. Under these circumstances, the criteria set out in [12VAC5-481-1161](#) may be applicable, as determined by the agency on a case-by-case basis.

f. Shall not abandon the device containing radioactive material.

g. Shall not export the device containing radioactive material except in accordance with applicable provisions of this chapter.

h. Shall transfer or dispose of the device containing radioactive material only by export as provided by subdivision 4 g of this subsection, by transfer to another general licensee as authorized in subdivision 4 i of this subsection, or to a person authorized to receive the device by a specific license issued by the agency, the NRC, or another agreement state that authorizes waste collection or as otherwise approved under the following provisions of this subdivision B 4 h:

(1) Within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the agency with the following information:

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

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

(c) The date of the transfer; and

(2) Obtain written agency approval before transferring the device to any other specific licensee not specifically identified in this subdivision; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the holder:

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

(b) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by subdivision 4 of this subsection) so that the device is labeled in compliance with [12VAC5-481-880](#); however, the manufacturer, model number, and

serial number shall be retained;

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

(d) Reports the transfer under subdivision 4 of this subsection.

i. Shall transfer the device to another general licensee only if:

(1) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this subsection, a copy of this part and [12VAC5-481-1090](#) and [12VAC5-481-1100](#) , and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the agency:

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

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

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

(d) The name, title, and phone number of the responsible individual identified by the transferee in accordance with subdivision 4 l of this subsection to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(2) 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.

j. Shall comply with the provisions of [12VAC5-481-1090](#) and [12VAC5-481-1100](#) for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter.

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

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

m. Shall annually register devices containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of

radium-226, or 1 mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use represents a separate general licensee and requires a separate registration and fee. The registration fee will be \$50 per device.

(1) The registration information shall be submitted to the agency within 30 days of the requested date for registration or as otherwise indicated in the request, and at a minimum include the following information and any other information specifically requested by the agency:

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

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

(c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under subdivision 4 l of this subsection.

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

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

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

(2) A general licensee holding devices meeting the criteria of subdivision 4 m of this subsection is subject to the bankruptcy notification requirement in [12VAC5-481-500 E](#).

n. Shall 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 of the device.

o. May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by subdivision 4 of this subsection 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.

5. The general license in this subsection does not authorize the manufacture or import of devices containing radioactive material.

6. The general license provided in this subsection is subject to the provisions of this part

and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

C. The general license provided in [12VAC5-481-420](#) B is subject to the provisions of [12VAC5-481-100](#) through [12VAC5-481-210](#) , [12VAC5-481-500](#) , [12VAC5-481-570](#) , [12VAC5-481-580](#) and Part XIII ([12VAC5-481-2950](#) et seq.) of this chapter.

D. Luminous safety devices for use in aircraft. In addition, this general license is subject to the provisions of [12VAC5-481-100](#) through [12VAC5-481-210](#) , [12VAC5-481-500](#) , [12VAC5-481-570](#) , [12VAC5-481-580](#) , and Part XIII ([12VAC5-481-2950](#) et seq.) of this chapter.

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 Ci (370 GBq) of tritium or 300 mCi (11.1 GBq) of promethium-147 and that each device has been manufactured, assembled, or initially transferred in accordance with a license issued under the provisions of [12VAC5-481-480](#) D or manufactured or assembled in accordance with a specific license issued by the NRC or another agreement state that authorizes manufacture or assembly of the device for distribution to persons generally licensed the agency or NRC.
2. Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this subdivision are exempt from the requirements of Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter, except that they shall comply with the provisions of [12VAC5-481-1090](#) and [12VAC5-481-1100](#) .
3. This general license does not authorize the manufacture, assembly, repair, or import of luminous safety devices containing tritium or promethium-147.
4. This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.
5. This general license does not authorize the ownership, receipt, acquisition, possession, or use of promethium-147 contained in instrument dials.
6. The general license provided in this subsection is subject to the general provisions of this subsection, the provisions of this part, and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

E. General license to own radioactive material.

1. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provision of this subsection, a general license under this subsection is not authorized to manufacture, produce, transfer, receive, possess, use, import, or export radioactive material, except as authorized in a specific license.
2. A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of this subsection, a general license under this subsection is not authorized to acquire, deliver, receive, possess,

use, transfer, import, or export special nuclear material, except as authorized in a specific license.

3. The general license provided in this subsection is subject to the general provisions of this subsection, the provisions of this part, and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

F. Calibration and reference sources.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer americium-241 in the form of calibration or reference sources in accordance with the provisions of subdivisions 4 and 5 of this subsection to any person who holds a specific license issued by the agency that authorizes receipt, possession, use, and transfer of radioactive material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subdivisions 4 and 5 of this subsection to any person who holds a specific license issued by the agency that authorizes him to receive, possess, use, and transfer radioactive material.

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

4. The general licenses in subdivisions 1 through 3 of this subsection apply only to calibration or reference sources that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC pursuant to 10 CFR 32.57 or 10 CFR 70.39, or that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency or another agreement state pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR Part 70.39.

5. The general licenses provided in subdivisions 1 through 3 of this subsection are subject to the provisions of [12VAC5-481-100](#) through [12VAC5-481-210](#) , [12VAC5-481-500](#) , [12VAC5-481-570](#) , [12VAC5-481-580](#) and Parts IV ([12VAC5-481-600](#) et seq.); X ([12VAC5-481-2250](#) et seq.); and XIII ([12VAC5-481-2950](#) et seq.) of this chapter. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

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

b. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label that includes one of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, as appropriate:

(1) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory 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) (Showing only the name of the appropriate material.)

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____ Name of manufacturer or importer

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

CAUTION—RADIOACTIVE MATERIAL

THIS SOURCE CONTAINS RADIUM-226.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____ Name of manufacturer or importer

c. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the agency, the NRC, or another agreement state to receive the source;

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

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

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

7. This general license does not authorize the export of calibration or reference sources containing americium-241, plutonium, or radium-226.

8. The general license provided in this subsection is subject to the general provisions of this subsection and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

G. General license for use of radioactive material for certain in vitro clinical or laboratory testing.

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital to receive, acquire, possess, transfer, or

use for any of the following stated tests in accordance with the provisions of this subsection the following radioactive materials in prepackaged units for use in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

- a. Iodine-125, in units not exceeding 10 μ Ci (370 kBq) each.
- b. Iodine-131, in units not exceeding 10 μ Ci (370 kBq) each.
- c. Carbon-14, in units not exceeding 10 μ Ci (370 kBq) each.
- d. Hydrogen-3 (tritium), in units not exceeding 50 μ Ci (1.85 MBq) each.
- e. Iron-59, in units not exceeding 20 μ Ci (740 kBq) each.
- f. Selenium-75, in units not exceeding 10 μ Ci (370 kBq) each.
- g. Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 μ Ci (1.85 kBq) of iodine-129 and 0.005 μ Ci (185 Bq) of americium-241 each.
- h. Cobalt-57, in units not exceeding 10 μ Ci (0.37 MBq) each.

2. A person shall not receive, acquire, possess, use, or transfer radioactive material under the general license established by subdivision 1 of this subsection unless that person:

- a. Has filed the In Vitro Testing GL form with the agency and has received from the agency a validated copy with a registration number assigned. The physician, veterinarian, clinical laboratory, or hospital shall furnish the name and address of the physician, veterinarian, clinical laboratory, or hospital; the location of use; and 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 by this subsection 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; or
- b. Has a license that authorizes the medical use of radioactive material that was issued under Part VII ([12VAC5-481-1660](#) et seq.) of [12VAC5-481](#) .

3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by subdivision 1 of this subsection shall comply with the following:

- a. The general licensee shall not possess at any one time under the general license in subdivision 1 of this subsection at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57, or iron-59 in excess of 200 μ Ci (7.4 MBq).
- b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
- c. The general licensee shall use the radioactive material only for the uses authorized by

subdivision 1 of this subsection.

d. The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it by a license pursuant to this chapter, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in this subsection as required by [12VAC5-481-910](#) .

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subdivision 1 of this subsection:

a. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of [12VAC5-481-480](#) G or in accordance with the provisions of a specific license issued by the NRC or another agreement state that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed, and

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

"This radioactive material may be received, acquired, possessed, and used only by physicians or veterinarians in the practice of veterinary medicine, 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 U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)"

5. The registrant possessing or using radioactive materials under the general license of subdivision 1 of this subsection shall report in writing to the agency, any changes in the information furnished to the agency in the Registration Certificate – In Vitro Testing With Radioactive Material Under General License within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of subdivision 1 of this subsection is exempt from the requirements of Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter with respect to radioactive materials covered by that general license, except that such persons using the Mock Iodine-125 described in subdivision 1 of this subsection shall comply with the provisions of [12VAC5-481-910](#) , [12VAC5-481-1090](#) , and [12VAC5-481-1100](#) .

7. The general license provided in this subsection is subject to the provisions of this part

and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

H. Strontium-90 in ice detection devices.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 μCi (1.85 MBq) of strontium-90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to [12VAC5-481-480](#) H or in accordance with the specifications contained in a specific license issued to the manufacturer by the NRC or another agreement state authorizing manufacture of the ice detection devices for distribution to persons generally licensed.

2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in subdivision 1 of this subsection:

a. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, (i) discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license pursuant to this part or Part IV ([12VAC5-481-600](#) et seq.) of this chapter, or from the NRC or another agreement state to manufacture or service such devices; or (ii) dispose of the device pursuant to the provisions of [12VAC5-481-910](#) .

b. Shall assure that all labels affixed to the device at the time of receipt, and that bear a statement that prohibits removal of the labels, are maintained thereon.

c. Are exempt from the requirements of Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter except that such persons shall comply with the provisions of [12VAC5-481-910](#) , [12VAC5-481-1090](#) , and [12VAC5-481-1100](#) .

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

4. The general license provided in this subsection is subject to the provisions of this part, and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

I. Certain items and self-luminous products containing radium-226.

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer in accordance with the provisions of the following subdivisions radium-226 contained in the following products manufactured prior to November 30, 2007.

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

b. Intact timepieces containing greater than 1 μCi (0.037 MBq), nonintact timepieces,

and timepiece hands and dials no longer installed in timepieces.

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

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

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

2. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in subdivision 1 of this subsection are exempt from the provisions of Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter, as well as [12VAC5-481-1090](#) and [12VAC5-481-1100](#), 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.

3. Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in subdivision 1 of this subsection:

a. Shall 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 shall be furnished to the agency within 30 days.

b. Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to [12VAC5-481-971](#) or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the agency.

c. Shall not export products containing radium-226 except in accordance with this chapter.

d. Shall 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 (42 USC § 6901 et seq.), as authorized under the Energy Policy Act of 2005 (42 USC § 15801 et seq.), by transfer to a person authorized to receive radium-226 by a specific license issued under this part or equivalent regulations of the NRC or another agreement state, or as otherwise approved by the agency.

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

information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request.

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

5. The general license provided in this subsection is subject to the general provisions of this subsection, the provisions of this part, and Parts IV ([12VAC5-481-600](#) et seq.) and X ([12VAC5-481-2250](#) et seq.) of this chapter unless indicated otherwise in the specific provision of the general license.

J. General license to install and service generally licensed devices. Any person who holds a specific license issued by the NRC or another agreement state authorizing the holder to manufacture, install, or service a device described in this subsection, is hereby granted a general license to install and perform nonradiological service (i.e., leak testing, surveys, routine maintenance) of the devices, provided that:

1. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or another agreement state; and
2. Such person assures that any labels required to be affixed to the device under regulations of the NRC or another agreement state licensing the manufacture of the device bear a statement that removal of the label is prohibited.

12VAC5-481-440. Filing Application for Specific Licenses.

Article 4. Specific Licenses

A. Applications for specific licenses shall be filed on a form prescribed by the agency.

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

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

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

E. Applications and documents submitted to the agency may be made available for public inspection in accordance with the Virginia Freedom of Information Act (§ [2.2-3700](#) et seq. of the Code of Virginia). The agency may withhold records in accordance with specific exemptions in the Virginia Freedom of Information Act or as otherwise specified by law.

F. 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:

1. Identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or an agreement state under equivalent regulations;
2. Contain the information in 10 CFR 32.210(c);
3. For sources or devices containing radioactive material manufactured prior to October 23, 2012, that are not registered with the NRC under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant shall provide:
 - a. All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and
 - b. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall 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;
4. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or
5. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used in lieu of identifying each sealed source and device.

G. Each application to possess radioactive material in unsealed form, on a foil or plated source, or sealed in glass in excess of the quantities in [12VAC5-481-3740](#) shall contain one of the following:

1. An evaluation showing that the projected dose to a person offsite due to a release of radioactive material would not exceed 0.01 Sv (1 rem) total effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
2. An emergency plan, reviewed and commented on by offsite response organizations expected to respond in the event of an accident that contains the following information:
 - a. Facility description. A brief description of the licensee or applicant's facility and surroundings.
 - b. Types of accidents. An identification of each type of radioactive materials accident for which actions by licensee staff or offsite response organizations will be needed to protect members of the public.
 - c. Classification of accidents. A method for classifying and declaring an accident as alert or site area emergency.

- d. Detection of accidents. Identification of the means for detecting each type of alert or site area emergency in a timely manner.
- e. Mitigation of consequences. A brief description of the means and equipment that are available for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
- f. Assessment of releases. A brief description of the methods and equipment available to assess releases of radioactive material.
- g. Responsibilities. A brief description of the responsibilities of the licensee or applicant's personnel who will respond if an accident occurs, including identification of personnel responsible for promptly notifying offsite response organizations, including the agency.
- h. Plan maintenance. A brief description of the positions assigned and methods to develop, maintain and update the plan.
- i. A list of offsite response organizations, description of their responsibilities and anticipated actions, and copy of formal commitments, if any.
- j. Notification and coordination. A brief description of the means to promptly notify the offsite response organizations and request offsite assistance including medical assistance for the treatment of contaminated injured onsite workers. The notification and coordination shall include alternate provisions in case key personnel, parts of the facility, or some equipment are unavailable. 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.
- k. 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 the agency. A 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. A licensee shall provide any comments received within the 60 days to the agency with the emergency plan.
- l. Training. A brief description of the frequency, performance objectives and plan for training that the licensee or applicant will provide workers on how to respond to an emergency, including any special instructions and orientation tours that the licensee or applicant will offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific hazards and emergency procedures. The training shall also prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of drills, exercises and team training for such scenarios.
- m. Drills and exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. The licensee or applicant shall invite offsite response organizations to

participate in biennial exercises. The exercises shall use accident scenarios postulated as the most probable for the specific site and the scenarios may not be known to most exercise participants. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

n. Safe condition. A brief description of the means of restoring the facility and surroundings to a safe condition after an accident.

o. 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, P.L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

H. An application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Part VII ([12VAC5-481-1660](#) et seq.) of this chapter shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Part III ([12VAC5-481-380](#) et seq.) of this chapter for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.
2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in [12VAC5-481-480](#) I.
3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an ANP as specified in [12VAC5-481-480](#) I 2.
4. Information identified in [12VAC5-481-480](#) I 1 c on the PET drugs to be noncommercially transferred to members of its consortium.

I. Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under Part VII ([12VAC5-481-1660](#) et seq.).

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII ([12VAC5-481-1660](#) et seq.) will be approved if:

- a. The applicant satisfies the general requirements specified in [12VAC5-481-450](#) ;
- b. The applicant submits evidence that the applicant is at least one of the following:
 - (1) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
 - (2) Registered or licensed with a state agency as a drug manufacturer;
 - (3) Licensed as a pharmacy by the Virginia Board of Pharmacy;

(4) Operating as a nuclear pharmacy within a federal medical institution; or

(5) A PET drug production facility registered with a state agency.

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

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in [12VAC5-481-850](#) 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.

(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in [12VAC5-481-850](#) and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

a. An authorized nuclear pharmacist (ANP) as defined in [12VAC5-481-10](#) ;

b. An individual that meets the requirements specified in [12VAC5-481-1770](#) and [12VAC5-481-1790](#) , and the licensee has received an approved license amendment identifying this individual as an ANP;

c. A pharmacist, as defined in [12VAC5-481-10](#) , designated as an ANP if:

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

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

d. An individual under the supervision of an ANP as specified in [12VAC5-481-1710](#) .

3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:

a. The individual's certification by a specialty board whose certification process has

been recognized by the NRC with the written attestation signed by a preceptor as required by [12VAC5-481-1770](#);

b. An NRC or another agreement state license;

c. NRC master materials licensee permit;

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

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

f. The Virginia Board of Pharmacy's license.

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

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

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

5. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

6. 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 in accordance with [12VAC5-481-1930](#). The licensee shall record the results of each test and retain each record for three years after the record is made.

12VAC5-481-450. General Requirements for the Issuance of Specific Licenses.

A. 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;

4. The applicant has described in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste;

5. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with this chapter; and

6. The applicant satisfies any applicable special requirements in [12VAC5-481-460](#) , [12VAC5-481-470](#) , [12VAC5-481-480](#) , or Part V ([12VAC5-481-1170](#) et seq.), Part VII ([12VAC5-481-1660](#) et seq.), Part XI ([12VAC5-481-2330](#) et seq.), Part XII ([12VAC5-481-2660](#) et seq.), Part XIV ([12VAC5-481-3140](#) et seq.), or Part XVI ([12VAC5-281-3460](#) et seq.) of this chapter.

B. 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 that 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 subsection 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.

C. Financial assurance and records for decommissioning.

1. A person applying for a specific license authorizing the possession and use of unsealed radioactive material shall submit a decommissioning funding plan as described in subdivision 6 of this subsection with the license application for any of the following types of materials:

a. Unsealed radioactive material with a half-life greater than 120 days and in quantities greater than 105 times the applicable quantities listed in [12VAC5-481-3750](#) .

b. Unsealed radioactive material involving a combination of isotopes with R divided by 105 being greater than one, where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in [12VAC5-481-3750](#) .

2. A person applying for a specific license authorizing the possession and use of radioactive material not covered by subdivision 1 of this subsection with a half-life greater than 120 days and in quantities specified in subdivision 5 of this subsection shall do either of the following:

a. Submit a decommissioning funding plan as described in subdivision 6 of this subsection.

b. Submit a written certification, signed by the chief financial officer or other individual designated by management to represent the licensee, that financial assurance has been provided in the amount prescribed in subdivision 5 of this subsection using one of the methods described in subdivision 6 of this subsection and a signed original of the financial instrument obtained to satisfy the requirements of subdivision 7 of this subsection. The written certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued by the agency but before receipt of radioactive material by the applicant. If the applicant defers execution of the financial instrument until after the license has been issued, the applicant shall submit to the agency a signed original of the financial instrument obtained before receipt of licensed material.

3. The following are exempt from the requirements of this subsection:

a. A state, local or other government agency, except for a government agency licensed to handle or process radioactive waste.

b. A person authorized to possess only radioactive materials with a half-life of 65 days or less.

c. Other persons exempted by the agency based on a review of the license application.

4. Implementation.

a. A person who possesses a specific license authorizing the possession and use of radioactive material issued on or after the effective date as stated in [12VAC5-481-160](#) that is of a type described in subdivision 1 of this subsection, shall provide financial assurance for decommissioning under this section.

b. A person who possesses a specific license issued before the effective date as stated in [12VAC5-481-160](#) shall do one of the following:

(1) For a license authorizing the use of radioactive material meeting the criteria of subdivision 1 of this subsection, submit a decommissioning funding plan as described in subdivision 6 of this subsection and a certification of financial assurance for at least \$1,125,000, under the criteria in subdivision 5 of this subsection, with any application for license renewal.

(2) For a license authorizing the use of radioactive material meeting the criteria of subdivision 2 of this subsection, submit a decommissioning funding plan as described in subdivision 6 of this subsection or a certification of financial assurance for

decommissioning according to the criteria of subdivision 5 of this subsection with any application for license renewal.

c. The term of the financial assurance shall be from the issuance or renewal of the license until the agency terminates the license.

d. A licensee's financial assurance arrangements may be reviewed annually by the agency to recognize any increases or decreases resulting from inflation or deflation, changes in engineering plans, activities performed or any other condition affecting costs for decommissioning to ensure that sufficient funding is available to cover liability that remains until license termination.

5. Required amounts for financial assurance.

a. A licensee shall provide the following minimum amounts of financial assurance for decommissioning, unless otherwise specified by the agency:

(1) \$1,125,000 if the quantity of material is greater than 104 but less than or equal to 105 times the applicable quantities of [12VAC5-481-3750](#) in unsealed form. For a combination of isotopes, R divided by 104 is greater than one but R divided by 105 is less than or equal to one.

(2) \$225,000 if the quantity of material is greater than 103 but less than or equal to 104 times the applicable quantities of [12VAC5-481-3750](#) in unsealed form. For a combination of isotopes, R divided by 103 is greater than one but R divided by 104 is less than or equal to one.

(3) \$113,000 if the quantity of material is greater than 1010 times the applicable quantities of [12VAC5-481-3750](#) in sealed sources or plated foils. For a combination of isotopes, R divided by 1010 is greater than one.

b. The agency may eliminate, reduce or raise the required amount of financial assurance under subdivision 5 a of this subsection for an individual applicant or licensee based on the cost estimate for decommissioning included in the decommissioning funding plan required under subdivision 6 a of this subsection.

6. Each decommissioning funding plan (DFP) shall be submitted for review and approval by the agency.

a. The DFP shall include a detailed cost estimate for decommissioning, in an amount reflecting:

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

(2) The cost of meeting the criteria for unrestricted use in [12VAC5-481-1161](#) B provided that if the applicant or licensee can demonstrate its ability to meet the provisions of [12VAC5-481-1161](#) C, the cost estimate may be based on meeting the criteria in [12VAC5-481-1161](#) C;

(3) The volume of onsite subsurface material containing residual radioactivity that will

require remediation to meet the criteria for license termination; and

(4) An adequate contingency factor;

b. The DFP shall include identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);

c. The DFP shall include a description of the method of assuring funds for decommissioning from subdivision 7 of this subsection, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

d. The DFP shall include a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning;

e. The DFP shall include a signed original of the financial instrument obtained to satisfy the requirements of subdivision 7 of this subsection (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning); and

f. The DFP shall (i) be submitted with license renewal and at intervals not to exceed three years and (ii) contain adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The DFP shall update the information submitted with the original or prior approved plan and shall specifically consider the effect of the following events on decommissioning costs:

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

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

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

(4) Facility modifications;

(5) Changes in authorized possession limits;

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

(7) Onsite disposal; and

(8) Use of a settling pond.

7. A licensee may use any of the following methods to provide financial assurance for decommissioning:

a. Prepayment. Prepayment is the deposit prior to operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets in an amount 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. Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1.0% real rate of return on investment.

b. Surety method, insurance or other guarantee. Payment of future decommissioning costs shall be guaranteed by a surety method, insurance or other guarantee. A surety method may be in the form of a surety bond, letter of credit or line of credit. Self insurance, or any method that essentially constitutes self-insurance, may not be used as a method of providing financial assurance. Any surety method or insurance used to provide financial assurance for decommissioning shall meet all of the following criteria:

(1) The surety method or insurance shall be open-ended or, if written for a specified term, 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 shall 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.

(2) The surety method or insurance shall be payable to a trust established for decommissioning costs. The agency shall approve the trustee and the trust.

(3) The surety method or insurance shall remain in effect until the agency terminates the license.

c. External sinking fund. An external sinking fund may be used 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 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 shall meet the requirements of subdivision 7 b of this subsection.

d. Statement of intent. A state or local government licensee exempt under subdivision 3 of this subsection shall submit a written statement of intent containing a cost estimate for decommissioning or an amount based on subdivision 5 of this subsection. The cost estimate shall indicate that funds for decommissioning will be obtained when necessary.

8. A licensee shall keep the following records of information related to decommissioning of a facility in an identified location until the site is released for unrestricted use:

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

concentrations.

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

Note: As-built architectural and engineering drawings need to reflect the final details of the structures and equipment as they were constructed.

c. Except for areas containing only sealed sources that have not leaked or where no contamination remains after a leak, or byproduct materials with half-lives of less than 65 days, a list containing all the following:

(1) All areas currently and formerly designated as restricted areas.

(2) All areas outside of restricted areas that require documentation under subdivision 8 (c) 1 of this subsection.

(3) All areas outside of restricted areas where current and previous wastes have been buried as documented under [12VAC5-481-1060](#) .

(4) All areas outside of restricted areas that contain radioactive material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in [12VAC5-481-510](#) or apply for approval for disposal under [12VAC5-481-920](#) .

d. Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning and records of the funding method used for assuring funds.

9. A licensee shall keep the records in subdivision 8 of this subsection until the site is decommissioned and approved by the agency for unrestricted use.

10. Prior to a licensed activity being transferred to another licensee under [12VAC5-481-500](#) B, the original licensee shall transfer all records under subdivision 8 of this subsection to the new licensee. The new licensee shall be responsible for maintaining the records until their license is terminated by the agency.

11. A person applying for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in subdivision 6 of this subsection.

12. A person applying for a specific license authorizing the possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

- a. Submit a decommissioning funding plan as described in subdivision 6 of this subsection; or
- b. Submit a certification that financial assurance for decommissioning has been provided in the amount of \$225,000 using one of the methods described in subdivision 7 of this subsection.

12VAC5-481-451. Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.

A. Any licensee who possesses or uses an aggregated quantity of Category 1 or Category 2 radioactive material equal to or in excess of those in subdivision 1 of this subsection shall establish a physical protection program that meets all requirements detailed in this section.

1. Radionuclides of concern.

Radionuclide	Category 1 (TBq) ^{1,2}	Category 1 (Ci) ^{1,2}	Category 2 (TBq) ^{1,2}	Category 2 (Ci) ^{1,2}
Am-241	60	1,620	0.6	16.2
Am-241/Be	60	1,620	0.6	16.2
Cf-252	20	540	0.2	5.4
Cm-244	50	1,350	0.5	13.5
Co-60	30	810	0.3	8.1
Cs-137	100	2,700	1	27
Gd-153	1,000	27,000	10	270
Ir-192	80	2,160	0.8	21.6
Pm-147	40,000	1,080,000	400	10,800
Pu-238	60	1,620	0.6	16.2
Pu-239/Be	60	1,620	0.6	16.2
Ra-226	40	1,080	0.4	10.8
Se-75	200	5,400	2	54
Sr-90 (Y-90)	1,000	27,000	10	270
Tm-170	20,000	540,000	200	5,400
Yb-169	300	8,100	3	81
Combinations of radioactive materials listed above ³	See footnote 4 below			

- 1The aggregate activity of multiple, collocated sources of the same radionuclides should be included when the total activity equals or exceeds the Category 1 or Category 2 threshold.
- 2The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.
- 3Radioactive materials are to be considered aggregated or collocated if breaching a common physical barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.
- 4If several radionuclides are aggregated, the sum of the ratios of the activity of each source, $A_{i,n}$, to the Category 1 or Category 2 threshold for radionuclide n , Q_n , listed for that radionuclide equals or exceeds one.
$$\left[\frac{\text{(aggregated source activity for radionuclide A)}}{\text{(quantities of concern for radionuclide A)}} \right] + \left[\frac{\text{(aggregated source activity for radionuclide B)}}{\text{(quantities of concern for radionuclide B)}} \right] + \text{etc.}$$

2. A licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material is exempt from the requirements of this section.

3. A licensee that possesses radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this section. The licensee shall implement the following requirements to secure the radioactive waste:

- a. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;
- b. Use a locked door or gate with monitored alarm at the access control point;
- c. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
- d. Immediately notify the local law-enforcement agency (LLEA) and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste.

B. Background investigations and access authorization program.

1. Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material.

- a. Each licensee that possesses an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements in this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements in this subsection upon an amendment request of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold. Any licensee that has not previously implemented the increased control requirements of this section shall implement the provisions of this subsection before aggregating radioactive material to a quantity that equals or exceeds the

Category 2 threshold.

b. The licensee's access authorization program shall ensure that the individuals specified in subdivision 1 c of this subsection are trustworthy and reliable.

c. Licensees shall subject the following individuals to an access authorization program:

(1) Any individual whose assigned duties require unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(2) Reviewing officials.

d. Licensees shall approve for unescorted access to Category 1 or Category 2 quantities of radioactive material only those individuals whose assigned job duties require unescorted access to Category 1 or Category 2 quantities of radioactive material.

e. Licensees need not subject the categories of individuals listed in subdivision 5 a of this subsection to the investigation elements of the access authorization program.

2. Access authorization program requirements.

a. Granting unescorted access authorization.

(1) Licensees shall implement the requirements of this subsection for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by subdivision C 2 c of this section before being allowed unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Reviewing officials.

(1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official shall be taken by a law-enforcement agency, a federal or state agency that provides fingerprinting services to the public, or a commercial fingerprinting service authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with subdivision 3 c of this subsection.

(3) Reviewing officials shall be permitted to have unescorted access to Category 1 or Category 2 quantities of radioactive material.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in subdivision 5 a of this subsection.

c. Informed consent.

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent shall include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation.

Licensees do not need to obtain signed consent from those individuals who meet the requirements of subdivision 3 b of this subsection. A signed consent shall be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his consent, the licensee may not initiate elements of the background investigation that were not in progress at the time the individual withdrew his consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause of denial or termination of unescorted access authorization.

d. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this subsection is sufficient cause for denial or termination of unescorted access.

e. Determination basis.

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all the information collected to meet the requirements of this subsection.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all the information collected to meet the requirements of this subsection and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on

information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access information.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures shall include the provisions for the notification of individuals who are denied unescorted access. The procedures shall include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures shall contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

g. Right to correct and complete information.

(1) Prior to any final adverse determination, licensees shall provide each individual subject to this subsection with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification shall be maintained by the licensee for a period of one year from the date of the notification.

(2) If, after reviewing his criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law-enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 28 CFR 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division will make any change necessary in accordance with the information supplied by that agency. Licensees shall provide at

least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. Records.

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of individuals approved for unescorted access authorization for three years after the list is superseded or replaced.

3. Background investigations.

a. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices containing the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation shall encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter. The background investigation shall include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection;

(2) Verification of true identity of the individual who is applying for unescorted access authorization. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document or maintain a photocopy of identifying documents on file in accordance with subdivision 6 of this subsection. Licensees shall certify in writing that the identification was properly reviewed and shall maintain the certification and all related documents for review upon inspection;

(3) Verification of employment history, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application;

(4) Verification that the individual participated in the education process during the

claimed period;

(5) Completion of reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to, the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subsection shall be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) To the extent possible, obtain independent information to corroborate the information provided by the individual (e.g., seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide the information or indicates an inability or unwillingness to provide information within a timeframe deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation and attempt to obtain the information from an alternate source.

b. Individuals who have been determined to be trustworthy and reliable for unescorted access to Category 1 or Category 2 quantities of radioactive material in accordance with [12VAC5-481-451](#) , "Increased controls and fingerprinting," as effective on October 3, 2008, can continue to have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement of subdivision 3 c of this subsection.

c. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 or Category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection. The reinvestigations shall be completed within 10 years of the date on which these elements were last completed.

4. Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material.

a. General performance objective and requirements.

(1) Except for those individuals listed in subdivision 5 a of this subsection and those individuals grandfathered under subdivision 3 b of this subsection, each licensee subject to the provisions of this section shall fingerprint each individual who is to be permitted unescorted access to Category 1 or Category 2 quantities of radioactive material. The licensee shall submit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as

part of the required background investigation to determine whether to grant or deny further unescorted access to Category 1 or Category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his fingerprints will be used to secure a review of his criminal history record and shall inform him of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to Category 1 or Category 2 quantities of radioactive material if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to Category 1 or Category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee based upon a background investigation conducted under this subsection, regulations or Fingerprint Orders from another agreement state, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of subdivision 6 c of this subsection.

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

(1) Licensees may not base a final determination to deny an individual unescorted access authorization to Category 1 or Category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

(2) Licensees may not use information received from a criminal history records check obtained under this subsection in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for processing of fingerprint checks.

(1) For the purpose of complying with this subsection, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-03B46M, Rockville, MD, 20852-2738, one completed, legible standard fingerprint card (form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan, or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by email to forms.resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

(2) Fees for processing of fingerprint cards are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to the "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at (301) 492-3531.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the Electronic Submittals page at <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History Program under Electronic Submission Systems.

(3) The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application for a criminal history records check.

5. Relief.

a. Fingerprinting, identification and criminal history records checks, and other elements of the background investigation required by this subsection are not required for the following individuals prior to granting unescorted access to Category 1 or Category 2 quantities of radioactive material:

(1) An employee of the NRC or of the executive branch of the U.S. government who has undergone fingerprinting for a prior U.S. government criminal history records check;

(2) A member of Congress;

(3) An employee of a member of Congress or congressional committee who has undergone fingerprinting for a prior U.S. government criminal history records check;

(4) The governor of a state or his designated state employee representative;

(5) Federal, state, or local law-enforcement personnel;

(6) State radiation control program directors and state homeland security advisors or their designated employee representatives;

(7) State radiation program employees conducting security inspections on behalf of the

NRC under an agreement executed under § 274i of the Atomic Energy Act (42 USC § 2021i);

(8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(9) Emergency response personnel who are responding to an emergency;

(10) Commercial vehicle drivers for road shipments of Category 2 quantities of radioactive material;

(11) Package handlers at transportation facilities such as freight terminals and railroad yards;

(12) Any individual who has an active federal security clearance and provides the appropriate documentation. Written confirmation from the agency or employer that granted the federal security clearance or reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for whom the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material. Written verification from the service provider shall be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Fingerprinting and identification and criminal history records checks required by this subsection are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check, and the individual provides the appropriate documentation. Written confirmation from the agency or employer that reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material. These programs include, but are not limited to:

(1) National Agency Check;

(2) Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;

(3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;

(4) Health and Human Services security risk assessments for possession and use of

select agents and toxins under 42 CFR Part 73;

(5) Hazardous material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and

(6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

6. Protection of information.

a. Each licensee that obtains background information on an individual under this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to Category 1 or Category 2 quantities of radioactive material. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

c. The personal information obtained on an individual from a background investigation may be provided to another licensee:

(1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in that individual's file; and

(2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

d. The licensee shall make background investigation records obtained under this subsection available for examination by an authorized representative of the agency to determine compliance with the regulations and laws.

e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

7. Access authorization program review.

a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. The review shall be performed at least annually.

b. The results of the reviews, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance

of the access authorization program; the cause of the conditions and, when appropriate, recommend corrective actions; and corrective actions taken. The licensee shall review the findings and take additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. Review records shall be maintained for three years.

C. Physical protection requirements during use.

1. Security program.

a. Each licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements of this subsection upon an amendment request for modification of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material. Any licensee that has not previously implemented the requirements of this subsection shall provide written notification to the agency at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

c. Each licensee's security program shall include the program features, as appropriate, described in subdivisions 2 through 8 of this subsection.

2. General security program requirements.

a. Security plan.

(1) Each licensee identified in subdivision 1 a of this subsection shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subsection. The security plan shall, at a minimum, (i) describe the measures and strategies used to implement the requirements of this subsection and (ii) identify the security resources, equipment, and technology used to satisfy the requirements of this subsection.

(2) The security plan shall be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of agency requirements. The licensee shall ensure that (i) the revision has been reviewed and approved by the individual with overall responsibility for the security program and (ii) the affected individuals are instructed on the revised plan

before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

b. Implementing procedures.

(1) The licensee shall develop and maintain written procedures that document how the requirements of this subsection and the security plan will be met.

(2) The implementing procedures and revisions to these procedures shall be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure shall be retained for three years after the record is superseded.

c. Training.

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training shall include at a minimum, instruction on:

(a) The licensee's security program and procedures to secure Category 1 or Category 2 quantities of radioactive material, and the purpose and function of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of agency requirements;

(c) The responsibility of the licensee to report promptly to the local law-enforcement agency and the agency any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of Category 1 or Category 2 quantities of radioactive material. The extent of the training shall be commensurate with the individual's potential involvement in the security of Category 1 or Category 2 quantities of radioactive material.

(3) Refresher training shall be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training shall include (i) review of the training requirements of this subsection and changes made to the security program since the last training; (ii) reports on all relevant security issues,

problems, and lessons learned; (iii) relevant results of agency inspections; and (iv) relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records shall include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. Protection of information.

(1) Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and prevent the unauthorized disclosure of their security plan, implementing procedures, and the list of individuals who have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to and for proper handling and protection against unauthorized disclosure of the security plan and implementing procedures.

(3) Before granting an individual access to the security plan or implementing procedures, licensees shall:

(a) Evaluate an individual's need to know the security plan or implementing procedures; and

(b) If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, the licensee shall complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in subdivisions B 3 a (2) through (7) of this section.

(4) Licensees need not subject any individual to background investigation elements for protection of information if that individual is included in the categories of individuals listed in subdivisions B 5 a (1) through (12) of this section or is a security service provider employee, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in subdivisions B 3 a (2) through (7) of this subsection, has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

(6) Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access authorization requirements for access to the information, the licensee shall

remove the person from the approved list as soon as possible, but no later than seven working days after the determination, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

(7) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form shall be password protected.

(8) The licensee shall retain as a record a copy of the information protection procedures and the list of individuals approved for access to the security plan or implementing procedures for three years after the document has been superseded.

3. Local law-enforcement agency (LLEA) coordination.

a. A licensee subject to this subsection shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA shall include:

(1) A description of the facilities and the Category 1 and Category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this subsection; and

(2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of material.

b. The licensee shall notify the agency within three business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

c. The licensee shall document its efforts to coordinate with the LLEA. The documentation shall be kept for three years.

d. The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

4. Security zones.

a. Licensees shall ensure that all aggregated Category 1 or Category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

b. Temporary security zones shall be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

c. Security zones shall, at a minimum, allow unescorted access only to approved individuals by:

(1) Isolation of Category 1 and Category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the Category 1 or Category 2 quantities of radioactive material within a security zone;

(2) Direct control of the security zone by approved individuals at all times; or

(3) A combination of continuous physical barriers and direct control.

d. For Category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

e. Individuals not approved for unescorted access to Category 1 or Category 2 quantities of radioactive material shall be escorted by an approved individual when in a security zone.

5. Monitoring, detection, and assessment.

a. Monitoring and detection.

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection shall be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility;

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel;

(c) A monitored video surveillance system;

(d) Direct visual surveillance by approved individuals located within the security zone;
or

(e) Direct visual surveillance by a licensee designed individual located outside the security zone.

(3) A licensee subject to this subsection shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability shall provide:

(a) For Category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability shall be provided by electronic sensors linked to an alarm, continuous monitored video surveillance, or direct visual surveillance; and

(b) For Category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

b. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

c. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessments system, licensees shall:

(1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(2) Provide an alternate communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmissions systems may not be subject to the same failure modes as the primary systems.

d. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

6. Maintenance and testing.

a. Each licensee subject to this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this subsection shall be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no frequency suggested by the manufacturer or the frequency specified is greater than three months, the testing shall be performed at least quarterly, not to exceed three months.

b. The licensee shall maintain records on the maintenance and testing activities for

three years.

7. Requirements for mobile devices. Each licensee that possesses mobile devices containing Category 1 or Category 2 quantities of radioactive material shall:

- a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and
- b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

8. Security program review.

- a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review shall include the radioactive material security program content and implementation. The review shall be conducted at least annually, not to exceed 12 months.
- b. The results of the review, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the security program, the cause of the condition, corrective actions taken, and, when appropriate, recommend corrective actions. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.
- c. The licensee shall maintain the review documentation for three years.

9. Reporting of events.

- a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency by telephone at 804-864-8150 during normal business hours and 804-624-2400 after hours. In no case shall the notification to the agency be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.
- b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the agency by telephone 804-864-8150 during normal business hours and 804-624-2400 after hours.

c. The initial telephonic notification shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include sufficient information for agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

D. Physical protection in transit.

1. Additional requirements for transfer of Category 1 and Category 2 quantities of radioactive material. A licensee transferring a Category 1 or Category 2 quantity of radioactive material to a licensee of the agency, the NRC, or another agreement state shall meet the license verification provisions listed in this subdivision instead of those listed in [12VAC5-481-570](#).

a. Any licensee transferring Category 1 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

b. Any licensee transferring Category 2 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

c. In an emergency where the licensee cannot reach the license-issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification shall include the license number, current revision number, issuing agency, expiration date, and for a Category 1 shipment, the authorized address. The licensee shall keep a copy of the certification. The certification shall be confirmed by use of the NRC's license verification system or by contacting the license-issuing authority by the end of the next business day.

d. The transferor shall keep a copy of the verification documentation as a record for three years.

2. Applicability of physical protection of Category 1 and Category 2 quantities of radioactive material during transit.

a. For shipments of category 1 quantities of radioactive material, each shipping licensee

shall comply with the requirements for physical protection contained in subdivisions 3 a, 3 e, 4, 5 a (1), 5 b (1), 5 c, 6 a, 6 c, 6 e, 6 g, and 6 h of this subsection.

b. For shipments of Category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 b through 3 e, 5 a (2), 5 a (3), 5 b (2), 5 c, 6 b, 6 d, 6 f, 6 g, and 6 h of this subsection.

c. The shipping licensee shall be responsible for meeting the requirements of this subsection unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this subsection.

3. Preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to discuss the state's intention to provide law-enforcement escorts and identify safe havens; and

(3) Document the preplanning and coordination activities.

b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

c. Each licensee that receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

d. Each licensee that transports or plans to transport a shipment of a Category 2 quantity of radioactive material and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to subdivision 3 b of this subsection, shall promptly notify the receiving licensee of the new no-later-than arrival time.

e. The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof as a record for three years.

4. As specified in subdivision 3 of this subsection, each licensee shall provide advance notification to the agency and the governor of a state, or the governor's designee, of the shipment of licensed material in a Category 1 quantity, through or across the boundary of

the state, before the transport or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for submitting advance notification;

(1) The notification shall be made to the agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governor's designees is available on the NRC website at <http://nrc-stp.ornl.gov/special/designee.pdf>. The notification to the agency shall be in accordance with [12VAC5-481-150](#).

(2) A notification delivered by mail shall be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail shall reach the agency at least four days before the transport of the shipment commences and shall reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

b. Each advance notification of shipment of Category 1 quantities of radioactive material shall contain the following information, if available at the time of the notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the Category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each state along the route;

(6) The estimated time and date of arrival for the shipment at the destination; and

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

c. Revision notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the agency and the governor of the state or the governor's designee.

(2) A licensee shall promptly notify the agency and governor of the state or the governor's designee of any changes to the information provided in accordance with this subdivision.

d. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the agency and the governor of each state or to the governor's designee previously notified. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

e. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

5. Requirements for physical protection of Category 1 and Category 2 quantities of radioactive material during shipment.

a. Shipments by road.

(1) Each licensee who transports or delivers to a carrier for transport in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, seven days a week and have the ability to communicate immediately, in an emergency, with the appropriate law-enforcement agencies;

(b) Ensure that redundant communications are established that allow the transport to contact the escort vehicle, when an escort vehicle is used, and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(c) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center shall be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route;

(d) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the U.S. Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(e) Develop written normal and contingency procedures to address (i) notifications to the communication center and law-enforcement agencies; (ii) communication protocols that shall include a strategy for the use of authentication codes and duress codes and provisions for refueling and other stops, detours, and locations where communication is

expected to be temporarily lost; (iii) loss of communication; and (iv) responses to an actual or attempted theft or diversion of a shipment.

(f) Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports Category 2 quantities of radioactive material shall maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

b. Shipments by rail.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route; and

(b) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package

tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall immediately conduct an investigation upon discovery that a Category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of Category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

6. Reporting of events.

a. The shipping licensee shall notify the appropriate LLEA and the agency within one hour of its determination that a shipment of Category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law-enforcement agency in the area of the shipment's last confirmed location. During the investigation required by this subsection, the shipping licensee will provide agreed upon updates to the agency on the status of the investigation.

b. The shipping licensee shall notify the agency within four hours of its determination that a shipment of Category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secure, the licensee shall immediately notify the agency.

c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a Category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of Category 1 radioactive material.

d. The shipping licensee shall notify the agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a Category 2 quantity of radioactive material.

e. The shipping licensee shall notify the agency and the LLEA as soon as possible upon

recovery of any lost or missing Category 1 quantities of radioactive material.

f. The shipping licensee shall notify the agency as soon as possible upon recovery of any lost or missing Category 2 quantities of radioactive material.

g. The initial telephonic notification required by subdivisions 6 a through 6 d of this subsection shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include the following information:

(1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed material involved;

(4) Actions that have been taken, or will be taken, to recover the material; and

(5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

h. Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

E. Records.

1. Each record required by this section shall be legible throughout the retention period specified. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. 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, and specifications shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

2. Licensees shall maintain the records that are required by this section for the period specified. If a retention period is not otherwise specified, these records shall be retained until the agency terminates the facility's license. All records related to this section may be destroyed upon agency termination of the facility license.

12VAC5-481-460. (Repealed.)

12VAC5-481-470. Special Requirements for Specific Licenses of Broad Scope.

This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment,

device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555-0001.)

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

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.
2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in [12VAC5-481-3760](#) , for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in [12VAC5-481-3760](#) , Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in [12VAC5-481-3760](#) , Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in [12VAC5-481-3760](#) , for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in [12VAC5-481-3760](#) , Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in [12VAC5-481-3760](#) , Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

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

1. The applicant satisfies the general requirements specified in [12VAC5-481-450](#);
2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
3. The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - a. The establishment of a radiation safety committee composed of such persons as a

radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

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

c. The establishment of appropriate administrative procedures to assure:

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

(2) Completion of safety evaluations of proposed uses of radioactive material that 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

(3) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with subdivision 3 c (2) of this subsection prior to use of the radioactive material.

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

1. The applicant satisfies the general requirements specified in [12VAC5-481-450](#); and

2. The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

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

b. The establishment of appropriate administrative procedures to assure,

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

(2) Completion of safety evaluations of proposed uses of radioactive material that 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

(3) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with subdivision 2 b (2) of this subsection prior to use of the radioactive material.

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

1. The applicant satisfies the general requirements specified in [12VAC5-481-450](#);

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

a. A college degree at the bachelor level, or equivalent training and experience, in the

physical or biological sciences or in engineering, and

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

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

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

1. Unless specifically authorized, persons licensed pursuant to [12VAC5-481-470](#) shall not:

a. Conduct tracer studies in the environment involving direct release of radioactive material;

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

c. Conduct activities for which a specific license issued by the agency under Part III ([12VAC5-481-380](#) et seq.), Part V ([12VAC5-481-1170](#) et seq.) or Part VII ([12VAC5-481-1660](#) et seq.) of this chapter is required; or

d. 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.

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

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

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

12VAC5-481-480. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices That Contain Radioactive Material.

A. Reserved.

B. Licensing the distribution of radioactive material in exempt quantities. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555-0001.)

C. Licensing the manufacture or initial transfer of devices to persons generally licensed under [12VAC5-481-430](#) B.

1. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under [12VAC5-481-430](#) B or equivalent regulations of the NRC, or another agreement state will be approved if:

a. The applicant satisfies the general requirements of [12VAC5-481-450](#);

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

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

(2) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10% of the limits specified in [12VAC5-481-640](#); and

(3) 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 dose to the appropriate organ as specified in [12VAC5-481-3580](#), Column IV;

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

(1) 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;

(2) 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

(3) The information called for in one of the following statements, as appropriate, in the

same or substantially similar form:

(a) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, 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

(b) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, 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. (The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.)

CAUTION—RADIOACTIVE MATERIAL

_____ Name of manufacturer or initial transferor;

d. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, and the words, "Caution Radioactive Material," the radiation symbol described in [12VAC5-481-850](#), and the name of the manufacturer or initial distributor;

e. Each device meeting the criteria of [12VAC5-481-430](#) B 4 m bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separate, 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 [12VAC5-481-850](#); and

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

2. In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, 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 that 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 that includes, but is not limited to:

a. Primary containment or source capsule;

- b. Protection of primary containment;
- c. Method of sealing containment;
- d. Containment construction materials;
- e. Form of contained radioactive material;
- f. Maximum temperature withstood during prototype tests;
- g. Maximum pressure withstood during prototype tests;
- h. Maximum quantity of contained radioactive material;
- i. Radiotoxicity of contained radioactive material; and
- j. Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under [12VAC5-481-430 B](#), or under equivalent regulations of the NRC, or another agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in [12VAC5-481-640](#) .

4. Each person licensed under this subsection to distribute devices to generally licensed persons shall:

- a. Furnish a copy of the general license contained in [12VAC5-481-430 B](#) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in [12VAC5-481-430 B](#);
- b. Furnish a copy of the general license contained in the NRC's, or another agreement state's, regulation equivalent to [12VAC5-481-430 B](#), or alternatively, furnish a copy of the general license contained in [12VAC5-481-430 B](#) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the NRC, or another agreement state. If a copy of the general license in [12VAC5-481-430 B](#) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, or another agreement state, under requirements substantially the same as those in [12VAC5-481-430 B](#);
- c. Report to the agency all transfers of such devices to persons for use under the general license in [12VAC5-481-430 B](#). 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 and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under [12VAC5-481-430](#) B during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

d. Furnish reports to other agencies.

(1) Report to the NRC all transfers of such devices to persons for use under the NRC's general license in 10 CFR 31.5.

(2) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to [12VAC5-481-430](#) B.

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

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

(5) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

e. Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in [12VAC5-481-430](#) B, or equivalent regulations of the NRC or another agreement state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of subdivision 4 of this subsection.

f. If a notification of bankruptcy has been made under [12VAC5-481-500](#) E or the license is to be terminated, each person licensed under this section shall provide, upon request, to the agency, the NRC and to any appropriate agreement state, records of final disposition required under subdivision 4 e of this subsection.

g. The licensee shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section shall be maintained for a period of three years following the date of the recorded event.

D. Special requirements for the manufacture, initial transfer, 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 [12VAC5-481-430](#) will be approved if:

1. The applicant satisfies the general requirements specified in [12VAC5-481-450](#).
2. The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:
 - a. Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;
 - b. Details of construction and design;
 - c. Details of the method of binding or containing the tritium or promethium-147;
 - d. Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;
 - e. Quality assurance procedures to be followed that are sufficient to ensure compliance with subdivision 8 of this subsection; and
 - f. Any additional information, including experimental studies and tests, required by the NRC to facilitate a determination of the safety of the device.
3. Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.
4. The agency determines that:
 - a. The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions likely to be encountered in normal use and handling of the device;
 - b. The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact with it by any person;
 - c. The device is so designed that it cannot easily be disassembled; and
 - d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 4 d of this subsection.

5. The applicant shall subject at least five prototypes of the device to tests as follows:

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

b. The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 c of this subsection.

c. Device designs are rejected for which the following has been detected for any unit:

(1) A leak resulting in a loss of 0.1% or more of the original amount of tritium or promethium-147 from the device;

(2) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(3) Any other evidence of physical damage.

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

7. Labeling.

a. A person licensed to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under [12VAC5-481-430](#) D, except as provided in subdivision 7 b of this subsection, shall affix to each device a label containing the radiation symbol prescribed by [12VAC5-481-850](#), such other information as may be required by the agency including disposal instructions when appropriate, and the following or a substantially similar statement that contains the information in the following statement:

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

CAUTION--RADIOACTIVE MATERIAL

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

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

b. If the agency determines that it is not feasible to affix a label to the device containing all the information called for in subdivision 7 a of this subsection, it may waive those

requirements and require in the following:

(1) A label is affixed to the device identifying:

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

(ii) The type of radioactive material; and

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

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

(ii) The type and quantity of radioactive material;

(iii) The model number;

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an agreement state; and

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

8. Quality assurance; prohibition of transfer.

a. Each person licensed under this subsection shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

b. Each person licensed under this subsection shall:

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

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in subdivision 8 c of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.

c. The licensee shall subject each inspection lot to the following:

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

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

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

d. No person licensed under this subsection shall transfer to persons generally licensed under [12VAC5-481-430 D](#) or under an equivalent general license of the NRC or other agreement state:

(1) Any luminous safety device tested and found defective under any condition of a license issued under this subsection, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 b (2) of this subsection, unless:

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

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivisions 8 b (2) and d (2) (i) of this subsection and any other criteria that may be required as a condition of the license issued under this subsection.

9. Transfer reports.

a. Each person licensed under this subsection shall file an annual report with the agency, which shall state the total quantity of tritium or promethium-147 transferred to persons generally licensed under [12VAC5-481-430 D](#). The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers have been made to persons generally licensed under [12VAC5-481-430 D](#) during the reporting period, the report shall indicate so.

b. Each person licensed under this subsection shall report annually all transfers of devices to persons for use under a general license in the NRC or another agreement state's regulations that are equivalent to [12VAC5-481-430 D](#) to (i) the NRC at Director, Office of Federal and State Materials and Environmental Management Programs, ATTN: Document Control Desk/GLTS, by an appropriate method listed in 10 CFR 30.6(a) and (ii) the responsible agreement state agency. The report shall state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to the NRC or particular agreement state during the reporting period, this information shall be

reported to the NRC and responsible agreement state agency.

E. 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 [12VAC5-481-430](#) F. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under [12VAC5-481-430](#) F will be approved if:

1. The applicant satisfies the general requirement of [12VAC5-481-450](#) .
2. The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
 - a. Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;
 - b. Details of construction and design;
 - c. Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
 - d. Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;
 - e. Details of quality control procedures to be followed in manufacture of the source;
 - f. Description of labeling to be affixed to the source or the storage container for the source; and
 - g. Any additional information, including experimental studies and tests, required by the NRC to facilitate a determination of the safety of the source.
3. Each source will contain no more than 5 microcuries of americium-241 or radium-226.
4. The agency determines, with respect to any type of source containing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226, that:
 - a. The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and
 - b. The source has been subjected to and has satisfactorily passed appropriate tests required by subdivision 5 of this subsection.
5. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 to tests as follows:
 - a. The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

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

c. The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226 after each stage of testing using methods of inspection adequate for determining compliance with the criteria in subdivision 5 d of this subsection.

d. Source designs are rejected for which the following has been detected for any unit (i) removal of more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 from the source or (ii) any other evidence of physical damage.

6. Labeling of devices. Each person licensed under this subsection shall affix to each source or storage container for the source a label that shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information in the following statement:

"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 (NRC) or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)"

7. Leak testing of each source. Each person licensed under this subsection shall perform a dry wipe test upon each source containing more than 0.1 microcurie (3.7 kilobecquerel) of americium-241 or radium-226 before transferring the source to a general licensee under [12VAC5-481-430](#) F or under equivalent regulations of the NRC or another agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.005 microcurie (0.185 kilobecquerel) of americium-241 or radium-226 by the methods described in this section, the source shall be rejected and shall not be transferred to a general licensee under [12VAC5-481-430](#) F, or equivalent regulations of the NRC or another agreement state.

F. Reserved.

G. 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 [12VAC5-481-430](#) G will be approved if:

1. The applicant satisfies the general requirements specified in [12VAC5-481-450](#).
2. The radioactive material is to be prepared for distribution in prepackaged units of:
 - a. Carbon-14 in units not exceeding 370 kBq (10 μ Ci) each.
 - b. Cobalt-57 in units not exceeding 370 kBq (10 μ Ci) each.
 - c. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 μ Ci) each.
 - d. Iodine-125 in units not exceeding 370 kBq (10 μ Ci) each.
 - e. Mock iodine-125 in units not exceeding 1.85 kBq (0.05 μ Ci) of iodine-129 and 185 Bq (0.005 μ Ci) of americium-241 each.
 - f. Iodine-131 in units not exceeding 370 kBq (10 μ Ci) each.
 - g. Iron-59 in units not exceeding 740 kBq (20 μ Ci) each.
 - h. Selenium-75 in units not exceeding 370 kBq (10 μ Ci) each.
3. Each prepackaged unit bears a durable, clearly visible label:
 - a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10 μ Ci) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 μ Ci) of hydrogen-3 (tritium); 740 kBq (20 μ Ci) of iron-59; or mock iodine-125 in units not exceeding 1.85 kBq (0.05 μ Ci) of iodine-129 and 185 Bq (0.005 μ Ci) of americium-241 each; and
 - b. Displaying the radiation caution symbol described in [12VAC5-481-850](#) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."
4. One of the following statements, as appropriate, or a substantially similar statement that 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 that accompanies the package:
 - a. 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 Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

_____ Name of manufacturer

- b. 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 a licensing state.

_____ Name of manufacturer

5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in [12VAC5-481-910](#) .

H. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under [12VAC5-481-430](#) H will be approved if:

1. The applicant satisfies the general requirements of [12VAC5-481-450](#);
2. The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:
 - a. Chemical and physical form and maximum quantity of strontium-90 in the device;
 - b. Details of construction and design of the source of radiation and its shielding;
 - c. Radiation profile of a prototype device;
 - d. Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;
 - e. Details of quality control procedures to be followed in manufacture of the device;
 - f. Description of labeling to be affixed to the device;
 - g. Instructions for handling and installation of the device;
 - h. Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device;
3. Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;
4. Each device will bear durable, legible labeling that includes the radiation caution symbol prescribed by [12VAC5-481-850](#) , a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited, and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;
5. The agency determines that:

- a. The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;
 - b. The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;
 - c. The device is so designed that it cannot be easily disassembled;
 - d. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by subdivision 6 of this subsection.
 - e. Quality control procedures have been established to satisfy the requirements of subdivision 8 of this subsection;
6. The applicant shall subject at least five prototypes of the device to tests as follows:
- a. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.
 - b. The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subdivision 6 c of this subsection.
 - c. Device designs are rejected for which the following has been detected for any unit:
 - (1) A leak resulting in a loss of 0.1% or more of the original amount of strontium-90 from the device; or
 - (2) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or
 - (3) Any other evidence of physical damage;
7. The device has been registered in the Sealed Source and Device Registry; and
8. Quality assurance; prohibition of transfer.
- a. Each person licensed under this subsection shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.
 - b. Each person licensed under this subsection shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square

centimeters of surface wiped shall be cause for rejection of the tested device.

c. Each person licensed under this subsection shall:

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

(2) Subject inspection lots to acceptance sampling procedures by procedures specified in subdivision 8 d of this subsection and in the license issued under this subsection, to provide at least 95% confidence that the lot tolerance percent defective of 5.0% will not be exceeded.

d. Each person licensed under this subsection shall subject each inspection lot to:

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

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

e. No person licensed under this subsection shall transfer to persons generally licensed under [12VAC5-481-430](#) H, or under an equivalent general license of the NRC or another agreement state:

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

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in subdivision 8 c (2) of this subsection, unless:

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

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with subdivision 8 c (2) of this subsection and any other criteria as may be required as a condition of the license issued under this subsection.

I. Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under Part VII ([12VAC5-481-1660](#) et seq.) of this chapter.

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by persons authorized pursuant to Part VII ([12VAC5-481-1660](#) et seq.) of this chapter will be approved if:

a. The applicant satisfies the general requirements specified in [12VAC5-481-450](#) ;

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

(1) 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);

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

(3) Licensed as a pharmacy by the Virginia Board of Pharmacy;

(4) Operating as a nuclear pharmacy within a federal medical institution; or

(5) A PET drug production facility registered with a state agency.

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

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in [12VAC5-481-850](#) 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.

(2) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol as described in [12VAC5-481-850](#) and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee authorized to manufacture, prepare or transfer for commercial distribution radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

a. An authorized nuclear pharmacist (ANP) as defined in [12VAC5-481-10](#) ;

b. An individual that meets the requirements specified in [12VAC5-481-1770](#) and [12VAC5-481-1790](#) , and the licensee has received an approved license amendment identifying this individual as an ANP;

c. A pharmacist, as defined in [12VAC5-481-10](#) , designated as an ANP if:

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

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

d. An individual under the supervision of an ANP as specified in [12VAC5-481-1710](#) .

3. Shall provide to the agency no later than 30 days after the date that the licensee allows, under subdivision 2 a or c of this subsection, the individual to work as an ANP:

a. The individual's certification by a specialty board whose certification process has been recognized by the NRC with the written attestation signed by a preceptor as required by [12VAC5-481-1770](#) ;

b. An NRC or another agreement state license;

c. NRC master materials licensee permit;

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

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

f. The Virginia Board of Pharmacy's license.

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

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

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

5. Nothing in this subsection relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

6. 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 in accordance with [12VAC5-481-1930](#) . The licensee shall record the results of each test and retain each record for three years after the record is made.

J. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part VII ([12VAC5-481-1660](#) et seq.) of this chapter for the medical use of radioactive material or use as a calibration, transmission or reference source will be approved if:

1. The applicant satisfies the general requirements in [12VAC5-481-450](#);
2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - a. The radioactive material contained, its chemical and physical form, and amount;
 - b. Details of design and construction of the source or device;
 - c. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;
 - d. For devices containing radioactive material, the radiation profile of a prototype device;
 - e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
 - f. Procedures and standards for calibrating sources and devices;
 - g. Legend and methods for labeling sources and devices as to their radioactive content; and
 - h. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device provided, that instructions that are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label;
3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the agency for distribution to persons licensed pursuant to Part VII ([12VAC5-481-1660](#) et seq.) of this chapter for the medical use of radioactive material or under equivalent licenses of the NRC, or another agreement state, provided that such labeling for sources that do not require long term storage may be on a leaflet or brochure that accompanies the source;

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

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

- a. Primary containment or source capsule;
- b. Protection of primary containment;
- c. Method of sealing containment;
- d. Containment construction materials;
- e. Form of contained radioactive material;
- f. Maximum temperature withstood during prototype tests;
- g. Maximum pressure withstood during prototype tests;
- h. Maximum quantity of contained radioactive material;
- i. Radiotoxicity of contained radioactive material; and
- j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices; and

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

K. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to [12VAC5-481-420](#) C or equivalent regulations of the NRC or another agreement state will be approved if:

- a. The applicant satisfies the general requirements specified in [12VAC5-481-450](#);
- b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10% of the limits specified in [12VAC5-481-640](#); and
- c. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to

the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
3. The agency may deny any application for a specific license under this subsection if the end use(s) of the industrial product or device cannot be reasonably foreseen.
4. Each person licensed pursuant to subdivision 1 of this subsection shall:
 - a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;
 - b. Label or mark each unit to:
 - (1) Identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
 - (2) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or another agreement state;
 - c. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";
 - d. Do the following:
 - (1) Furnish a copy of the general license contained in [12VAC5-481-420](#) C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license contained in [12VAC5-481-420](#) C is transferred; or
 - (2) Furnish a copy of the general license contained in the NRC's or another agreement state's regulation equivalent to [12VAC5-481-420](#) B and a copy of the NRC's or another agreement state's certificate, or alternatively, furnish a copy of the general license contained in [12VAC5-481-420](#) C and a copy of agency form "Certificate - Use of Depleted Uranium under a General License" to each person to whom depleted uranium in a product or device for use pursuant to the general license of the NRC or another agreement state is transferred, with a note explaining that use of the product or device is regulated by the NRC or another agreement state under requirements substantially the same as those in [12VAC5-481-420](#) C;
 - e. Report to the agency all transfers of industrial products or devices to persons for use

under the general license in [12VAC5-481-420](#) C. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of 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 [12VAC5-481-420](#) C during the reporting period, the report shall so indicate;

f. Do the following:

- (1) Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in 10 CFR 40.25;
- (2) For devices transferred to another agreement state, report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection for use under a general license in that state's regulations equivalent to [12VAC5-481-420](#) C;
- (3) 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;
- (4) If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC; and
- (5) If no transfers have been made to general licensees within another agreement state during the reporting period, this information shall be reported to the responsible state agency upon the request of that agency; and keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in [12VAC5-481-420](#) C or equivalent regulations of the NRC or another agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

L. Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

12VAC5-481-490. Issuance of Specific Licenses.

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

or necessary.

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

1. Minimize danger to public health and safety or property;
2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
3. Prevent loss or theft of material subject to this part.

12VAC5-481-500. Specific Terms and Conditions of Licenses.

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

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

A request for license transfer shall include (i) the identity, technical, and financial qualifications of the proposed transferee and (ii) financial assurance for decommissioning information required under [12VAC5-481-450](#) C.

C. Each person licensed by the agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

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

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

1. The licensee;
2. An entity (as that term is defined in 11 USC § 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or
3. An affiliate (as that term is defined in 11 USC § 101(2)) of the licensee.

F. The notification specified in subsection E of this section shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

G. PET Distribution.

1. Authorization under [12VAC5-481-440](#) H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other state or local requirements governing radioactive drugs.
2. Each licensee authorized under [12VAC5-481-440](#) H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:
 - a. Satisfy the labeling requirements in [12VAC5-481-480](#) I 1 d for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.
 - b. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in [12VAC5-481-480](#) I 3.
3. A licensee that is a pharmacy authorized under [12VAC5-481-440](#) H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:
 - a. An ANP that meets the requirements in [12VAC5-481-480](#) I 2; or
 - b. An individual under the supervision of an ANP as specified in [12VAC5-481-1710](#) .
4. A pharmacy, authorized under [12VAC5-481-440](#) H to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an ANP, shall meet the requirements of [12VAC5-481-480](#) I 2.

12VAC5-481-510. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Building or Outdoor Areas.

- A. Except as provided in [12VAC5-481-520](#) , a specific license shall expire at the end of the specified day in the month and year stated in the license. If an application for license renewal has been filed at least 30 days prior to the expiration date stated in the existing license and the agency denies the renewal application, the license shall expire on the date as stated in the determination of denial. If an application for license renewal is filed less than 30 days from the expiration date stated in the existing license, the agency may deny the renewal application and the license shall expire on the expiration date stated in the license.
- B. A specific license revoked by the agency expires at the end of the day on the date of the agency's final determination, or on the expiration date stated in the determination, or as otherwise provided by an agency order.
- C. A specific license remains valid, with respect to possession of radioactive material, until the agency notifies the licensee in writing that the license is terminated. While the license is

valid, the licensee shall do all of the following:

1. Limit actions involving radioactive material to those related to decommissioning and other activities related to preparation for release for unrestricted use.
2. Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the agency notifies the licensee in writing that the license is terminated.

D. A licensee shall do all of the following:

1. Notify the agency within 60 days of any of the following:
 - a. Expiration of the license pursuant to subsections A or B of this section.
 - b. The licensee's deciding to permanently cease principal activities 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.
 - c. The absence of conduct of any principal activities under the license for a period of 24 months.
 - d. The absence of conduct of any principal activities 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.
2. If any separate building or outdoor area contains residual radioactivity so that the building or outdoor area is unsuitable for release, do one of the following:
 - a. Begin decommissioning its site, separate building or outdoor area if a decommissioning plan has been previously approved by the agency.
 - b. Submit a decommissioning plan within 12 months if required by subsection F of this section and begin decommissioning upon approval of that plan.

E. Concurrent with the notification required by subsection D of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to [12VAC5-481-450](#) C in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance shall be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to subdivision H 5 of this section. Following approval of the decommissioning plan and with the agency's approval, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site.

F. A licensee shall submit a decommissioning plan to the agency if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site, separate building or outdoor area have not been previously approved by the agency and

the procedures and activities may adversely effect the health and safety of workers or the public. The procedures may not be carried out prior to the agency's approval of the decommissioning plan. Examples of applicable procedures and activities include any of the following cases:

1. Procedures that would involve techniques not applied routinely during cleanup or maintenance operations.
2. Procedures by which workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation.
3. Procedures that could result in significantly greater airborne concentrations of radioactive materials than are present during operation.
4. Procedures that could result in significantly greater releases of radioactive material to the environment than those associated with operation.

G. The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to subsection D of this section 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.

H. The proposed decommissioning plan for the site or separate building or outdoor area shall include all of the following elements:

1. A description of the conditions of the site, separate building or outdoor area sufficient to evaluate the acceptability of the plan.
2. A description of planned decommissioning activities.
3. A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.
4. A description of the planned final radiation survey.
5. 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.
6. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in subsection J of this section.

I. Except as provided in subsection H of this section, a licensee shall complete decommissioning of the site or separate building or outdoor area no later than 24 months following the initiation of decommissioning. When decommissioning involves the entire site, a licensee shall request license termination no later than 24 months following the initiation of decommissioning.

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

1. Whether it is technically feasible to complete decommissioning within the allotted 24-month period.
2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period.
3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay.
4. Whether a significant reduction in radiation exposure to workers may be achieved by allowing short-lived radionuclides to decay.
5. Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, court decisions, 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.

K. As the final step in decommissioning, a licensee shall do all the following:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed agency form for disposition of radioactive materials or equivalent information.
2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in [12VAC5-481-1161](#).
3. 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 megabecquerels per 100 square centimeters, disintegrations per minute per 100 square centimeters or 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.
4. Specify the survey instruments used and certify that each instrument is properly calibrated and tested.

L. The agency shall terminate a specific license, including an expired license, by written notice to the licensee when the agency determines all of the following have occurred:

1. Radioactive material has been properly disposed of.
2. Reasonable effort has been made to eliminate residual radioactive contamination, if

present.

3. The licensee has filed with the agency sufficient information, including a radiation survey, to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in [12VAC5-481-1161](#) .

4. The licensee has submitted records required under [12VAC5-481-571](#) to the agency.

12VAC5-481-520. Renewal of Licenses.

A. Applications for renewal of specific licenses shall be filed in accordance with [12VAC5-481-440](#) .

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

12VAC5-481-530. Amendment of Licenses at Request of Licensee.

Amendment requests for a license shall be filed in accordance with [12VAC5-481-440](#) and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

12VAC5-481-540. 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 [12VAC5-481-450](#) through [12VAC5-481-480](#) and in Parts V ([12VAC5-481-1170](#) et seq.), VII ([12VAC5-481-1660](#) et seq.), XI ([12VAC5-481-2330](#) et seq.), XII ([12VAC5-481-2660](#) et seq.), XIV ([12VAC5-481-3140](#) et seq.), or XVI ([12VAC5-481-3460](#) et seq.) of this chapter, as applicable.

12VAC5-481-550. Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of These Regulations.

Article 5. Licenses Held at the Time of the Effective Date of These Regulations

Any person who, on the effective date as stated in [12VAC5-481-160](#) , possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the NRC, shall be deemed to possess a like license issued under this part and the Act, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or on the date or expiration specified in the NRC license, whichever is earlier.

12VAC5-481-560. Persons Possessing Narm on Effective Date of These Regulations.

Any person who, on September 20, 2006, possesses NARM for which a specific license is required by the Act or this part shall be deemed to possess such a license issued under the Act

and this part. Such license shall expire 90 days after September 20, 2006; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

12VAC5-481-570. Transfer of Material.

Article 6. Transfer of Material

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

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

1. To the agency only after receiving prior approval from the agency.
2. To the United States Department of Energy;
3. To any person exempt from these regulations to the extent permitted under such exemption;
4. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the NRC, or another agreement state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, or another agreement state; or
5. As otherwise authorized by the agency in writing.

C. Before transferring radioactive material to a specific licensee of the agency, the NRC, or another agreement state, or to a general licensee who is required to register with the agency, the NRC, or another agreement state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

D. Any of the following methods for the verification required by subsection C of this section is acceptable:

1. The transferor may possess and read a current copy of the transferee's specific license or registration certificate.
2. 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.
3. 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.

4. The transferor may obtain other information compiled by a reporting service from official records of the agency, the NRC, or another agreement state, regarding the identity of licensees and the scope and expiration dates of licenses and registration.

5. When none of the methods of verification described in subdivisions 1 through 4 of this subsection are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the agency, the NRC, or another agreement state, that the transferee is licensed to receive the radioactive material.

E. Shipment and transport of radioactive material shall be in accordance with the provisions of Part XIII ([12VAC5-481-2950](#) et seq.) of this chapter.

12VAC5-481-571. Receipt, Transfer and Disposal Records.

Article 7. Records

A. Record retention. A licensee shall retain records required by [12VAC5-481-100](#) or by license condition. If a retention period is not otherwise specified by this chapter or license condition, the record shall be retained until the agency terminates each license.

B. Transfer of records to the agency. Prior to license termination, a licensee authorized to possess radioactive material, in an unsealed form, with a half-life greater than 120 days, shall forward to the agency all records of disposal of licensed material made under [12VAC5-481-910](#) to [12VAC5-481-950](#) , including burials authorized before January 28, 1981, and the results of measurements and calculations required by [12VAC5-481-1000](#) .

C. Transfer of records to new licensee.

1. If licensed activities are transferred or assigned in accordance with [12VAC5-481-570](#) , each licensee authorized to possess radioactive material in unsealed form, with a half-life greater than 120 days, shall transfer the following records to the new licensee:

a. Records of disposal of licensed material made under [12VAC5-481-910](#) to [12VAC5-481-950](#) , including burials authorized before January 28, 1981.

b. Records of the results of measurements and calculations required by [12VAC5-481-1000](#).

2. The new licensee shall be responsible for maintaining the records required in subdivision C 1 of this section until the license is terminated.

D. Transfer of records of decommissioning activities. A licensee shall forward the records required by [12VAC5-481-450](#) C to the agency prior to license termination.

12VAC5-481-580. Modification and Revocation of Licenses.

Article 8. Modification and Revocation of Licenses

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

B. Any license may be revoked, suspended, or modified, in whole or in part, for any 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 that would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the agency.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct that 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.

12VAC5-481-590. Reciprocal Recognition of Licenses.

Article 9. Reciprocity

Licenses of radioactive, source, and special nuclear material in quantities not sufficient to form a critical mass.

1. Subject to these regulations, any person who holds a specific license from the NRC or another agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within the Commonwealth for a period not in excess of 180 days during the one-year reciprocal approval period, 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 three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-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 this subdivision;
- 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 that may be inconsistent with applicable regulations of the agency;
- d. The out-of-state licensee supplies such other information as the agency may request;

e. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subdivision except by transfer to a person:

(1) Specifically licensed by the agency, the NRC or another agreement state to receive such material, or

(2) Exempt from the requirements for a license for such material under [12VAC5-481-400](#) A; and

f. The out-of-state licensee submits the payment required by [12VAC5-490-40](#) to the agency.

2. Notwithstanding the provisions of subdivision 1 of this section, any person who holds a specific license issued by the NRC or another agreement state authorizing the holder to manufacture, transfer, install, or service a device described in [12VAC5-481-430](#) B 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 NRC or another agreement 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 this 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 he installs such device a copy of the general license contained in [12VAC5-481-430](#) B 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 NRC or another 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.