TITLE 12. HEALTH

STATE BOARD OF HEALTH

Final Regulation

REGISTRAR'S NOTICE: The following regulatory action is exempt from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 4 c of the Code of Virginia, which excludes regulations that are necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation. The State Board of Health will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **12VAC5-481. Virginia Radiation Protection Regulations (amending 12VAC5-481-390, 12VAC5-481-400, 12VAC5-481-421, 12VAC5-481-480, 12VAC5-481-1210, 12VAC5-481-3120).**

Statutory Authority: § 32.1-229 of the Code of Virginia.

Effective Date: February 22, 2017.

Agency Contact: Steve Harrison, Director - Office of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8151, FAX (804) 864-8155, or email steve.harrison@vdh.virginia.gov.

Summary:

As an agreement state with the federal Nuclear Regulatory Commission (NRC), Virginia is required to ensure that its regulations are compatible with Title 10, Energy, of the Code of Federal Regulations (CFR). This regulatory action amends 12VAC5-481 to implement revisions of Title 10 of CFR from 2011 until 2013.

The amendments (i) clarify and update the requirements for advance notification of shipment of irradiated reactor fuel and nuclear waste; (ii) add or correct citations; and (iii) make other technical corrections.

Article 2

Exemptions from the Regulatory Requirements

12VAC5-481-390. Source material.

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~~ The exemption contained in this subsection shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

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

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

b. The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 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 mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

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~~ subsection 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~~ this date. 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~~ this date.

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~~ (12VAC5-481-2250 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 μCi (3.7 MBq) of promethium 147 per watch or 200 μCi (7.4 MBq) of promethium 147 per any other timepiece;

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

(6) 60 μCi (2.22 MBq) of promethium 147 per watch dial or 120 μCi (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 this subsection ~~E~~, should apply to the agency for a license in accordance with 12VAC5-481-480 C and for a certificate of registration with the NRC in accordance with 10 CFR 32.210.

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 § 32.1-229 of the Code of Virginia and in Parts III (12VAC5-481-380 et seq.), IV (12VAC5-481-600 et seq.), V (12VAC5-481-1170 et seq.), VII (12VAC5-481-1660 et seq.), X (12VAC5-481-2250 et seq.), XII (12VAC5-481-2660 et seq.), and XIV (12VAC5-481-3140 et seq.) of 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.

12VAC5-481-421. 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~~ subdivision 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 or equivalent agreement state provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name, 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.

12VAC5-481-480. 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.~~ DC 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, ~~initially~~ 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 D 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~~ 5 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 subdivisions 1 through 6 or this subdivision 8 of 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~~ Nuclear Material Safety and Safeguards, 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 μCi) each.

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

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

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

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

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

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

h. Selenium-75 in units not exceeding 370 kBq (10 μCi) 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 μCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 μCi) of hydrogen-3 (tritium); 740 kBq (20 μCi) of iron-59; or mock iodine-125 in units not exceeding 1.85 kBq (0.05 μCi) of iodine-129 and 185 Bq (0.005 μCi) of americium-241 each; and

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~~ 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~~ that 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~~ that 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~~ subdivisions 8 c (2) and 8 e (2) (i) 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~~ who 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/ryubidium-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~~ 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)~~ use or uses 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.

12VAC5-481-1210. Performance requirements for industrial radiography equipment.

A. Equipment used in industrial radiographic operations must meet the following minimum criteria:

Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981)~~:~~. This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, NY 10036; telephone: (212) 642-4900.

B. In addition to the requirements specified in this section the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources~~:~~:

1. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

a. Chemical symbol and mass number of the radionuclide in the device;

b. Activity and the date on which this activity was last measured;

c. Model or product code and serial number of the sealed source;

d. Name of the manufacturer of the sealed source; and

e. Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of Part XIII (12VAC5-481-2950 et seq.) of this chapter.

3. Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the agency or other approval body.

C. In addition to the requirements specified in subsections A and B of this section, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers~~:~~:

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers that must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

4. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER—RADIOACTIVE."

The label may not interfere with the safe operation of the exposure device or associated equipment.

5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

6. Guide tubes must be used when moving the source out of the device.

7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

9. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

D. All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section~~; and~~.

E. As an exception to subsection A of this section, equipment used in industrial radiographic operations need not comply with 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

12VAC5-481-3120. Advance notification of transport of nuclear waste.

A. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport.

B. Advance notification for transport of licensed material is required when:

1. The licensed material is required to be in Type B packaging for transportation;

2. The licensed material is being transported ~~through Virginia~~ to or across state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

3. The quantity of licensed material in a single package exceeds:

a. 3000 times the A_1 value of the radionuclides as specified in 12VAC5-481-3770;

b. 3000 times the A_2 value of the radionuclides as specified in 12VAC5-481-3770; or

c. 1000 terabecquerel (27,000 curies).

C. Each advance notification required by subsections A and B of this section shall contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);

3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

4. The seven-day period during which arrival of the shipment at state boundaries or tribal reservation boundaries is estimated to occur;

5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

6. A point of contact with a telephone number for current shipment information.

D. The notification required by subsections A and B of this section shall be made in writing to ~~the~~ each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by ~~messenger~~ any other means than mail shall reach ~~the~~ each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three years.

1. A list of names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

2. Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating tribes, including telephone and mailing addresses of tribal officials and tribal officials' designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf.

3. A list of the names and mailing addresses of the governors' designees and tribal officials' designees of participating tribes is available on request from the Director, Division of Material Safety, State, Tribal and Rulemaking Program, Office of Nuclear Material Safety

and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

E. The licensee shall notify the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency of any changes to schedule information provided pursuant to subsections A and B of this section. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency. The licensee shall maintain for three years a record of the name of the individual contacted.

F. Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A copy of the notice shall be retained by the licensee for three years.

VA.R. Doc. No. R17-4897; Filed December 29, 2016, 8:17 a.m.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Final Regulation

Titles of Regulations: **12VAC30-30. Groups Covered and Agencies Responsible for Eligibility Determination (amending 12VAC30-30-20).**

12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-130).

12VAC30-135. Demonstration Waiver Services (repealing 12VAC30-135-10 through 12VAC30-135-90).

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396 et seq.

Effective Date: February 22, 2017.

Agency Contact: Victoria Simmons, Regulatory Coordinator, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-6043, FAX (804) 786-1680, or email victoria.simmons@dmas.virginia.gov.

Summary:

Pursuant to Item 301 UU of Chapter 665 of the 2015 Acts of Assembly, the amendments move the family planning program from demonstration waiver regulations to state plan regulations. The amendments (i) increase the income level for eligibility for the program; (ii) authorize use of the Department of Medical Assistance Services Central Processing Unit or other contractor for determining eligibility, provided that DMAS determines that this is the most practicable approach; (iii) clarify that individuals eligible for full-benefit coverage under Medicaid or FAMIS are not eligible under this program; and (iv) authorize coverage for additional testing, beyond the initial testing, for sexually transmitted infections and newer methods of cervical cancer screening.

Summary of Public Comments and Agency's Response: No public comments were received by the promulgating agency.

12VAC30-30-20. Optional groups other than the medically needy.

The Title IV A agency determines eligibility for Title XIX services.

1. Caretakers and pregnant women who meet the income and resource requirements of AFDC but who do not receive cash assistance.

2. Individuals who would be eligible for AFDC, SSI or an optional state supplement as specified in 42 CFR 435.230, if they were not in a medical institution.

3. A group or groups of individuals who would be eligible for Medicaid under the plan if they were in a NF or an ICF/MR, who but for the provision of home and community-based services under a waiver granted under 42 CFR Part 441, Subpart G would require institutionalization, and who will receive home and community-based services under the waiver. The group or groups covered are listed in the waiver request. This option is effective on the effective date of the state's § 1915(c) waiver under which this ~~group(s)~~ group is covered. In the event an existing § 1915(c) waiver is amended to cover this ~~group(s)~~ group, this option is effective on the effective date of the amendment.

4. Individuals who would be eligible for Medicaid under the plan if they were in a medical institution, who are terminally ill, and who receive hospice care in accordance with a voluntary election described in § 1905(o) of the Act.

5. The state does not cover all individuals who are not described in § 1902(a)(10)(A)(i) of the Act, who meet the income and resource requirements of the AFDC state plan and who are under the age of 21. The state does cover reasonable classifications of these individuals as follows:

a. Individuals for whom public agencies are assuming full or partial financial responsibility and who are:

(1) In foster homes (and are under the age of 21).

(2) In private institutions (and are under the age of 21).

(3) In addition to the group under subdivisions 5 a (1) and (2) of this section, individuals placed in foster homes or private institutions by private nonprofit agencies (and are under the age of 21).

b. Individuals in adoptions subsidized in full or part by a public agency (who are under the age of 21).

c. Individuals in NFs (who are under the age of 21). NF services are provided under this plan.

d. In addition to the group under subdivision 5 c of this section, individuals in ICFs/MR (who are under the age of 21).