STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

June 29, 2010

Terrence Reis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Reis:

During our IMPEP review last month we were informed that we needed to notify you of our references to the U.S. Department of Transportation (US DOT) regulations to account for the exception from adopting the bracketed compatibility rules in RATS ID 2004-1.

Our references to US DOT regulations can be found in rules 420-3-26-.02(22)(a), 420-3-26-.02(23)(a) and (b) and 420-3-26-.02(24)(a).

We believe that these references satisfy the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at 334-206-5368 or David Walter at 334-206-5394, or david.walter@adph.state.al.us.

Sincerely,

James L. McNees, CHP, Director
Alabama Office of Radiation Control

The RSA Tower • 201 Monroe Street • Montgomery, AL 36104
P.O. Box 303017 • Montgomery, AL 36130-3017

## 420-3-26-.02

## LICENSING

(1) **Purpose.**

(a) This Rule 420-3-26-.02 provides for the licensing of radioactive material.

(b) In addition to the requirements of this Rule 420-326-.02, all specific licensees are subject to the requirements of Rules 420-3-26-.01, 420-3-26-.03, 420-3-26-.10. and 420-3-26-.13. Licensees engaged in industrial radiographic operations are subject to the requirements of Rule 420-3-26-.04, licensees using radioactive material in the healing arts are subject to the requirements of Rule 420-3-26-.07, licensees using radioactive material for wireline service operation, subsurface tracer studies, or fishing operations are subject to Rule 420-3-26-.12, and licensees using radioactive material in irradiators are subject to the requirements of Rule 420-3-26-.14 of these Rules.

(c) General licensees are subject to the requirements of Rules 420-3-26-.01; 420-3-26-.02(4)(a)2; 420-3-26-.02(7)(a) through (h); 420-3-26-.02(12)(c), (e) and (g); 420-3-26-.02(18); 420-3-26-.02(19); 420-3-26-.03; 420-3-26-.10; and 420-3-26-.13.

(2) **Scope.** No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this Rule 420-3-26-.02 or as otherwise provided in this Rule 420-3-26-.02. Terms and conditions of specific and general licenses are specified in Rule 420-3-26-.02(12).

## EXEMPTIONS

(3) **Source Material.**

(a) Any person is exempt from this Rule 420-3-26-.02 to the extent that such person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person is exempt from this Rule 420-3-26-.02 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.

(c) Any person is exempt from this Rule 420-3-26-.02 to the extent that 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 percent by weight thorium, uranium, or any combination of these, or

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

2. Source material contained in the following products:

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

(ii) Glassware, glass enamel, and glass enamel frit containing not more than 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or glass or ceramic used in construction;

(iii) Glassware containing not more than 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

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

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

4. Any finished product or part fabricated of, or containing, tungsten or magnesium-thorium alloys; providing that, the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subparagraph 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,

(i) The counterweights are manufactured in accordance with a specific license issued by the Agency, the U. S. Nuclear Regulatory Commission, or any Agreement State authorizing distribution by the licensee pursuant to this subparagraph or equivalent regulations by the NRC or any Agreement State;

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

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

(iv) The exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any 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 containers provided, that:

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

(ii) The uranium metal is encased in milled steel, or equally fire resistant metal, of minimum wall thickness of one-eighth inch (3.2 mm).

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

(i) The shaping, grinding, or polishing of such lens into optical systems and

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

devices without any alteration of the lens; or,

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

8. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcuries of uranium.

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

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

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

(d) The exemptions in paragraph (c) do not authorize the manufacture of any of the products described.

(4) **Radioactive Materials.**

(a) **Exempt Concentrations**

1. Except as provided in paragraph (a)2. below, any person is exempt from this Rule 420-3-26-.02 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 Schedule C.

2. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons under paragraph (a)l. or equivalent regulations of the U. S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, except in accordance with a license issued pursuant to 420-326-.02(10)(i) or the general license provided in 420-3-26-.02(6) or (7) of this Rule 420-3-26-.02.

(b) **Certain Items Containing Radioactive Material.** Except for persons who apply tritium, promethium 147, or radium 226 to, or persons who incorporate tritium, promethium 147, or radium 226 into, the following products, any person is exempt from these rules to the extent that he receives, possesses, uses, transfers, owns, or acquired the following products:[2]

1. Timepieces or hands or dials containing radium or not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(i) 25 millicuries of tritium per timepiece;

(ii) 5 millicuries of tritium per hand;

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

(iv) 100 microcuries of promethium 147 per watch or 200 microcuries of promethium 147 per any other timepiece;

(v) 20 microcuries of promethium 147 per watch hand or 40 microcuries of promethium 147 per other timepiece hand;

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

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

(I) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;

[2] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements, may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545

(II) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface;

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

2. Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium 147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium 147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

3. Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicuries of tritium per balance part.

4. Automobiles shift quadrants containing not more than 25 millicuries of a tritium.

5. Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.

6. Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

7. Electron tubes: provided that each tube does not contain more than one of the following specified quantities of radioactive material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electronic tube;

(ii) 1 microcurie of cobalt 60;

(iii) 5 microcuries of nickel 63;

(iv) 30 microcuries of krypton 85;

(v) 5 microcuries of cesium 137;

(vi) 30 microcuries of promethium 147;

and provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed 1 millirad per hour at 1 centimeter from

any surface when measured through 7 milligrams per square centimeters of absorber.[3]

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

(i) Each source contains no more than one exempt quantity set forth in Schedule B of this rule, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this rule, provided that the sum of such fractions shall not exceed unity.

(iii) For americium 241, 0.05 microcurie is considered an exempt quantity under 420-3-26-.02(4)(b)8.

9. Spark gap irradiators containing not more than 1 microcurie of cobalt 60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.

(c) **Resins Containing Scandium 46 and Designed for Sand Consolidation in Oil Wells**. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium 46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specification contained in a specific license or equivalent licensing document issued by the Agency, Licensing State, or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U. S. Nuclear Regulatory Commission.[4] This exemption does not authorize the manufacture of any resins containing scandium 46.

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[3] For the purpose of this subparagraph, “electron tubes” include spark gap tubes, power tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other complete sealed tube that is designed to conduct or control electrical currents.

[4] For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

(d) **Gas and Aerosol Detectors Containing Radioactive Material.** Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life of property from fires and airborne hazards provided that:

(1). Detectors containing byproduct material shall have been manufactured imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32 which license authorized the transfer of the detectors to persons who are exempt from regulatory requirements; or

(2). Detectors containing other than byproduct, source or special nuclear material shall have been manufactured or transferred in accordance with a specific license issued by the Agency, Licensing State, or any Agreement State pursuant to licensing requirements equivalent to those set forth in Section 32.26 of 10 CFR Part 32, which license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(e) **Self-luminous Products Containing Radioactive Material**.

1. **Tritium, Krypton 85, or Promethium 147.** Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton 85, or promethium 147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton 95, or promethium 147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission pursuant to Section 32-88 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption on this paragraph (e) does not apply to tritium, krypton 85, or promethium 147 used in products for frivolous purposes or in toys or adornments.

2. **Radium 226.** Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie of radium 226.

(f) **Exempt Quantities.**

1. Except as provided in subparagraphs 3. and 4. of this paragraph, any

person is exempt from these rules 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 Schedule B.

2. Any person who possesses radioactive material received or acquired under the general license formerly provided in Section 420-3-26-.02 is exempt from the requirements for a license set forth in this Rule 420-3-26-.02 to the extent that such person possesses, uses, transfers, or owns such radioactive material.

3. This paragraph (f) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, 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 Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this paragraph or equivalent regulations of the U. S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, except in accordance with a specific license issued by the U. S. Nuclear Regulatory commission pursuant to Section 32.18 of 10 CFR Part 32[5] which license states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph (f) or the equivalent regulations of the U. S. Nuclear Regulatory Commission, Licensing State, or any Agreement State.

(g) **Radioactive Drug: Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans.**

1. Except as provided in paragraph 2. of this section, any person is exempt from the requirements for a license set forth in this rule provided that such person receives, possesses, uses, owns, transfers, or acquires capsules containing 1 microcurie (37 kilobecquerels) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use in humans.

2. Any person who desires to use the capsules for research involving human subject shall apply for and receive a specific license pursuant to 420-3-26-.02(10)(e).

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

[5] See footnote 4.

(5) **Types of Licenses.** Licenses for radioactive materials are of two types: general and specific.

(a) The Agency issues a specific license to a named person who has filed an application for a license under the provisions of this Rule 420-3-26-.02.

(b) A general license is provided by rule, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular license.

(6) **General Licenses - Source Material.**

(a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and State and local government agencies to use and transfer not more than 15 pounds (6.80 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.04 kg) of source material in any one calendar year.

(b) Persons who receive, possess, use or transfer source material pursuant to the general license issued in paragraph (a) of this section are exempt from the provisions of Rule 420-3-26-.03 and Rule 420-3-26-.10 of these rules to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this Rule 420-3-26-.02.

(c) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. The general license under this paragraph does not authorize any person to receive, possess, use, or transfer source material.

(d) **Depleted Uranium in Industrial Products and Devices.**

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 420-3-26-.02(6)(d)2., 3., 4., and 5., depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in 420-3-26-.02(6)(d) applies only to industrial products or devices which have been manufactured either in accordance with a specific

license issued to the manufacturer of the products or devices pursuant to 420-326-.02(10)(1) or in accordance with a specific license issued to the manufacturer by the U. S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U. S. Nuclear Regulatory Commission or an Agreement State.

3. (i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 420-3-26-.02(6)(d) shall file Agency Form GLDU "Registration Certificate - Use of Depleted Uranium Under General License," with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Agency Form GLDU the following information and such other information as may be required by that form:

(I) Name and address of the registrant;

(II) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 420-3-26-.02(6)(d)1. and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and,

(III) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 420-3-26-.02(6) (d)3.(i)(II).

(ii) The registrant possessing or using depleted uranium under the general license established by 420-3-26-.02(6)(d)l. shall report in writing to the Agency any changes in information furnished by him in Agency Form GLDU "Registration Certificate - Use of Depleted Uranium." The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 420-3-26-.02(6)(d)l.:

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

(ii) Shall not abandon such depleted uranium.

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 420-3-26-.02(18). In the case where the transferee receives the depleted uranium pursuant to the general license established by 420-3-26-

.02(6)(d)l., the transferor shall furnish the transferee a copy of this Rule 420-3-26-.02 and a copy of Agency Form GLDU. In cases where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 420-3-26-.02(6)(d)l., the transferor shall furnish the transferee a copy of the regulation and a copy of Agency Form GLDU accompanied by a note explaining that use of the product or device is regulated by the U. S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this Rule 420-3-26-.02.

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

(v) Shall not export such depleted uranium except in accordance with a license issued by the U. S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110[6]

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by.420-3-26-.02(6)(d)l. is exempt from the requirements of Rules 420-3-26-.03 and 420-3-26-.10 of these rules with respect to the depleted uranium covered by that general license.

(7) **General Licenses - Radioactive Material Other than Source Material.**

(a) **Certain Devices and Equipment.** A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Agency, the U. S. Nuclear Regulatory Commission, or any Agreement State, and authorizing distribution under the general license of this paragraph or its equivalent. The general license provided in this paragraph (a) is subject to provisions of 420-3-26-.01(6) through 420-3-26-.01(11), 420-3-26-.02(4)(a)2., 420-3-26.02 (7), 420-3-26-.02(12), 420-3-26-.02(18), 420-3- 26-.02(19), 420-3-26- 02(21), Rule 420-326-.03 and Rule 420-3-26-.10 of these rules[7].

1. **Static Elimination Device.** Device designed for use as static eliminators

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[6] See footnote 4.

[7] Attention is directed particularly to the provisions or Rule 420-3-26-.03 which relate to the labeling of containers.

which contain, as a sealed source or sources, radioactive material consisting of a total of not more than five hundred (500) microcuries of polonium 210 per device or a total of not more than fifty (50) millicuries of hydrogen 3 (tritium) per device.

(b) **Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere**

1. A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state, or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs 2., 3., and 4 of Rule 420-3-26-.02(7)(b), radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

2. (i) The general license in paragraph 1. of Rule 420-3-26-.02(7)(b) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(I) A specific license issued under this Rule; or

(II) An equivalent specific license issued by another Agreement State or Licensing State.

(ii) The devices must have been received from one of the specific licensees described in Rule 420-3-26-.02(7)(b)2(i) or through a transfer made under paragraph 3(xi) of Rule.420-3-26-.02(7)(b) and which will be possessed and used at a single physical location.

(iii) The general license in paragraph 1 of Rule 420-3-26-.02(7)(b) applies only to radioactive material which will be possessed and used at a single physical location

(iv) Notwithstanding the requirements listed in 420-3-26-.02(7)(b)2.(ii) and (iii), state and local emergency response agencies are exempt from requirements that devices described in 420-3-26-.02(7)(b)1.be possessed and used at a single location.

3. Any person who acquires, receives, possesses, uses, or transfers radioactive material in a device pursuant to the general license in paragraph 1 of Rule 420-3-26-.02(7)(b):

(i) Shall assure that all labels affixed to the device at the time of receipt and

bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

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

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

(II) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) Shall assure that the tests required by paragraph 3(ii) of Rule 420-3-26-.02(7)(b) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

(II) By a person holding a specific license issued by the Agency, another Agreement State, or the U. S. Nuclear Regulatory Commission to perform such activities;

(iv) Shall maintain records showing compliance with the requirements of paragraphs 3(ii) and 3(iii) of Rule 420-3-26-.02(7)(b). The records must show the results of the tests. The records also must show the dates of performance of, and the names of persons performing testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(I) Each record of a test for leakage of radioactive material required by paragraph 3(ii) of Rule 420-3-26-.02(7)(b) must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed.

(II) Each record of a test of the off-on mechanism and indicator required by paragraph 3(ii) of Rule 420-3-26-.02(7)(b) must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed.

(III) Each record that is required by paragraph 3(iv) of Rule 420-3-26-.02(7)(b) must be retained for three years from the date of the recorded event or until the device is transferred of disposed.

(v) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (0.185 becquerel) or more of removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or another person holding a specific license to repair such devices that was issued by the Agency, another Agreement State, or the U. S. Nuclear Regulatory Commission. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Agency. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director, Office of Radiation Control, P. O. Box 303017, Montgomery, Alabama 36130-3017 within thirty days. Under these circumstances, the criteria set out in Rule 420-3-26-.03(60), "Radiological Criteria for Unrestricted Use" may be applicable, as determined by the Agency on a case-by-case basis.

(vi) Shall not abandon the device containing radioactive material.

(vii) Shall not export the device containing radioactive material except in accordance with regulations of the U. S. Nuclear Regulatory Commission.

(viii) Shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph 3(vii) of Rule 420-3-26-.02(7)(b), by transfer to another general licensee as authorized in paragraph 3(xi) of Rule 420-3-26-.02(7)(b), or to a person authorized to receive the device by a specific license issued under this Rule 420-3-26-.02, or to a person authorized to receive the device by a specific license issued under Rule 420-3-26-.02 that authorizes waste collection, or equivalent regulations of another Agreement State or the U. S. Nuclear Regulatory Commission, or as otherwise approved under paragraph 3(x)of Rule 420-3-26-.02(7)(b).

(ix) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017. The report must contain:

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

(II) The name, address, and license number of the person receiving the device

(license number not applicable if exported); and

(III) The date of the transfer.

(x) Shall obtain written Agency approval before transferring the device to any specific licensee not specifically identified in paragraph 3(viii) of Rule 420-3-26-.02(7)(b).

(xi) Shall transfer the device to another general licensee only if:

(I) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this Rule 420-3-26-.02, a copy of Rule 420-3-26-.03, and any safety documents identified in the label of the device. Within thirty days of the transfer, the transferor shall report to the Director, Office of Radiation Control, P.O. Box 303017-3017, Montgomery, Alabama 36130-3017:

I. The manufacturer's (or initial transferor's) ; name.

II. The model number and the serial number of the device transferred;

III. The transferee's name, and mailing address for the location of use; and

IV. The name, title, and phone number of the responsible individual identified by the licensee in accordance with paragraph (b)3(xiv) of Rule 420-3-26-.02(7)(b) to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or

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

(xii) Shall comply with the provisions of Rule 420-3-26-.03(51) and (52) for reporting stolen, lost, or missing sources or devices and reporting radiation incidents but shall be exempt, unless otherwise specified, from the other requirements of Rule 420-3-26-.03 and Rule 420-3-26-.10.

(xiii) Shall respond to written requests from the Agency to provide information relating to the general license within thirty calendar days of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017 a written justification for the request.

(xiv) Shall appoint an individual responsible for having knowledge of the

appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of any responsibility in this regard.

(xv) Shall register, in accordance with paragraphs (7)(b)3(xv)(II) and (III) of Rule 420-3-26-.02(7)(b), devices containing at least 10 millicuries (370MBg) of cesium-137, 0.1 millicurie (3.7MBg) of strontium-90, 1.0 millicurie (37 MBg.) of cobalt-60, 0.1 millicurie of radium-226, or 1.0 millicurie (37MBg) of americium-241 or any other transuranic(i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described in paragraph (7)(b)3(xv)(II)IV of Rule 420-3-26-.02(7)(b), represents a separate general license and requires a separate registration.

I. If in possession of a device meeting the criteria of paragraph (b)3(xv) of Rule 420-3-26-.02(7)(b), shall register these devices with the Agency. The registration information must be submitted to the Agency within thirty days of the date of receipt of the device(s). In addition, a general licensee holding devices meeting the criteria of paragraph (b)3(xv) of Rule 420-3-26-.03(7)(b) is subject to the bankruptcy notification requirement in Rule 420-3-26-.02(12)(e).

II. In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Agency:

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

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

(III) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph (b)3(xiv) of Rule 420-3-26-.02(7)(b).

(IV) Address or location at which the device(s) are used and/or stored.

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

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

(xvi) Shall report changes to the mailing address for the location of use (including change in the name of licensee) to the Director, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017 within thirty days of the effective date of the change.

(xvii) May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (b)3(ii) of Rule 420-3-26-.02(7)(b) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(xviii) Shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States by or against:

(I) The licensee;

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

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

4. The general license in paragraph (7)(a) of Rule 420-3-26-.02(7) does not authorize the manufacture or import of devices containing radioactive material.

(c) **Luminous Safety Devices for Aircraft.**.

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium 147 contained in luminous safety devices for use in aircraft provided:

(i) Each device contains not more than 10 curies of tritium or 300 millicuries of promethium 147; and

(ii) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission or each device has been manufactured or assembled in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to

licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32[8] of the regulations of the U. S. Nuclear Regulatory Commission.

2. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in subparagraph 1.of this paragraph are exempt from the requirements of Rule 420-3-26-.03 and 420-3- 26-.10 except that they shall comply with the provisions of 420-3-26-.02(23) and 420-3-26 -.02(24).

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

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

5. The general license provided in this paragraph is subject to the provisions of 420-3-26-.01(6), 420-3-26-.01(7), 420-3-26-.01(8), 420-3-26-.01(10), 420-3-26-.01(11), 420-3-26-.01(12), 420-3-26-.02(12), 420-3-26-.02(18), 420-3-26-.02(21), and Rule 420-3-26-.10.

(d) **Calibration and Reference Sources**.

1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of subparagraphs 3. and 4. of this paragraph (d), americium 241 in the form of calibration or reference sources:

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

(ii) Any person who holds a specific license issued by the U. S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

2. A general license is hereby issued to receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subparagraphs 3. and 4. of this paragraph (d) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use and transfer radioactive material.

3. The general licenses in subparagraphs 1. and 2. of this paragraph apply

[8] See footnote 4.

only to calibration or reference sources which have been manufactured in accordance with specifications contained in a specific license issued to the manufacturer or importer of the sources by the U. S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 of Section 70.39 of 10 CFR Part 70[9]. or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the Agency or any Agreement State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U. S. Nuclear Regulatory Commission.[9]

4. The general licenses in subparagraphs 1. and 2. of this paragraph are subject to the provisions of 420-3-26-.01(6), 420-3-26-.01(7), 420-3-26-.01(8), 420-3-26-.01(10), 420-3-26-.01(11), 420-3-26-.02 (12), and 420-3-26-.02(19), Rule 420-3-26-.03 and Rule 420-3-26-.10 of these rules. In addition, persons who own, receive, acquire, possess, use, and transfer one or more calibration or reference sources pursuant to these general licenses:

(i) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium 241 and 5 microcuries of plutonium in such sources;

(ii) Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for 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 or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

[9] See footnote 4.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM 241). (PLUTONIUM).[10] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of Manufacturer or Importer);

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

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

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

5. These general licenses do not authorize the manufacturer of calibration or reference sources containing americium 241 or plutonium.

(e) **Ownership of Radioactive Material.** A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Rule, this general license does not authorize the manufacture, production, transfer, receipt, possession, or use of radioactive material.

(f) **General License for Medical Diagnostic Uses.** Deleted as of January 31, 1990.

(g) **Ice Detection Devices**.

1. A general license is hereby Issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains no more than fifty microcuries of strontium 90 and each device has been manufactured or imported in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license or

[10] Showing only the name of the appropriate material equivalent licensing document issued by the Agency or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR Part 32 of the regulations of the U. S. Nuclear Regulatory Commission.

2. Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in subparagraph 1. of this paragraph (g);

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the U. S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of this Rule 420-3-26-.02;

(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;

(iii) Are exempt from the requirements of Rules 420-3-26-.03 and 420-3-26-.10 except that such persons shall comply with the provisions of 420-3-26-.03(38), 420-3-26-.03(51), and 420-3-26-.03(52) of these rules;

(iv) Are exempt from the requirements of this Rule 420-3-26-.02 except that such persons shall comply with the provisions of 420-3-26-.02(12), 420-3-26-.02(19), 420-326-.01(6), 420-3-26-.01(7), and. 420-3-26-.01(8).

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

4. The general license provided in this paragraph is subject to the provisions of 420-3-26-.01(6), 420-3-26-.01(7), 420-3-26-.01(8), 420-3-26-.01(10), 420-3-26-.01(11), 420-3-26-.01(12), 420-3-26-.02(12), 420-3-26-.02(18), 420-3-26-.02(19), and 420-3-26-.02 (21).

(h) **General License for Use of Radioactive Material for certain in Vitro Clinical or Laboratory Testing.**

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests[11], in accordance with the provisions of subparagraphs 2., 3., 4., 5., and 6. of this paragraph, the following radioactive materials in prepackaged units:

[11] The New Drug Provisions of the federal Food, Drug, and Cosmetic Act also govern the availability, and use of any specific diagnostic drugs in interstate commerce.

(i) Iodine 125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(ii) Iodine 131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iii) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iv) Hydrogen 3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(v) Iron-59 in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive materials, or the radiation therefrom, to human beings or animals.

(vi) Cobalt-57, in units not exceeding 10 microcuries each, for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive materials, or the radiation therefrom, to human beings or animals.

(vii) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive materials, or the radiation therefrom, to human beings or animals.

(viii) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of americium 241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2. No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by 420-3-26-.02(7)(h)l. until he has filed Agency Form IV-GL "Certificate - In Vitro Testing with Radioactive Material Under General License," with the Agency and received from the Agency a validated copy of Agency Form IV-GL with certification number assigned. The physician, clinical laboratory, or hospital shall furnish on Agency Form IV-GL the following information and such other information as may be required by that form:

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

(ii) The location of use; and

(iii) A statement that the physician, clinical laboratory, veterinarian, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive materials as authorized under the general license in subparagraph 1. of this paragraph and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.

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

(i) The general licensee shall not possess at any one time, pursuant to the general license in 420-3-26-.02(7)(h)l. at any one location of storage or use a total amount of iodine 125, iodine131, iron 59, cobalt 57, and/or selenium 75 in excess or 200 microcuries.

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

(iii) The general licensee shall use the radioactive material only for the uses authorized by subparagraph 1. of this paragraph.

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

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

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 420-3-26-.02(10)(k) or in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission, Licensing State, or an Agreement State which authorizes the manufacture and distribution of iodine 125, iodine 131, carbon 14, hydrogen 3 (tritium), iron 59, cobalt 57, mock iodine 125, or selenium 75 for distribution to persons generally licensed pursuant to 420-3-26-.02(h) or its equivalent, and

(ii) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed

to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

_____
Name of Manufacturer

5. The physician, clinical laboratory or hospital possessing or using radioactive materials under the general license of subparagraph 1. of this paragraph shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate-- In Vitro Testing with Radioactive Material Under General License," Form IV-GL. The report shall be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of subparagraph 1. of this paragraph is exempt from the requirements of Rule 420-3-26-.03 and 420-3-26-.10 of these rules with respect to radioactive materials covered by that general license, except that such persons using the mock iodine-125 described in paragraph 1.(viii) of this section shall comply with the provisions of 420-3-26-.03(38), 420-3-26-.03(51), and 420-3-26-.03(52) of Rule 420-3-26-.03.

## SPECIFIC LICENSE

(8) **Filing of Application for Specific Licenses.**

(a) Applications for specific licenses shall be filed on a form prescribed by the Agency.

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

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

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

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

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

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

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

(b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety of property;

(c) The issuance of the license will not be inimical to the health and safety of the public; and

(d) The applicant satisfied any applicable special requirements in this Rule 420-3-26-.02.

(10) **Special Requirements for Issuance of Specific Licenses for Radioactive Materials.**

(a) **Human Use of Radioactive Materials in Institutions**. In addition to the requirements set forth in 420-326-.02(9) above, a specific license for human use of radioactive material in institutions will be issued only if:

1. The applicant has appointed a medical isotope committee, in accordance with 420-3-26-.07(19), of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioisotopes within that institution. Membership and functions of the committee are described in 420-3-26-.07(19); and

2. The applicant possesses adequate facilities for the clinical care of patients; and

3. The physician designated on the application as the individual user has substantial experience in handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients; and,

4. If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

(b) **Licensing of Individual Physicians for Human Use of Radioactive Materials.**

1. An application by an individual physician or groups of physicians for a specific license for human use of radioactive material will be approved if:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9) of this Rule 420-3-26-.02;

(ii) The application is for use in the applicant's practice in an office(s) outside a medical institution;

(iii) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(iv) The applicant has extensive experience in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. (The physician(s) shall furnish suitable evidence of such experience with the application. A statement from the medical isotope committee in the institution where the applicant acquired experience, indicating the amount and nature of experience, may be submitted as evidence of such experience).

2. The Agency will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:

(i) The use of radioactive material is limited to:

(I) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(II) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(III) The performance of in vitro diagnostic studies; or

(IV) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(ii) The physician brings the radioactive material with him and removes the radioactive material when he departs. (The institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and

(iii) The medical institution does not hold a radioactive material license under 420-3-26-.02 (10)(a).

(c) Deleted January 31, 1990.

(d) **Human Use of Sealed Sources.** In addition the requirements set forth in 420-3-26-.02(9) above, a specific license for human use of sealed sources will be issued only if the applicant, or if the application is made by an institution, the individual user;

1. Has specialized training in the therapeutic use of the sealed source considered (teletherapy unit, beta applicator, etc.) as specified in Rule 420-3-26-.07 or has experience equivalent to such training, and

2. Is a physician.

(e) **Multiple Quantities or Types of Radioactive material for Use in Research and Development.** In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license for multiple quantities or types of radioactive material for use in research and development will be issued only if:

1. The applicant's staff has substantial experience in the use of a variety of radioisotopes for a variety of research and development uses; and,

2. The applicant has established an isotope committee (composed of such persons as a radiological safety officer, a representative of the business office, and one or more persons trained or experienced in the safe use of radioactive materials) which will review and approve, in advance of purchase of radioisotopes, proposals for such use; and

3. The applicant has appointed a radiological safety officer who will advise and assist on radiological safety problems.

(f) **Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 420-3-26-.02(7)(b).**

1. An application for a specific license to manufacture or distribute devices

containing radioactive material, excluding special nuclear materials to persons generally licensed under 420-3-26-.02(7)(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) The applicant satisfies the general requirements of 420-3-26-.02(9);

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

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

(II) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in 420-3-26-.03(6), and

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

| | |
|---|---|
| Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye | 15 rems |
| Hands and forearms; feet and ankles, localized areas of skin averaged over areas no larger than 1 square centimeter | 200 rems |
| Other organs | 50 rems |

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

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

(II) The requirement, or lack of requirement, for leak testing, or for testing any

on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

(III) The information called for in the following statement in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____[12], are subject to a general license or the equivalent and the regulations of the U. S. Nuclear Regulatory Commission or a State with which the U. S. 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 distributor)

(iv) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number **and serial number**, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in Rule 420-3-26-.03(27)(a), and the name of the manufacturer and initial distributor.

(v) Each device meeting the criteria of Rule 420-3-26-.02(7)(b)3(xv) bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution - Radioactive Material," and if practicable, the radiation symbol described in Rule 420-3-26-.03(27)(a).

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, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the

[12] 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 devices.

Agency will consider information which includes, but is not limited to:

(i) Primary containment (source capsule);

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype tests;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material; and

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

3. In the event the applicant desires that the general license under 420-3-26-.02(7)(b), or under equivalent regulations of the U. S. Nuclear Regulatory Commission, Licensing State, or an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in 420-3-26-.03(6).

4. **Conditions of licenses**.

(i) If a device containing radioactive material is to be transferred for use under a general license contained in Rule 420-3-26-.02(7)(b), each person that is licensed under this rule shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the

information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(I) A copy of the general license contained in 420-3-26-.02(7)(b); if paragraphs (ii), (iii) and (iv) of Rule 420-3-26-.02(7)(b)3 do not apply to the particular device, those paragraphs may be omitted.

(II) A copy of Rule 420-3-26-.02(7)(b), Rule 420-3-26-.02(30), Rule 420-3-26-.03(51), and Rule 420-3-26-.03(52).

(III) A list of the services that can only be performed by the general licensee;

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

(V) An indication that the policy of the Agency, other Agreement States, and the U.S. Nuclear Regulatory Commission is to issue civil penalties for improper disposal.

(ii) If radioactive material is to be transferred in a device for use under an equivalent general license of another Agreement State or the U.S. Nuclear Regulatory Commission , each person that is licensed under Rule 420-3-26-.02(10)(f) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(I) A copy of the appropriate Agreement State or U. S. Nuclear Regulatory Commission rules or regulations equivalent to Agency Rules 420-3-26-.02(7)(b), 420-3-26-.02(30), 420-3-26-.03(51), and 420-3-26-.03(52). If certain paragraphs of the regulations do not apply to a particular device, those paragraphs may be omitted.

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

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

(IV) The name or title, address, and phone number of the contact at the Agreement State regulatory agency or U. S. Nuclear Regulatory Commission office from which additional information can be obtained.

(iii) An alternative approach to informing customers may be proposed by the

licensee for approval by the Agency.

(iv) Each device that is transferred after the effective date of this Rule must meet the labeling requirements in Rule 420-3-26-.02(10(f)1(iii) through (v).

(v) If a notification of bankruptcy has been made under Rule 420-3-26-.02(12)(e) or the license is to be terminated, each person licensed under Rule 420-3-26-.02(10)(f) shall provide, upon request, to the Agency, to the U. S. Nuclear Regulatory Commission, and to any appropriate Agreement State, records of final disposition required under paragraph (10)(f)5(ii) of Rule 420-3-26-.02(10).

5. **Material Transfer Reports and Records:** Each person licensed under Rule 420-3-26-.02(10)(f) to initially transfer devices to generally licensed persons shall comply with the requirements of this rule.

(i) The person shall report by letter to the Director, Office of Radiation Control P.O. Box 303017, Montgomery, Alabama 36130-3017 all transfers of such devices to persons for use under the general license in Rule 420-3-26-.02(7)(b) and all receipts of devices from persons licensed under Rule 420-3-26-.02(7)(b).The report must be submitted on a quarterly basis on a form prescribed by the Agency or in a clear and legible report containing all the data required by the form prescribed by the Agency.

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

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

II. The name, title, and phone number of the person identified as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

III. The date of transfer;

IV. The type, model number, and serial number of the device transferred; and

V. The quantity and type of radioactive material contained in the device.

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

(III) For devices received from a Rule 420-3-26-.02(7)(b) licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(IV) If the licensee makes changes to a device possessed by a Rule 420-3-26-.02(7)(b) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(V) The report must cover each calendar quarter, must be filed within thirty days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

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

(VII) If no transfers have been made to or from persons generally licensed under Rule 420-3-26-.02(7)(b) during the reporting period, the report must so indicate.

(ii) The person shall report all transfers of devices to persons for use under a general license in an Agreement State or in a state subject to regulations of the U. S. Nuclear Regulatory Commission that are equivalent to Rule 420-3-26-.02(7)(b) to the responsible Agreement State agency or the U. S. Nuclear Regulatory Commission, as appropriate. The report must be submitted on a form prescribed by the Agreement State or on U. S. Nuclear Regulatory Commission Form 653 - “Transfers of Industrial Devices” or in a clear and legible report containing all of the data required by the form.

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

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

II. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

III. The date of transfer;

IV. The type, model number, and serial number of the device transferred; and

V. The quantity and type of radioactive material contained in the device.

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

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

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

(V) The report must cover each calendar quarter, must be filed within thirty days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

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

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

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

(g) **Use of Sealed Sources in Industrial Radiography**[14]. In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license for use of sealed sources in industrial radiography will be issued only if:

[14] Industrial radiography for the purpose of this paragraph means the examination of the macroscopic structure of materials by nondestructive methods of utilizing sources of radiation.

1. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of Rule 420-3-26-.04(16).

2. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

3. The applicant submits written operating and emergency procedures as described in Rule 420-3-26-.04(17).

4. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in Rule 420-3-26-.04(16)(e).

5. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation and responsibility.

6. The applicant identifies and lists the qualifications of the individual(s) designated as the Radiation Safety Officer (420-3-26-.04(15)) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

7. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze wipe samples, the application must include a description of the procedures to be followed. The description must include the following:

i. Instruments to be used;

ii. Methods of performing the analysis; and

iii. Pertinent experience of the person who will analyze the wipe samples.

8. If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 420-3-26-.04(8).

9. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

10. The applicant identifies the locations where all records required by these Rules will be maintained.

(h) **Multiple Quantities or Types of Radioactive Material for Use in Processing.** In addition to the requirements set forth in 420-3-26-.02(9), a specific license for multiple quantities or types of radioactive material for use in processing for distribution to other authorized persons will be issued only if:[15]

1. The applicant's staff has substantial experience in the use of a variety of radioisotopes for processing and distribution; and

2. The applicant has appointed a radiological safety officer who will advise and assist on radiological safety matters.

(i) **Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.** In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 420-3-26-.02(4)(a)l. will be issued only if:

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

2. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule C, that reconcentration of the radioactive material in concentrations exceeding those in Schedule C is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to,

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[15] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material, intended for use by the general public may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545

a human being.

3. Each person licensed under this paragraph (i) shall file an annual report with the Agency describing the type and quantity of each product or material into which radioactive material has been introduced during the reporting period, name and address of the person who owns or possesses the product or material into which radioactive material has been introduced into each such product or material, and the initial concentrations of radioactive material in the product or material at time of transfer of the radioactive material by the license. The report shall be submitted within 30 days after the end of each calendar year in which the licensee introduces radioactive material into a product or material pursuant to a license granted under this paragraph.

(j) **Manufacture and Distribution of Byproduct Materials for Medical Use Under General License.**

Deleted as of January 31, 1990.

(k) **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 420-3-26-.02(7)(h) will be approved if:

1. The applicant satisfies the general requirements specified in 420-3-26-.02(9).

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

(i) Iodine-125 in units not exceeding 10 microcuries each.

(ii) Iodine-131 in units not exceeding 10 microcuries each.

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

(iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

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

(vi) Cobalt-57 in units not exceeding 10 microcuries each.

(vii) Selenium-75 in units not exceeding 10 microcuries each.

(viii) Mock Iodine-125 in units not exceeding 0.05 microcuries of Iodine-129

and 0.005 microcuries of americium-241 each.

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

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

(ii) Displaying the radiation caution symbol described in 420-3-26-.03(27) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS."

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

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

_____
(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 must also contain directions to the licensee regarding the waste disposal requirements set out in 420-3-26-.03(38) of these rules.

(1) **Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Application.**

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 420-3-26-.02(6)(d) or

equivalent regulations of the U. S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9);

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use and 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 year a radiation dose in excess of 10 percent of the limits specified in 420-3-26-.03(6).

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium or 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 420-3-26-.02(10)(1) 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 420-3-26-.02(10)(1) if the end use of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to 420-3-26-.02(10)(1) shall:

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

(ii) Label or mark each unit to:

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

(II) State that the receipt, possession, use, and transfer of the product or device

are subject to a general license or the equivalent and the regulations of the U. S. Nuclear Regulatory Commission or of an Agreement State;

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

(iv) (I) Furnish a copy of the general license contained in 420-3-26-.02(6)(d) and a copy of Agency Form GLDU to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 420-3-26-.02(6)(d); or

(II) Furnish a copy of the general license contained in the U. S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 420-3-26-.02(6)(d) and a copy of the U. S. Nuclear Regulatory Commission or Agreement State's certificate; or alternatively, furnish a copy of the general license contained in 420-3-26-.02(6)(d) and a copy of Agency Form GLDU to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U. S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U. S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 420- 3-26-.02(6)(d).

(v) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in 420-326-.02(6)(d). 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 a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 420-3-26-.02(6)(d) during the reporting period, the report shall so indicate;

(vi) (I) Report to the U. S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U. S. Nuclear Regulatory Commission general license in Section 40-25 of 10 CFR Part 40.[16]

(II) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 420-3-26- .02(10)(1) for use under a general license in that State's regulations equivalent to 420-3-26-.02(6)(d).

[16] See footnote 4.

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

(IV) If no transfers have been made to the U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U. S. Nuclear Regulatory Commission.

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

(vii) 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 420-3-26-.02(6)(d) or equivalent regulations of the U. S. Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of three years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(m) **Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use.** An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 420-3-26-.02(10)(a) or (b) will be approved if:

1. The applicant satisfies the general requirements specified in 420-3-26-.02(9) of this Rule 420-3-26-.02;

2. The applicant submits evidence that:

(i) The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA; or

(ii) The manufacture and distribution of the radioactive pharmaceutical containing radioactive material is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act;

3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage; and

4. (i) The label affixed to each package of the radiopharmaceutical-contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to 420-3-26-.02(10)(a) or (b) or under equivalent licenses of the U. S. Nuclear Regulatory Commission or an Agreement State.

(ii) The labels, leaflets or brochures required by 420-3-26-.02(10)(m)4.(i) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or with the approval of FDA, may be combined with the labeling required by FDA.

(n) **Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive material.** An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 420-3-26-.02(10)(a) or (b) will be approved if:

1. The applicant satisfies the general requirements specified in 420-3-26-.02(9);

2. The applicant submits evidence that:

(i) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a biologic product license issued by FDA; or

(ii) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act;

3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kits;

4. The label affixed to the generator or reagent kit contains information on

the radionuclide, quantity, and date of assay; and

5. The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Agency pursuant to 420-3-26-.02(10)(a) or (b) or under equivalent licenses of the U. S. Nuclear Regulatory Commission or an Agreement State. The labels, leaflets or brochures required by 420-3-26-.02(10)(n) are in addition to the labeling required by FDA and they may be separate from or with the approval of FDA may be combined with the labeling required by FDA.

(o) **Licensing the Distribution of NARM in Exempt Quantities** [17]

1. An application for a specific license to distribute NARM to persons exempted from these Rules pursuant to 420-3-26-.02(4)(f) will be approved if:

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

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

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

2. The license issued under 420-3-26-.02(10)(o) is subject to the following conditions;

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

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

(ii) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities' shall be contained in any outer package for transfer to persons exempt pursuant to 420-3-26-.02(4)(f). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

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

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

(II) Bears the words "Radioactive Material".

(iv) In addition to the labeling information required by 420-3-26-.02(10)(o)2.(iii), the label affixed to the immediate container, or an accompanying brochure shall:

(I) State that the contents are exempt from Agreement State requirements,

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

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

3. Each person licensed under 420-3-26-.02(10)(o) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 420-3-26-.02(4)(f) or the equivalent regulations of an Agreement State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 420-3-26-.02(10)(o) during the reporting period, the

report shall so indicate.

(p) **Commercial Waste Disposal by Land Burial.** In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, the Agency shall weigh the environmental, economic, technical, and other benefits against environmental costs and consider available alternatives. The Agency shall conclude that the issuance of the proposed license, with any appropriate conditions to protect environmental values, justified before commencement of construction of the plant or facility in which the activity will be conducted. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the site or the protection of environmental values.

(q) **Special Financial Surety Requirements.** In the case of an application for a license or an amendment to a license listed in subparagraph 4 below, financial surety arrangements must be made for site reclamation as follows:

1. Pursuant to Act 582, and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety or performance bonds, cash deposits, certificate of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 420-3-26-.02(10)(q)4. shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the Act and these Rules.

(i) The amount of funds to be ensured by such surety arrangements shall be based on Agency approved cost estimates.

(ii) Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

2. The arrangements required in 420-3-26-.02(10)(q)l. shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

3. (Deleted 1998)

4. The following specific licensees are required to make financial surety arrangements:

(i) Major processors;

(ii) Waste handling licensees; and

(iii) Former U. S. Atomic Energy Commission or U. S. Nuclear Regulatory Commission licensed production and utilization facilities.

5. The following persons are exempt from the requirements of 420-3-26-.02(10) (q) 1.

(i) All State, local, or other government agencies unless they are subject to 420-3-26-.02(10)(q)4.,

(ii) Persons authorized to possess no more than 1,000 times the quantity specified in Schedule B of 420-3-26-.02 or combination of radioactive material listed therein as given in Schedule B, of 420-3-26-.02,

(iii) Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or

(iv) Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half life greater than 30 days.

(r) **Long Term Care Requirements.** Certain applications for a specific license pursuant to Act 82-328 Code of Alabama and as otherwise provided, a long-term care fund shall be established by the following specific licensees prior to the issuance of the license or prior to the termination of the license if the applicant chooses at the time of the licensure to provide a surety in lieu of a long-term care fund:[18]

1. Waste handling licensees, and

2. Source material milling licensees.

(s) **Licensing Wireline Service Operations and Subsurface Studies.** In

[18] Long-term care funding may also be required for former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities.

addition to the requirements set forth in 420-3-26-.02(9) above, a specific license authorizing the use of radioactive material for wireline service operations and/or subsurface tracer studies will be issued only if:

1. The applicant has developed an adequate program for training logging supervisors and logging assistants and such program specifies the;

(i) Initial training,

(ii) On-the-job training,

(iii) Annual safety reviews provided by the licensee,

(iv) Methods the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Agency Rules and the applicant's operating and emergency procedures, and

(v) Methods the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the Agency's Rules and the applicant's operating and emergency procedures;

2. The applicant has developed and submitted to the Agency written operating and emergency procedures as described in 420-3-26-.12(16);

3. The applicant has established and submits his program for annual inspections of the job performance of each logging supervisor to ensure that Agency Rules, license requirements, and the applicant's operating and emergency procedures are followed. Records of these inspections must be maintained for three years;

4. The applicant submitted a description of his overall organizational structure as it applies to the radiation safety responsibilities in wireline service operations and in subsurface tracer studies, including specific delegations of authority;

5. The applicant has or can contract for personnel with experience in the recovery of equipment lodged in wells;

6. Evidence of a liability insurance policy for $1,000,000.00 to cover any liability as a result of any operations; and,

7. If the applicant wishes to perform leak testing of sealed sources, he shall identify the manufacturers and model numbers of the leak test kit(s) to be used. If the applicant wishes to analyze his own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures including;

(i) Instruments to be used,

(ii) Methods of performing the analysis, and

(iii) Pertinent experience of the person who will analyze the wipe samples.

(t) **Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Rule 420-3-26-.02(a) or (b).**

1. An application for a specific license to manufacturer, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to rule 420-3-26-.02(10)(a) or (b) will be approved if:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9);

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

(I) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer; or

(II) Registered or licensed with the State of Alabama as a drug manufacturer; or

(III) Licensed as a pharmacy by the Alabama State Board of Pharmacy.

(iii) 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 licensees; and

(iv) The applicant satisfies the following labeling requirements:

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

than 100 days, the time may be omitted.

(II) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" oir "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 described by paragraph (1)(ii)(III) of this section:

(i) May prepare radioactive drugs for medical uses described in 420-3-26-.07 provided that the radioactive drug is prepared either by an authorized nuclear pharmacist, as specified in paragraph (2)(ii) and (2)(iii) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 420-3-26-.07(22)(b).

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

(I) This individual qualifies as an authorized nuclear pharmacist as defined in 420-3-26-.07(2)(e).

(II) This individual meets the requirements specified in 420-3-26-.07(28) and (30), and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

(iii) Shall provide to the Agency a copy of each individual's certification by the Board of Pharmaceutical Specialties or a Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the State Board of Pharmacy license, no later than 30 days after the date that the licensee allows, pursuant to paragraph 2(ii)(I) of this section, the individual to work as an authorized nuclear pharmacist.

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

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

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

(iii) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal and State requirements, or the requirements of the Alabama State Board of Pharmacy.

(u) **Licensing of Irradiators.** A specific license for the use of radioactive material in an irradiator will be issued if the applicant satisfies the general requirements of 420-3-26-.02(9) and the following requirements:

1. The applicant must describe the training provided to irradiator operators including:

(i) Classroom training and on-the-job simulator training;

(ii) Safety reviews;

(iii) Means employed by the applicant to test each operator's understanding of Agency rules, licensing requirements, and the operating, safety, and emergency procedures for the irradiator; and,

(iv) Minimum training and experience of personnel who provide training.

2. The application must include a copy of the written operating and emergency procedures listed in 420-3-26-.14(18) that describes the radiation safety aspects of the procedures.

3. The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authority of the radiation safety officer and those management personnel who have radiation safety responsibility or authority. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position o f radiation safety officer.

4. The application must include a description of the access control systems required by 420-3-26-.12(9), the radiation monitors described by 420-3-26-.14(10), the method of detecting leaking sources required by 420-3-26-.14(21), including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

5. If the applicant intends to perform leak testing, the applicant shall

establish procedures for performing leak testing of dry-source-storage sealed sources and submit a copy of these procedures to the Agency. The procedures must include:

(i) Methods of collecting leak test samples;

(ii) Qualifications of the individual who collects the samples;

(iii) Instruments to be used; and

(iv) Methods of analyzing the samples.

6. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading and unloading at its facility, the loading or unloading must be done by persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to load or unload irradiator sources.

7. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by 420-3-26-.14(22).

(v) **Manufacturer and Distribution of Sources or Devices Containing Radioactive Material for Medical Use**

1. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Rule 420-3-26-.07 for use as a calibration, transmission or reference source, or for the uses listed in Rules 420-3-26-.07(35),(60), (70), and (72), will be approved if:

(i) The applicant satisfies the general requirements of Rule 420-3-26-.02(9):

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

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

(II) Details of design and construction of the source or device;

(III) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity in stresses likely to be encountered in normal use and accidents;

(IV) For devices containing radioactive material, the radiation profile of a prototype source;

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

(VI) Procedures and standards for calibrating sources and devices;

(VII) Legend and methods for labeling sources and devices as to their radioactive content; and

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

(ii) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the Agency has approved distribution of the (name of the source or device) to persons licensed to use the radioactive material identified in Rules 420-3-26-.07(35), (60), (70), and (72) as appropriate, and to persons who hold an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

2. Testing for leakage or contamination.

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

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

(I) Primary containment (source capsule);

(II) Protection of primary containment;

(III) Method of sealing containment;

(IV) Containment construction materials;

(V) Form of contained radioactive material;

(VI) Maximum temperature withstood during prototype tests;

(VII) Maximum pressure withstood during prototype tests;

(VIII) Maximum quantity of contained radioactive material;

(IX) Radiotoxicity of contained radioactive material; and

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

(11) **Issuance of Specific Licenses.**

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

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulations, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Rule 420-3-26-.02 as it deems appropriate or necessary in order to:

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

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

3. Prevent loss or theft of material subject to this Rule 420-3-26-.02.

(c) The Agency may refuse to issue a license to any person who has been refused issuance or renewal of a license, by authority of the Agency, another Agreement State, Licensing State, or the Nuclear Regulatory Commission, or whose license has been revoked, suspended, or restricted by such licensing authority, if such suspension, revocation, or restriction has occurred within one (1) calendar year. If it is a repeat suspension, revocation, or restriction, then the period for refusal is two (2) years.

(12) **Specific Terms and Conditions of Licenses.**

(a) Each license issued pursuant to this Rule 420-3-26-.02 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) No license issued or granted pursuant to this rule nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily, directly or indirectly, through transfer of control of any license to any person, unless the Agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give consent in writing.

(c) Each person licensed by the Agency pursuant to this Rule 420-3-26-.02 shall confine his use and possession of the material licensed to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant this Rule shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with transportation requirements specified in Rules 420-3-.02(21), (22), (23), (24), and (25).

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

(e) 1. Each licensee, including licensees required to register by Rule 420-3-26-.02(7)(b)3(xv), shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

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

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

2. This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and,

(ii) The date of the filing of the petition.

(f) Licensees required to submit emergency plans by 420-3-6-.02(27)(a) shall follow the emergency plan approved by the Agency. The licensee may change the

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

(g) The Agency may incorporate, in any license issued pursuant to this Rule, at the time of issuance, or thereafter by appropriate rule, license condition, or order, such additional requirements with respect to the receipt, possession, use, and transfer of radioactive material as it deems appropriate or necessary in order to:

1. Promote the common defense and security;

2. Protect health or to minimize danger to life or property;

3. Protect restricted data;

4. Require such reports and the keeping of such records and to provide for such inspections as may be necessary or appropriate to effectuate the purpose of the Act and the Rules thereunder.

(13) **Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.**

(a) Except as provided in 420-3-26-.02(14)(b) and 420-3-26-.02(13)(d)3. of this section, each specific license expires at the end of the day, in the month and year stated in the license.

(b) Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in paragraphs (d)l.(iv) and (v) of this section. The licensee is subject to the provisions of paragraphs (d) and (e) of this section, as applicable.

(c) No less than 30 days before the expiration date specified in a specific license, the licensee shall either;

1. Submit an application for license renewal under 420-3-26-.02(14); or

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

(d) 1. If a licensee does not submit an application for license renewal

under 420-3-26-.02(14), the licensee shall, on or before the expiration date specified in the license

(i) Terminate use of the radioactive material;

(ii) Remove radioactive contamination to the extent practicable except for those procedures covered by 420-3-26-.02(13)(d)2.(i);

(iii) Properly dispose of radioactive material;

(iv) Submit a completed form DRM; and

(v) Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate

(I) Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

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

2. In addition to the information required under 420-3-26-.02(13)(d)l.(iv) and (v), the licensee shall submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously approved by the Agency and could increase potential health and safety impacts to workers or to the public such as in any of the following case:

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

(ii) Worker would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation; or

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

(iv) Procedures could result in significantly greater release of radioactive

material to the environment than those associated with operation.

3. Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

4. The proposed decommissioning plan, if required by 420-3-26-.02(13)(d)2.(i) or by license condition, must include:

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

(ii) A description of methods used to assure protection of workers and the environment against radiation hazards during decommissioning;

(iii) A description of the planned final radiation survey; and

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

(v) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include justification for the delay based upon criteria in paragraph (i) of this section.

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

6. Upon approval of the decommissioning plan by the Agency, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in 420-3-26-.02(13)(d)l.(v) and shall certify the disposition of accumulated wastes from decommissioning.,

(e) Each specific license continues in effect, beyond the expiration date, if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

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

2. Continue to control entry to restricted areas until they are suitable for

release in accordance with Agency requirements.

(f) If the information submitted under 420-3-26-.02(13)(d)l.(v) or (d)3.does not adequately demonstrate that the premises are suitable for release for unrestricted use, the Agency shall inform the licensee of the appropriate further actions required for termination of the license.

(g) Specific licenses will be terminated by written notice to the licensee when the Agency determines that:

1. Radioactive material has been properly disposed;

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

3. (i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

(h) Except as provided in paragraph (i) of this section:

1. Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of the decommissioning.

2. When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

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

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

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

3. Whether a sufficient volume reduction in wastes requiring disposal will

be achieved by allowing short-lived radionuclides to decay;

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

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

(j) As the final step in decommissioning, the licensee shall:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting information specified by the Agency; and

2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of the survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with Rules 420-3-26-.03(60) and (61). The licensee shall, as appropriate:

(i) Report levels of gamma radiation in units of microroentgen (millisieverts) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per square centimeters - removable or fixed - for surfaces, microcuries (megabecquerels) per milliliter for water, and picocuries (becquerels) per gram for solids such as soils or concrete; and

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

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

1. Radioactive material has been properly disposed;

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

3. (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Agency requirements; or other information has been submitted by the licensee sufficient to demonstrate that the premises are suitable for release in accordance with rules 420-3-26-.03(59) and (60); or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with rules 420-3-26-.03(59) and (60).

4. Records required by 420-3-26-.02(30)(d) and (f) have been received by the Agency.

(l) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 6 months of notification a decommissioning plan if required by rule 420-3-26-.02(13)(d)2, and begin decommissioning upon approval of the plan if:

1. The license has expired ; or

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

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

4. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

(m) Coincident with the notification required by rule 420-3-26-.02(13)(l), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to rule 420-3-26-.02(26) in conjunction with a license issuance or renewal or as required by this rule. The amount of financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate of decommissioning pursuant to rule 420-3-26-.02(13)(d)4(iv).

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective.

2. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological

contamination is reduced at the site with the approval of the Agency.

(n) The Agency may grant a request to extend the time periods established in rule 420-3-26-.02(13)(l) if the Agency determines that this relief is not detrimental to the public interest. The request must be submitted no later than 30 days before notification pursuant to rule 420-3-26-.02(13)(l). The schedule for decommissioning set forth in rule 420-3-26-.02(13)(l) may not commence until the Agency has made a determination on the request.

(14) **Renewal of License.**

(a) Applications for renewal of specific licenses shall be filed in accordance with 420-3-26-.02(8).

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

(15) **Amendment of Licenses at Request of Licensee.** Applications for amendment of a license shall be filed in accordance with 420-3-26-.02(8) and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

(16) **Agency Action on Applications to Renew or Amend.** In considering an application by a licensee to renew or amend his license, the Agency will apply criteria set forth in 420-3-26-.02(9) and 420-3-26-.02(10), as applicable.

(17) **Inalienability of Licenses.** No license issued or granted under this Rule and no right to possess or utilize radioactive material granted by any license issued pursuant to this Rule 420-3-26-.02 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(18) **Transfer of Material.**

(a) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(b) Any licensee may transfer radioactive material:

1. To the Agency;

2. To the U. S. Department of Energy

3. To any person exempt from the regulations in this Rule 420-3-26-.02 to the extent permitted under such exemption;

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

5. As otherwise authorized by the Agency in writing.

(c) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of 420-3-26-.02(21).

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

(e) The following methods for verification required by 420-3-26-.02(18)(d) are acceptable:

1. The transferor may have in his possession and read, a current copy of the transferee's specific license;

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

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

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

5. When none of the methods of verification described in 420-3-26-.02(18)(e)l. through 4., are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U. S. Nuclear Regulatory Commission, Licensing State, or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

(19) **Modification, Revocation, and Termination of Licenses.**

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Agency.

(b) Any license may be revoked, suspended, or modified in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by application or statement of fact of any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the license, or of any rule, regulation, or order of the Agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, the facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

(e) The Agency may suspend, revoke, or amend any license in the event that the person to whom such license was granted has a license revoked, suspended, or restricted by a licensing authority of another Agreement State or the U. S. Nuclear Regulatory Commission.

(f) The Agency may cause the withholding or recall of radioactive material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Agency, or who uses such materials in violation of law or regulation of the Agency, or in a manner other than disclosed in the application therefore or approved by the Agency.

(20) **Reciprocal Recognition of Licenses.**

(a) Subject to these rules, any person who holds a specific license from the U. S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, and issued by the Agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document with this State for a period not in excess of 30 days in any calendar year provided that:

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

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

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

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

5. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person;

(i) Specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission, Licensing State, to receive such material; or,

(ii) Exempt from the requirements for such material under 420-3-26-.02(4)(a).

(b) Notwithstanding the provisions of paragraph (a) of this 420-3-26-.02(20), any person who holds a specific license issued by the U. S. Nuclear Regulatory Commission, Licensing State, or an Agreement State to authorize the holder to manufacture, transfer, install, or service a device described in 420-3-26-.02(7)(b)l. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, or service such a device in this State provided that:

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

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

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

4. The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 420-3-26-.02(7) (b)l.

(c) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another Agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazards to public health and safety or property.

## TRANSPORTATION

(21) **Transportation of Radioactive Material**. No person shall deliver radioactive material except as authorized in a general or specific license issued by the Agency or as exempted in 420-3-26-.02(22).

(22) **Exemptions.**

(a) Common and contract carriers, freight forwarders, and warehousemen who are subject to the rules and regulations of the U. S. Department of Transportation or the U.S. Postal Service are exempt from these rules to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage

incident thereto. Common and contract carriers who are not subject to the rules and regulations of the U. S. Department of Transportation or U. S. Postal Service are subject to 420-3-26-.02(21) and other applicable sections of these rules.

(b) Any licensee is exempt from 420-3-26-.02(21) to the extent that he delivers to a carrier for transport packages each of which contains no radioactive material having a specific activity in excess of 0.002 microcuries per gram.

(c) Any licensee who delivers radioactive material to a carrier for transport, where such transport is subject to the regulations of the U. S. Postal Service, is exempt from the provisions of 420-3-26-.02(21).

(23) **Intrastate Transport.**

(a) A general license is hereby issued to any common or contract carrier to receive, possess, transport, and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, shipping papers, placarding of the transporting vehicle, and incident reporting.[19]

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U. S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, shipping papers, placarding of the transporting vehicle, and incident reporting.[19]

(c) Persons who transport radioactive material pursuant to the general licenses in 420-3-26-.02(23)(a) or (b) are exempt from the requirements of Rule 420-3-26-.03 and Rule 420-3-26-.10 of these rules to the extent that they transport radioactive material.

(24) **Preparation of Radioactive material for Transport.** A general license is hereby issued to a licensee to deliver radioactive material to carrier[20] for transport

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[19] Any notification of incidents referred to in those requirements shall be filed with, or made to, the Agency.

[20] For the purpose of this rule, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material

provided that:

(a) The licensee complies with the applicable requirements of the regulation, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the packaging of radioactive material, providing shipping papers and to the monitoring, marking, and labeling of those packages.

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

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

(25) **Advance Notification of Transport of Large Quantities of Nuclear Waste.**

(a) Except as specified in paragraph (b) of this section, prior to the transport or delivery to a carrier for transport of licensed material outside the confines of the licensee's plant or other place of use or storage, each licensee shall provide advance notification to the governor of a state, or the governor's designee [21], of the shipment to, through, or across the boundary of the state.

(b) Advance notification is required only when;

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

2. The licensed material is being transported to, through, or across state boundaries to a disposal site or to a collection point for transport to a disposal site; and

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

(i) 5,000 curies of special form radionuclides;

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to a carrier for transport.

[21] A list of the mailing addresses of the governors and governor's designee is available upon request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555

(ii) 5,000 curies of uncompressed gases of argon-37, krypton-85m, krypton-87, xenon-131m, or xenon-135;

(iii) 50,000 curies of argon-37, or of uncompressed gases of krypton-87, or xenon-133, or of hydrogen-3 as a gas, as luminous paint, or absorbed on solid material;

(iv) 20 curies of other non-special form radionuclides for which $A_2$[22] is greater than four curies; or

(v) 200 curies of other non-special form radionuclides for which $A_2$[22] is greater than four curies.

(c) Each advance notification required by 420-3-26-.02(25)(a) 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 the regulations of the U. S. Department of Transportation, 49 CFR 172.202 and 172.203 (d) ;

3. The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;
4. The 7-day period during which arrival of the shipment at State boundaries is estimated to occur;
5. The destination of the shipment, and the 7-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 420-3-26-.02(25)(a) shall be made in writing to the office of each appropriate governor or governor's designee and to the Agency. A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 1 year.

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[22] Identified in 10 CFR 71, Appendix A effective March 31, 1999. Available as shown in footnote 4.

(e) The licensee shall notify each appropriate governors or governor's designee, and the Agency of any changes to schedule information provided pursuant to 420-3-26-.02 (25)(a). Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate State or States. The licensee shall maintain for 1 year 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 to the governor, or governor's designee, of each appropriate State and to the Agency. A copy of the notice shall be retained by the licensee for 1 year.

(26) **FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING.**

Notwithstanding and in addition to the financial requirements specified in this Rule 420-3-26-.02, the following shall apply with regard to decommissioning fund requirements:

(a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding $10^5$ times the applicable quantities set forth in Appendix F to Rule 420-3-26-.03 shall submit a decommissioning funding plan as described in 420-3-26-.02(26)(f). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by $10^5$ is greater than ~~1~~ 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F.

(b) Each holder of, or applicant for any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding $10^{12}$ times the applicable quantities specified in Appendix F of Rule 420-3-26-.02 (or when a combination of isotopes are involved if R, as defined in 420-3-26-.02(26)(a), divided by $10^{12}$ is greater than 1) shall submit a decommissioning funding plan as described in 420-3-26-.02 (26)(g). The decommissioning funding plan must be submitted to the Agency by December 2, 2006.

(c) Each applicant for a specific license authorizing the possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 420-3-26-.02(26)(e) shall either:

1. Submit a decommissioning funding plan as described in 420-3-26-

.02(26)(g); or

2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 420-3-26-.02(26)(e) using one of the methods described in 420-3-26-.02(26)(g). For an applicant, this certification may state that the appropriate assurance will be obtained after the applicant has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirement of paragraph (g) of this section must be submitted to the Agency before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency a signed original of the financial instrument obtained to satisfy the requirements of paragraph (g) of this section.

(d) 1. Each holder of a specific license issued on or after October 1, 1991, which is of a type described in 420-3-26-.02(26)(a) or (b), shall provide financial assurance for decommissioning in accordance with the criteria set forth in this Rule 420-3-26-.02(26).

2. Each holder of a specific license issued before October 1, 1991, and of a type described in 420-3-26-.02(26)(a) shall submit, on or before January 1, 1992, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount equal to $1,125,000 in accordance with the criteria set forth in this Rule 420-3-26-.02(26).If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

3. Each holder of a specific license issued before October 1, 1991, and of the type described in 420-3-26-.02(26)(b) shall submit, on or before January 1, 1992 a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this Rule 420-3-26-.02(26).

4. Any licensee who has submitted who has submitted an application before October 1, 1991, for renewal of license in accordance with 420-3-26-.02(14) shall provide financial assurance for decommissioning in accordance with this rule 420-3-26-.02(26). This assurance must be submitted when this rule becomes effective October 1, 1991.

5. Waste collectors and waste processors, and waste processors, as defined in Appendix G to Rule 420-3-26-.03 must provide financial assurance in an amount based on a decommissioning funding plan as described in Rule 420-3-26-.02(26). The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of the of disposal of the

maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the criteria of Rule 420-3-26-.03. The decommissioning funding plan must be submitted by December 2, 2006.

(e) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by December 2, 2006. Licensees required to submit the $113,000 or $225,000 amount must do so by June 2, 2007. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan. For quantities:

| | | |
|---|---|---|
| 1. | Greater than $10^4$ but less than or equal to $10^5$ times The applicable quantities of Appendix F of 420-3-26-.03 in unsealed form. (For a combination of isotopes, if R, as defined in 420-3-26-.02(26)(a), divided by $10^4$, is greater than 1 but R divided by $10^5$ is less or equal to 1) | $1,125,000 |
| 2. | Greater than $10^3$ but less than or equal to $10^4$ times the applicable quantities of Appendix F of 420-3-26-.03 in unsealed form. (For a combination of isotopes, if R, as defined in 420-3-26-.02(26)(a), divided by $10^3$ is greater than 1 but R divided by $10^4$ is less than or equal to 1) | $225,000 |
| 3. | Greater than $10^{10}$ but less than or equal to $10^{12}$ times the applicable quantities of Appendix F of 420-3-26-.03 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 420-3-26.02(26)(a) divided by $10^{10}$ is greater than 1, but R divided by $10^{12}$ is less than or equal to 1) | $113,000 |

(f) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method assuring funds for decommissioning from 420-3-26-.02(26)(g), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of 420-3-26-.02(26)(g).

(g) Financial assurance for decommissioning must be provided by one or more of the following methods:

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

2. A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or a line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to this Rule. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this Rule for commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial tests may be used if the guarantee and test are as contained in Appendix B of this Rule. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and tests are as contained in Appendix C of this Rule. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and tests are as contained in Appendix D to this Rule. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this rule or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

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

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

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

3. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provision must be as stated in 420-3-26-.02(26)(g)2.

4. In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 420-3-26-.02(26)(e), and indicating that funds for decommissioning will be obtained when necessary.

5. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(h) Each person licensed under this Rule 420-3-26-.02 shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use by the Agency. Before licensed activities are transferred or assigned in accordance with 420-3-26-.02(12)(b), licensees shall transfer all records described in this rule to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their location may be used. Information the Agency considers important to decommissioning consists of:

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

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

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

(i) All areas designated and formerly designated restricted areas as defined in 420-3-26-.01(2)(a)93;

(ii) All areas outside of restricted areas that require decontamination under 420-3-26-.02(26)(i)1.

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 420-3-26-.03(48); and

(iv) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 420-3-26 -.03(60)or apply for approval for disposal under 420-3-26-.03(34).

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

(27) **Emergency Plan For Large Quantities**

(a) Each application to possess radioactive material in an unsealed or a sealed form, on foils or plated sources, or sealed in glass in excess of the quantities in "Schedule E-Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan", must contain either:

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

2. An emergency plan responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under 420-3-26-.02(27)(a)(1):

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

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

3. The release fraction in the respirable size range would be lower than the release fraction shown in Schedule E due to the chemical or physical form of the material;

4. The solubility of the material would reduce the dose received;

5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule E;

6. Operating restrictions or procedures would prevent a release fraction as large as shown in Schedule E; or

7. Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under 420-3-26-.02(27)(a)(2) must include the following information:

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

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

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

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

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

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

7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off site response organizations and the Agency; also responsibilities

for developing, maintaining, and updating the plan.

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

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

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

11. Restoration of safe conditions. A brief description of the means of restoring the facility to safe condition after an accident.

12. Exercises. Provisions for conducting quarterly communications checks with off site response organizations and biennial on site exercises to test response to simulated emergencies. Quarterly communications checks with off site response organizations must include the check and update of all necessary phone numbers. The licensee shall invite off site response organizations to participate in the biennial exercises. Participation of off site response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

13. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of

1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

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

(28) **Emergency Plan Reporting Requirements.**

(a) Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.)

(b) Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Rule 420-3-26-.03; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

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

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

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

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

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

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

(i) The quantity of material involved is greater than 5 times the lowest annual limit on intake on the material specified in Appendix B of Rule 420-3-26-.03; and

(ii) The damage affects the licensed material or its container.

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

1. Licensees shall make reports required by 420-3-26.02(28)(a) and (b) by telephone to the Agency to the extent that the information is available at the time of notification. The information provided in these reports must include:

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

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

(iii) The exact location of the event;

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

(v) Any personnel exposure data available.

2. Written report. Each licensee who makes a report required by 420-3-26-.02(28)(a) and (b) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all the necessary information and appropriate distribution is made. These reports must be sent to the Director, Office of Radiation Control, Alabama Department of Public Health, 201 Monroe Street, Montgomery, Alabama 36104. The reports must include the following:

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

(ii) The exact location of the event;

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

(iv) Date and time of the event;

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

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

**Reporting Requirements**

(29) **Reporting Requirements.**

(a) Immediate Report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.)

(b) Twenty four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Rule 420-3-26-.03 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

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

(i) The equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials

exceeding regulatory limits, or to mitigate the consequences of an accident.

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

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

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable contamination on the individuals clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment involving radioactive material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Rule 420-3-26-.03 for the material; and

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

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

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

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

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

(iii) The exact location of the event;

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

(v) Any personal radiation exposure data available.

2. Written report. Each licensee who makes a report required by paragraphs (a) and (b) of this section shall submit a written follow-up report within 30 days of the initial report. written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These reports must be sent to the Agency at the address specified in Rule 420-3-26-.01(12). The reports must include the following:

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

(ii) The exact location of the event;

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

(iv) Date and time of the event;

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

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

(30) **Records**.

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

1. The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

2. The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in other rules of this Rule dictate otherwise.

3. The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Agency terminates each license that authorizes disposal of the material.

(b) The licensee shall retain each record that is required by this Rule for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) Records which must be maintained pursuant to this Rule may be the original or a reproduced copy. The record may also be stored in electronic media with the

capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

1. Records of disposal of licensed material made under 420-3-26-.03(34) (including burials authorized before January 28, 1981), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37); and

2. Records required by 420-3-26-.03(42)(b)4.

(e) If licensed activities are transferred or assigned in accordance with 420-3-26-.02(12)(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

1. Records of disposal of licensed material made under 420-3-26-.03(34) (including burials authorized before January 28, 1981), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37); and

2. Records required by 420-3-26-.03(42)(b)4.

(f) Prior to license termination, each licensee shall forward the records required by420-3-26-.02(11)(b) to the Agency.

SCHEDULE A
(OMITTED)

Authority: §§ 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, also 22-2-1, 22-2-2, 22-2-5, and 22-2-6, Code of Alabama, 1975. Act 82-328 Section 5.b.l.

Author: Kirksey E. Whatley, Director, Office of Radiation Control, Alabama Department of Public Health

History: New 6-15-66; Revised 6-17-68, 3-18-70, 3-17-70, 9-1973; Repromulgated 8-21-74;-Revised 5-21-75, 9-15-76, 1-18-78; Recodified 6-11-78; Revised 11-21-79; Repromulgated and Revised 10-21-81. Revised and Re-

promulgated effective 12-31-83. Revised and Repromulgated effective 1-31-90. Revised Effective 10-1-91. Revised and Repromulgated effective April 22, 1994. Revised effective March 18, 1998. Revised and Repromulgated effective May 25, 2000. Amended effective June 23, 2006, filed May 19, 2006.

## SCHEDULE B EXEMPT QUANTITIES

| Radioactive Material | Microcuries |
|---|---|
| Antimony-122 (Sb 122) | 100 |
| Antimony-124 (Sb 124) | 10 |
| Antimony-125 (Sb 125) | 10 |
| Arsenic-73 (As 73) | 100 |
| Arsenic-74 (As 74) | 10 |
| Arsenic-76 (As 76) | 10 |
| Arsenic-77 (As 77) | 100 |
| Barium-131 (Ba 131) | 10 |
| Barium-133 (Ba 133) | 10 |
| Barium-140 (Ba 140) | 10 |
| Bismuth-210 (Bi 210) | 1 |
| Bromine-82 (Br 82) | 10 |
| Cadmium-109 (Cd 109) | 10 |
| Cadmium-115m (Cd 115m) | 10 |
| Cadmium-115 (Cd 115) | 100 |
| Calcium-45 (Ca 45) | 10 |
| Calcium-47 (Ca 47) | 10 |
| Carbon-14 (C 14) | 100 |
| Cerium-141 (Ce 141) | 100 |
| Cerium-143 (Ce 143) | 100 |
| Cerium-144 (Ce 144) | 1 |
| Cesium-129 (Cs 129) | 100 |
| Cesium-131 (Cs 131) | 1,000 |
| Cesium-134m (Cs 134m) | 100 |
| Cesium-134 (Cs 134) | 1 |
| Cesium-135 (Cs 135) | 10 |
| Cesium-136 (Cs 136) | 10 |
| Cesium-137 (Cs 137) | 10 |
| Chlorine-36 (Cl 36) | 10 |
| Chlorine-38 (Cl 38) | 10 |
| Chromium-51 (Cr 51) | 1,000 |
| Cobalt-57 (Co 57) | 100 |
| Cobalt-58m (Co 58m) | 10 |
| Cobalt-60 (Co 60) | 1 |
| Copper-64 (Cu 64) | 100 |
| Dysprosium-165 (Dy 165) | 10 |
| Dysprosium-166 (Dy 166) | 100 |
| Erbium-169 (Er 169) | 100 |

| Radioactive Material | Microcuries |
|---|---|
| Erbium-171 (Er 171) | 100 |
| Europium-152 (Eu 152)9.2h | 100 |
| Europium-152 (Eu 152)13 yr | 1 |
| Europium-154 (Eu 154) | 1 |
| Europium-155 (Eu 155) | 10 |
| Fluorine-18 (F 18) | 1,000 |
| Gadolinium-153 (Gd 153) | 10 |
| Gadolinium-159 (Gd 159) | 100 |
| Gallium-67 (Ga 67) | 100 |
| Gallium-72 (Ga 72) | 10 |
| Germanium-68 (Ge 68) | 10 |
| Germanium-71 (Ge 71) | 100 |
| Gold-195 (Au 195) | 10 |
| Gold-198 (Au 198) | 100 |
| Gold-199 (Au 199) | 100 |
| Hafnium-181 (Hf 181) | 10 |
| Holmium-166 (Ho 166) | 100 |
| Hydrogen-3 (H 3) | 1,000 |
| Indium-111 (In 111) | 100 |
| Indium-113m (In 113m) | 100 |
| Indium-114m (In 114m) | 10 |
| Indium-115m (In 115m) | 100 |
| Indium-115 (In 115) | 10 |
| Iodine-123 (I 123) | 100 |
| Iodine-125 (I 125) | 1 |
| Iodine-126 (I 126) | 1 |
| Iodine-129 (I 129) | 0.1 |
| Iodine-131 (I 131) | 1 |
| Iodine-132 (I 132) | 10 |
| Iodine-133 (I 133) | 1 |
| Iodine-134 (I 134) | 10 |
| Iodine-135 (I 135) | 10 |
| Iridium-192 (Ir 192) | 10 |
| Iridium-194 (Ir 194) | 100 |
| Iron-52 (Fe 52) | 10 |
| Iron-55 (Fe 55) | 100 |
| Iron-59 (Fe 59) | 10 |
| Krypton-85 (Kr 85) | 100 |
| Krypton-87 (Kr 87) | 10 |
| Lanthanum-140 (La 140) | 10 |

| Radioactive Material | Microcuries |
|---|---|
| Lutetium-177 (Lu 177) | 100 |
| Manganese-52 (Mn 52) | 10 |
| Manganese-54 (Mn 54) | 10 |
| Manganese-56 (Mn 56) | 10 |
| Mercury-197m (Hg 197m) | 100 |
| Mercury-197 (Hg 197) | 100 |
| Mercury-203 (Hg 203) | 10 |
| Molybdenum-99 (Mo 99) | 100 |
| Neodymium-147 (Nd 147) | 100 |
| Neodymium-149 (Nd 149) | 100 |
| Nickel-59 (Ni 59) | 100 |
| Nickel-63 (Ni 63) | 10 |
| Nickel-65 (Ni 65) | 100 |
| Niobium-93m (Nb 93m) | 10 |
| Niobium-95 (Nb 95) | 10 |
| Niobium-97 (Nb 97) | 10 |
| Osmium-185 (Os 185) | 10 |
| Osmium-191M (Os 191m) | 100 |
| Osmium-191 (Os 191) | 100 |
| Osmium-193 (Os 193) | 100 |
| Palladium-103 (Pd 103) | 100 |
| Palladium-109 (Pd 109) | 100 |
| Phosphorus-32 (P 32) | 10 |
| Platinum-191 (Pt 191) | 100 |
| Platinum-193m (Pt 193m) | 100 |
| Platinum-193 (Pt 193) | 100 |
| Platinum-197m (Pt 197m) | 100 |
| Platinum-197 (Pt 197) | 100 |
| Polonium-210 (Po 210) | 0.1 |
| Potassium-42 (K 42) | 10 |
| Potassium-43 (K 43) | 10 |
| Praseodymium-142 (Pr 142) | 100 |
| Praseodymium-143 (Pr 143) | 100 |
| Promethium-147 (Pm 147) | 10 |
| Promethium-149 (Pm 149) | 10 |
| Rhenium-186 (Re 186) | 100 |
| Rhenium-188 (Re 188) | 100 |
| Rhodium-103m (Rh 103m) | 100 |
| Rhodium-105 (Rh 105) | 100 |
| Rubidium-81 (Rb 81) | 10 |

| Radioactive Material | Microcuries |
|---|---|
| Rubidium-86 (Rb 86) | 10 |
| Rubidium-87 (Rb 87) | 10 |
| Ruthenium-97 (Ru 97) | 100 |
| Ruthenium-103 (Ru 103) | 10 |
| Ruthenium-105 (Ru 105) | 10 |
| Ruthenium-106 (Ru 106) | 1 |
| Samarium-151 (Sm 151) | 10 |
| Samarium-153 (Sm 153) | 100 |
| Scandium-46 (Sc 46) | 10 |
| Scandium-47 (Sc 47) | 100 |
| Scandium-48 (Sc 48) | 10 |
| Selenium-75 (Se 75) | 10 |
| Silicon-31 (Si 31) | 100 |
| Silver-105 (Ag 105) | 10 |
| Silver-110m (Ag 110m) | 1 |
| Silver-111 (Ag 111) | 100 |
| Sodium-22 (Na 22) | 10 |
| Sodium-24 (Na 24) | 10 |
| Strontium-85 (Sr 85) | 10 |
| Strontium-89 (Sr 89) | 1 |
| Strontium- 9 0(Sr 90) | 0.1 |
| Strontium-91 (Sr 91) | 10 |
| Strontium-92 (Sr 92) | 10 |
| Sulphur-35 (S 35) | 100 |
| Tantalum-182 (Ta 182) | 10 |
| Technetium-96 (Tc 96) | 10 |
| Technetium-97m (Tc 97m) | 100 |
| Technetium-99m (Tc 99m) | 100 |
| Technetium-99 (Tc 99) | 10 |
| Tellurium-125m (Te 125m) | 10 |
| Tellurium-127m (Te 127m) | 10 |
| Tellurium-127 (Te 127) | 100 |
| Tellurium-129m (Te 129m) | 10 |
| Tellurium-129 (Te 129) | 100 |
| Tellurium-131m (Te 131m) | 10 |
| Tellurium-132 (Te 132) | 10 |
| Terbium-160 (Tb 160) | 10 |
| Thallium-200 (Tl 200) | 100 |
| Thallium-201 (Tl 201) | 100 |
| Thallium-202 (Tl 202) | 100 |

| Radioactive Material | Microcuries |
|---|---|
| Thallium-204 (Tl 204) | 10 |
| Thulium-170 (Tm 170) | 10 |
| Thulium-171 (Tm 171) | 10 |
| Tin-113 (Sn 113) | 10 |
| Tin-125 (Sn 125) | 10 |
| Tungsten-181 (W 181) | 10 |
| Tungsten-185 (W 185) | 10 |
| Tungsten-187 (W 187) | 100 |
| Vanadium-48 (V 48) | 10 |
| Xenon-131m (Xe 131m) | 1,000 |
| Xenon-133 (Xe 133) | 100 |
| Xenon-135 (Xe 135) | 100 |
| Ytterbium-175 (Yb 175) | 100 |
| Yttrium-87 (Y 87) | 10 |
| Yttrium-88 (Y 88) | 10 |
| Yttrium-90 (Y 90) | 10 |
| Yttrium-91 (Y 91) | 10 |
| Yttrium-92 (Y 92) | 100 |
| Yttrium-93 (Y 93) | 100 |
| Zinc-65 (Zn-65) | 10 |
| Zinc-69m (Zn 69m) | 100 |
| Zinc-69 (Zn 69) | 1,000 |
| Zirconium-93 (Zr 93) | 10 |
| Zirconium-95 (Zr 95) | 10 |
| Zirconium-97 (Zr 97) | 10 |
| Any radioactive material not listed above other than alpha-emitting radioactive material | 0.1 |

**SCHEDULE C**
**EXEMPT CONCENTRATIONS**

| Element (atomic number) | Isotope | Column I Gas concentration $\mu$Ci/ml 1/ | Column II Liquid and solid concentration $\mu$Ci/ml 2/ |
|---|---|---|---|
| Antimony (51) | Sb-122 | | $3x10^{-4}$ |
| | Sb-124 | | $2x10^{-4}$ |
| | Sb-125 | | $1x10^{-3}$ |
| Argon (18) | Ar-37 | $1x10^{-3}$ | |
| | Ar-41 | $4x10^{-7}$ | |
| Arsenic (33) | As-73 | | $5x10^{-3}$ |
| | As-74 | | $5x10^{-4}$ |
| | As-76 | | $2x10^{-4}$ |
| | As-77 | | $8x10^{-4}$ |
| Barium (56) | Ba-131 | | $2x10^{-3}$ |
| | Ba-140 | | $3x10^{-4}$ |
| Beryllium (4) | Be-7 | | $2x10^{-2}$ |
| Bismuth (83) | Bi-206 | | $4x10^{-4}$ |
| Bromine (35) | Br-82 | $4x10^{-7}$ | $3x10^{-3}$ |
| Cadmium (48) | Cd-109 | | $2x10^{-3}$ |
| | Cd-115m | | $3x10^{-4}$ |
| | Cd-115 | | $3x10^{-4}$ |
| Calcium (20) | Ca-45 | | $9x10^{-5}$ |
| | Ca-47 | | $5x10^{-4}$ |
| Carbon (6) | C-14 | $1x10^{-6}$ | $8x10^{-3}$ |
| Cerium (58) | Ce-141 | | $9x10^{-4}$ |
| | Ce-143 | | $4x10^{-4}$ |
| | Ce-144 | | $1x10^{-4}$ |
| Cesium (55) | Cs-131 | | $2x10^{-2}$ |
| | Cs-134m | | $6x10^{-2}$ |
| | Cs-134 | | $9x10^{-5}$ |
| Chlorine (17) | Cl-38 | $9x10^{-7}$ | $4x10^{-3}$ |
| Chromium (24) | Cr-51 | | $2x10^{-2}$ |
| Cobalt (27) | Co-57 | | $5x10^{-3}$ |
| | Co-58 | | $1x10^{-3}$ |
| | Co-60 | | $5x10^{-4}$ |
| Copper (29) | Cu-64 | | $3x10^{-3}$ |
| Dysprosium (66) | Dy-165 | | $4x10^{-3}$ |
| | Dy-166 | | $4x10^{-4}$ |

1/ Values are given in Column I only for those materials normally used as gases.
2/ $\mu$Ci/g for solids.

| Element (atomic number) | Isotope | Column I Gas concentration $\mu$Ci/ml 1/ | Column II Liquid and solid concentration $\mu$Ci/ml 2/ |
|---|---|---|---|
| Erbium (68) | Er-69 | | $9x10^{-4}$ |
| | Er-171 | | $1x10^{-3}$ |
| Europium (63) | Eu-152 (.2h) | | $6x10^{-4}$ |
| | Eu-155 | | $2x10^{-3}$ |
| Fluorine (9) | F-18 | $2x10^{-6}$ | $8x10^{-3}$ |
| Gadolinium (64) | Gd-153 | | $2x10^{-3}$ |
| | Gd-159 | | $8x10^{-4}$ |
| Gallium (31) | Ga-72 | | $4x10^{-4}$ |
| Germanium (32) | Ge-71 | | $2x10^{-2}$ |
| Gold (79) | Au-196 | | $2x10^{-3}$ |
| | Au-198 | | $5x10^{-4}$ |
| | Au-199 | | $2x10^{-3}$ |
| Hafnium (72) | Hf-181 | | $7x10^{-4}$ |
| Hydrogen (1) | H-3 | $5x10^{-6}$ | $3x10^{-2}$ |
| Indium (49) | In-113m | | $1x10^{-2}$ |
| | In-114m | | $2x10^{-4}$ |
| Iodine (53) | I-126 | $3x10^{-9}$ | $2x10^{-5}$ |
| | I-131 | $3x10^{-9}$ | $2x10^{-5}$ |
| | I-132 | $8x10^{-8}$ | $6x10^{-4}$ |
| | I-133 | $1x10^{-8}$ | $7x10^{-5}$ |
| | I-134 | $2x10^{-7}$ | $1x10^{-3}$ |
| Iridium (77) | Ir-190 | | $2x10^{-3}$ |
| | Ir-192 | | $4x10^{-4}$ |
| | Ir-194 | | $3x10^{-4}$ |
| Iron (26) | Fe-55 | | $8x10^{-3}$ |
| | Fe-59 | | $6x10^{-4}$ |
| Krypton (36) | Kr-85m | $1x10^{-6}$ | |
| | Kr-85 | $3x10^{-6}$ | |
| Lanthanum (57) | La-140 | | $2x10^{-4}$ |
| Lead (82) | Pb-203 | | $4x10^{-3}$ |
| Lutetium (71) | Lu-177 | | $1x10^{-3}$ |
| Manganese (25) | Mn-52 | | $3x10^{-4}$ |
| | Mn-54 | | $1x10^{-3}$ |
| | Mn-56 | | $1x10^{-3}$ |
| Mercury (80) | Hg-197m | | $2x10^{-3}$ |
| | Hg-197 | | $3x10^{-3}$ |
| | Hg-203 | | $2x10^{-4}$ |

1/ Values are given in Column I only for those materials normally used as gases.
2/ $\mu$Ci/g for solids.

| Element (atomic number) | Isotope | Column I Gas concentration $\mu$Ci/ml 1/ | Column II Liquid and solid concentration $\mu$Ci/ml 2/ |
|---|---|---|---|
| Molybdenum (42) | Mo-99 | | $2x10^{-3}$ |
| Neodymium (60) | Nd-147 | | $6x10^{-4}$ |
| | Nd-149 | | $3x10^{-3}$ |
| Nickel (28) | Ni-65 | | $1x10^{-3}$ |
| Niobium (Columbium) (41) | Nb-95 | | $1x10^{-3}$ |
| | Nb-97 | | $9x10^{-3}$ |
| Osmium (76) | Os-185 | | $7x10^{-4}$ |
| | Os-191m | | $3x10^{-2}$ |
| | Os-191 | | $2x10^{-3}$ |
| | Os-193 | | $6x10^{-4}$ |
| Palladium (46) | Pd-103 | | $3x10^{-3}$ |
| | Pd-109 | | $9x10^{-4}$ |
| Phosphorus (15) | P-32 | | $2x10^{-4}$ |
| Platinum (78) | Pt-191 | | $1x10^{-3}$ |
| | Pt-193m | | $1x10^{-2}$ |
| | Pt-197m | | $1x10^{-2}$ |
| | Pt-197 | | $1x10^{-3}$ |
| Potassium (19) | K-42 | | $3x10^{-3}$ |
| Praseodymium (59) | Pr-142 | | $3x10^{-4}$ |
| | Pr-143 | | $5x10^{-4}$ |
| Promethium (61) | Pm-147 | | $2x10^{-3}$ |
| | Pm-149 | | $4x10^{-4}$ |
| Rhenium (75) | Re-183 | | $6x10^{-3}$ |
| | Re-186 | | $9x10^{-4}$ |
| | Re-188 | | $6x10^{-4}$ |
| Rhodium (45) | Rh-103m | | $1x10^{-1}$ |
| | Rh-105 | | $1x10^{-3}$ |
| Rubidium (37) | Rb-86 | | $7x10^{-4}$ |
| Ruthenium (44) | Ru-97 | | $4x10^{-3}$ |
| | Ru-103 | | $8x10^{-4}$ |
| | Ru-105 | | $1x10^{-3}$ |
| | Ru-106 | | $1x10^{-4}$ |
| Samarium (62) | Sm-153 | | $8x10^{-4}$ |
| Scandium (21) | Sc-46 | | $4x10^{-4}$ |
| | Sc-47 | | $9x10^{-4}$ |
| | Sc-48 | | $3x10^{-4}$ |
| Selenium (34) | Se-75 | | $3x10^{-3}$ |

1/ Values are given in Column I only for those materials normally used as gases.
2/ $\mu$Ci/g for solids.

| Element (atomic number) | Isotope | Column I Gas concentration $\mu$Ci/ml 1/ | Column II Liquid and solid concentration $\mu$Ci/ml 2/ |
|---|---|---|---|
| Silicon (14) | Si-31 | | $9x10^{-3}$ |
| Silver (47) | Ag-105 | | $1x10^{-3}$ |
| | Ag-110m | | $3x10^{-4}$ |
| | Ag-111 | | $4x10^{-4}$ |
| Sodium (11) | Na-24 | | $2x10^{-3}$ |
| Strontium (38) | Sr-85 | | $1x10^{-3}$ |
| | Sr-89 | | $1x10^{-4}$ |
| | Sr-91 | | $7x10^{-4}$ |
| | Sr-92 | | $7x10^{-4}$ |
| Sulfur (16) | S-35 | $9x10^{-8}$ | $6x10^{-4}$ |
| Tantalum (73) | Ta-182 | | $4x10^{-4}$ |
| Technetium (43) | Tc-96m | | $1x10^{-1}$ |
| | Tc-96 | | $1x10^{-3}$ |
| Tellurium (52) | Te-125m | | $2x10^{-3}$ |
| | Te-127m | | $6x10^{-4}$ |
| | Te-127 | | $3x10^{-3}$ |
| | Te-129m | | $3x10^{-4}$ |
| | Te-131m | | $6x10^{-4}$ |
| | Te-132 | | $3x10^{-4}$ |
| Terbium (65) | Tb-160 | | $4x10^{-4}$ |
| Thallium (81) | Tl-200 | | $4x10^{-3}$ |
| | Tl-201 | | $3x10^{-3}$ |
| | Tl-202 | | $1x10^{-3}$ |
| | Tl-204 | | $1x10^{-3}$ |
| Thulium (69) | Tm-170 | | $5x10^{-4}$ |
| | Tm-171 | | $5x10^{-3}$ |
| Tin (50) | Sn-113 | | $9x10^{-4}$ |
| | Sn-125 | | $2x10^{-4}$ |
| Tungsten (Wolfram) (74) | W-181 | | $4x10^{-3}$ |
| | W-187 | | $7x10^{-4}$ |
| Vanadium (23) | V-48 | | $3x10^{-4}$ |
| Xenon (54) | Xe-131m | $4x10^{-6}$ | |
| | Xe-133 | $3x10^{-6}$ | |
| | Xe-135 | $1x10^{-6}$ | |
| Ytterbium (70) | Yb-175 | | $1x10^{-3}$ |

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu$Ci/g for solids.

| Element (atomic number) | Isotope | Column I Gas concentration $\mu$Ci/ml 1/ | Column II Liquid and solid concentration $\mu$Ci/ml 2/ |
|---|---|---|---|
| Yttrium (39) | Y-90 | | $2x10^{-4}$ |
| | Y-91m | | $3x10^{-2}$ |
| | Y-91 | | $3x10^{-4}$ |
| | Y-92 | | $6x10^{-4}$ |
| | Y-93 | | $3x10^{-4}$ |
| Zinc (30) | Zn-65 | | $1x10^{-3}$ |
| | Zn-69m | | $7x10^{-4}$ |
| | Zn-69 | | $2x10^{-2}$ |
| Zirconium (40) | Zr-95 | | $6x10^{-4}$ |
| | Zr-97 | | $2x10^{-4}$ |
| Beta- and/or gamma emitting radioactive material not listed above with half-life of less than 3 years. | | $1x10^{-10}$ | $1x10^{-6}$ |

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule C, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 420-3-26-.02(4) where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentrations present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = 1$$

1/ Values are given only for those materials normally used as gases.

2/ $\mu$Ci/gm for solids.

**SCHEDULE D**
**(Deleted 1998)**

## SCHEDULE E

## QUANTITIES OF RADIOACTIVE MATERIAL REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN

| Radioactive material | Release Fraction | Quantity (Curies) |
|---|---|---|
| Actinium-228 | 0.001 | 4,000 |
| Americium-241 | .01 | 2 |
| Americium-242 | .001 | 2 |
| Americium-243 | .001 | 2 |
| Antimony-124 | .01 | 4,000 |
| Antimony-126 | .01 | 6,000 |
| Barium-133 | .01 | 10,000 |
| Barium-140 | .01 | 30,000 |
| Bismuth-207 | .01 | 5,000 |
| Bismuth-210 | .01 | 600 |
| Cadmium-109 | .01 | 1,000 |
| Cadmium-113 | .01 | 80 |
| Calcium-45 | .01 | 20,000 |
| Californium-252 | .001 | 9 (20 mg) |
| Carbon-14 | .01<br>Non CO | 50,000 |
| Cerium-141 | .01 | 10,000 |
| Cerium-144 | .01 | 300 |
| Cesium-134 | .01 | 2,000 |
| Cesium-137 | .01 | 3,000 |
| Chlorine-36 | .5 | 100 |
| Chromium-51 | .01 | 300,000 |
| Cobalt-60 | .001 | 5,000 |
| Copper-64 | .01 | 20,000 |
| Curium-242 | .001 | 60 |
| Curium-243 | .001 | 3 |
| Curium-244 | .001 | 4 |
| Curium-245 | .001 | 2 |
| Europium-152 | .01 | 500 |
| Europium-154 | .01 | 400 |
| Europium-155 | .01 | 3,000 |
| Germanium-68 | .01 | 2,000 |
| Gadolinium-153 | .01 | 5,000 |

| | | |
|---|---|---|
| Gold-198 | .01 | 30,000 |
| Hafnium-172 | .01 | 400 |
| Holmium-166m | .01 | 7,000 |
| Hydrogen-3 | .5 | 100 |
| Iodine-125 | .5 | 20,000 |
| Iodine-131 | .5 | 10 |
| Indium-114m | .01 | 1,000 |
| Iridium-192 | .001 | 40,000 |
| Iron-55 | .01 | 40,000 |
| Krypton-85 | 1.01 | 6,000,000 |
| Lead-210 | .01 | 8 |
| Manganese-56 | .01 | 60,000 |
| Mercury-203 | .01 | 10,000 |
| Molybdenum-99 | .01 | 30,000 |
| Neptunium-237 | .001 | 2 |
| Nickel-63 | .01 | 20,000 |
| Niobium-94 | .01 | 300 |
| Phosphorus-32 | .5 | 100 |
| Phosphorus-33 | .5 | 1,000 |
| Polonium-32 | .01 | 10 |
| Potassium-42 | .01 | 9,000 |
| Promethium-145 | .01 | 4,000 |
| Promethium-147 | .01 | 4,000 |
| Ruthenium-106 | .01 | 200 |
| Samarium-151 | .01 | 4,000 |
| Scandium-46 | .01 | 3,000 |
| Selenium-75 | .01 | 10,000 |
| Silver-110m | .01 | 1,000 |
| Sodium-22 | .01 | 9,000 |
| Sodium-24 | .01 | 10,000 |
| Strontium-89 | .01 | 3,000 |
| Strontium-90 | .01 | 90 |
| Sulfur-35 | .5 | 900 |
| Technetium-99 | .01 | 10,000 |
| Technetium-99m | .01 | 400,000 |
| Tellurium-127m | .01 | 5,000 |
| Tellurium-129m | .01 | 5,000 |
| Terbium-160 | .01 | 4,000 |
| Thulium-170 | .01 | 4,000 |
| Tin-113 | .01 | 10,000 |
| Tin-123 | .01 | 3,000 |
| Tin-126 | .01 | 1,000 |
| Titanium-44 | .01 | 100 |

| | | |
|---|---|---|
| Vanadium-48 | .01 | 7,000 |
| Xenon-133 | 1.0 | 900,000 |
| Yttrium-91 | .01 | 2,000 |
| Zinc-65 | .01 | 5,000 |
| Zirconium-63 | .01 | 400 |
| Zirconium-95 | .01 | 5,000 |
| Any other beta/gamma emitter | .01 | 10,000 |
| Mixed fission products | .01 | 1,000 |
| Decontaminated equipment, beta/gamma | .001 | 10,000 |
| Irradiated material, any form other than solid combustible | .01 | 1,000 |
| Mixed radioactive waste, beta/gamma | .01 | 1,000 |
| Packaged mixed waste, beta/gamma[2] | .001 | 10,000 |
| Any other alpha emitter | .001 | 2 |
| Contaminated equipment, alpha | .0001 | 20 |
| Packaged waste, alpha[2] | .0001 | 20 |
| Combinations of radioactive materials listed above[1] | | |

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

2. Waste packaged in Type B containers does not require an emergency plan.

**APPENDIX A**

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

I. Introduction:

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

II. Financial Test:

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

1. The parent company must have:

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

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

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

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least 6 times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

2. The parent company must have:

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

(ii) Tangible net worth at least 6 times the total current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

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

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least 6 times the current decommissioning cost estimates for all facilities or parts thereof (or prescribed amount if certification is used).

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

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

2. If the parent company no longer meets the requirements of Section. A. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in Agency Rules within 120 days of such notice.

III. Parent Company Guarantee:

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

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

B. If the licensee fails to provide alternative financial assurance as specified in Agency Rules within 90 days following receipt by the licensee and Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

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

D. If a trust is established for decommissioning costs, the trustee and trust

must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

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

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

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

**APPENDIX B**

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

I. Introduction

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

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

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

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

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

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

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

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

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

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

III. Company Self-Guarantee**.** The terms of a self guarantee which an applicant or licensee furnishes must provide that:

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

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

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

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

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

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

**APPENDIX C**

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

I. Introduction

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

II. Financial Test

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

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

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

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

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

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

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

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

III. Company Self-Guarantee

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

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

B. The licensee shall provide alte4rnative financial assurance as specified in

the rules within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

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

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

**APPENDIX D**

**Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance for Decommissioning by Nonprofit Colleges, Universities, and Hospitals**

I. Introduction

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

II. Financial Test

A. For colleges and universities, to pass the financial test a college or university must meet either the criteria in paragraph II.A.(1) or the criteria in paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located within the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater for all decommissioning activities for which the

college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test a hospital must meet either the criteria in paragraph II.B.(1) or the criteria in paragraph II.B.(2) of this appendix:

(1). For applicants or licensees that issue bonds, a current rating for its most current uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, all, of the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

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

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

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

3. If the licensee no longer meets the requirements of Section I of this

appendix, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial data requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

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

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

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

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

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

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service.

## 420-3-26-.01

## GENERAL PROVISIONS

(1) **Scope**. Except as otherwise specifically provided, these rules apply to all persons who receive possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.[1] The provisions of Rule 420-3-26-.03 of this rule shall not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of diagnosis or therapy by persons licensed to practice one or more of the healing arts within the authority granted them by healing arts statute or persons licensed to practice dentistry or podiatry within the authority granted them by licensing laws applying to dentists and podiatrists.

(2) **Definitions**.

(a) As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain rule will be found in that rule.

1. "$A_1$" means the maximum activity of special form radioactive material permitted in a Type A package. "$A_2$" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are listed in Rule 420-3-26-.03(32) of these rules.

2. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

3. "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 meV. For purposes of this definition, "particle accelerator" is an equivalent term.

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1. Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

4. "Accelerator-produced material" means any material made radioactive by a particle accelerator.

5. "Act" means Act No. 582, Alabama Law, Regular Session, 1963. Codified as 22-14-1 Code of Alabama.

6. "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

7. "Adult" means an individual 18 or more years of age.

8. "Agency" means the Alabama state board of Health.

9. "Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

10. "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

11. "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

    (i) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of 420-3-26-.03 of these rules.

    (ii) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

12. "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal

and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

13. "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials,"including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from licensed or registered sources regulated by the Agency.

14. "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

15. "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, quantities of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

16. "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

17. "Byproduct material" means:

    (i) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

    (ii) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

18. "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these rules except at the beginning of a year.

19. "Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

20. "CFR" means Code of Federal Regulations.

21. "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

22. "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

23. "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

24. "Committed effective dose equivalent" ($H_{E,\ 50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma\ w_T H_{T,50}$).

25. "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

26. "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E+10 transformations per second (tps).

27. "Deep dose equivalent" ($H_d$), which applies to external whole body

exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 $mg/cm^2$).

28. "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

29. "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

30. "Dose equivalent ($H_T$)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

31. "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

32. "Effective dose equivalent ($H_E$)" means the sum of the products of the dose equivalent to each organ or tissue ($H_T$) and the weighting factor ($w_T$) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma\, w_T H_T$).

33. "Embryo/fetus" means the developing human organism from conception until the time of birth.

34. "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

35. "Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

36. "Exposure" means being exposed to ionizing radiation or to

radioactive material.

37. "Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). See 420-3-26-.01(13) Units of Exposure and Dose for the special unit.

38. "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

39. "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

40. "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

41. "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 $mg/cm^2$).

42. "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

43. "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

44. "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

45. "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part

261.

46. "Healing arts" means the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, and for non-humans, veterinary medicine.

47. "High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

48. "Human use" means the internal or external administration of radiation or radioactive material to human beings.

49. "Individual" means any human being.

50. "Individual monitoring" means the assessment of:

    (i) Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

    (ii) Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See the definition of DAC-hours in 420-3-26-.03.

51. "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

52. "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, orders, requirements, and conditions of the Agency.

53. "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

54. "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

55. "License" means a license issued by the Agency in accordance with the rules adopted by the Agency.

56. "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Agency.

57. "Licensee" means any person who is licensed by the Agency in accordance with these rules and the Act.

58. "Licensing State" means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

59. "Limits" [See "Dose limits"].

60. "Lost or missing licensed or registered source of radiation" means licensed or registered source of radiation whose location is unknown. This definition includes licensed or registered material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

61. "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Rule 420-3-26-.03(32) of these rules.

62. "Member of the public" means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

63. "Minor" means an individual less than 18 years of age.

64. "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

65. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.[**]

66. "Natural radioactivity" means radioactivity of naturally occurring nuclides.[**]

67. "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

68. "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

69. "Package" means the packaging together with its radioactive contents as presented for transport.

70. "Particle accelerator" [See "Accelerator"].

71. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing other than the U.S.

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[**]For purposes of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc. (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

Nuclear Regulatory Commission, and other Federal Government Agencies licensed by the U. S Department of Energy, and other than Federal Government Agencies licensed by the U. S. Nuclear Regulatory Commission.

72. "Personnel monitoring equipment" [See "Individual monitoring devices"].

73. "Pharmacist" means [an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.

74. "Physician" means an individual licensed by the State of Alabama to dispense drugs in the practice of medicine.

75. "Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

76. "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130 °F (54.4 °C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

77. "Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those

having equivalent qualifications.

78. "Quality factor" (Q) means the modifying factor, listed in Tables I and II of Rule 420-3-26-.01(13), that is used to derive dose equivalent from absorbed dose.

79. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

80. "Radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

81. "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

82. "Radiation dose" [See "Dose"].

83. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

84. "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection rules.

85. "Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

86. "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

87. "Radiobioassay" [See "Bioassay"].

88. "Registrant" means any person who is registered with the Agency and

is legally obligated to register with the Agency pursuant to these rules and the Act.

89. "Registration" means registration with the Agency in accordance with the rules adopted by the Agency.

90. "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

91. "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

92. "Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

93. "Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

94. "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "Exposure" and 420-3-26-.03(13).

95. "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

96. "Shallow dose equivalent" ($H_s$), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 $mg/cm^2$) averaged over an area of 1 square centimeter.

97. "SI" means the abbreviation for the International System of Units.

98. "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

99. "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

100. Source material" means:

(i) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

101. "Source material milling" means any activity that results in the production of radioactive material.

102. "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

103. "Special form radioactive material" means radioactive material that satisfies the following conditions:

(i) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(ii) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

(iii) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition

applicable at the time of its design or construction.

104. "Special nuclear material" means:

(i) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that *** the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(ii) Any material artificially enriched by any of the foregoing but does not include source material.

105. "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{200} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

106. "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

107. "Test" means the process of verifying compliance with an applicable

*** This wording is provided for states that cannot automatically adopt changes made by the U.S. Nuclear Regulatory Commission.

regulation.

108. "These rules" mean rules 420-3-26-.01 through 420-3-26-.13, inclusive.

109. "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

110. "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in Rule 420-3-26-.03(46)(a)6. of these rules.

111. "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 *et seq*., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

112. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

113. "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

114. "Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, spent nuclear fuel, or

byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the U.S. Nuclear Regulatory Commission.

115. "Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

116. "Week" means 7 consecutive days starting on Sunday.

117. "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

118. "Worker" means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

119. "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

120. "Working level month" (WLM) means an exposure to 1 working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

121. "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

**Exemptions from the Regulatory Requirements**

(3) **Exemptions**.

(a) **General Provision**. The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of

these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) **U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors**. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

1. Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

3. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

4. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:

   (i) that the exemption of the prime contractor or subcontractor is authorized by law; and

   (ii) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

**General Regulatory Requirements**

(4) **Records**. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules. Records shall be maintained as long as specified

in the rules or until the Agency authorizes disposal.

(5) **Inspections**.

(a) Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

(c) The Agency may immediately impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe these rules or provisions of the act.

(6) **Tests and Surveys**. Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) Sources of radiation;

(b) Facilities wherein sources of radiation are used or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

**Additional Regulatory Requirements**

(7) **Additional Requirements**. The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

**Enforcement Requirements**

(8) **Violations**. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(9) **Impounding**. Sources of radiation shall be subject to impounding pursuant to Section 15 of the Act.

(10) **Prohibited Uses**.

(a) A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(b) A shoe-fitting fluoroscopic device shall not be used.

(c) It shall be unlawful for any person to use, receive, own, or possess any source of radiation unless it is registered, licensed or exempted by the Agency and is operated in accordance with all applicable provisions of Rules 420-3-26-.01 through 420-3-260.13 inclusive.

(11) **Deliberate Misconduct**.

(a) Any licensee, registrant, applicant for a license or a certificate of registration, employee of a licensee, registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or registration, who knowingly provides to any licensee, registration holder, applicant, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registration holder's**,** or applicant's activities in these Rules, may not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, or order; or any term, condition, or limitation of any license or registration issued by the Agency; or

2. Deliberately submit to the Agency, a licensee, registrant, an applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

(b) A person who violates paragraphs (a)1. or (a)2. of this rule will be subject to enforcement in accordance with procedures in Rule 420-3-26-.13.

(c) For the purposes of paragraph (a)1. of this rule, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, registrant, or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license or registration issued by the Agency.

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

**Communications**

(12) **Communications**. All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Agency at its mailing address as follows:

Office of Radiation Control
Alabama Department of Public Health
P. O. Box 303017
Montgomery, Alabama 36130-3017

(13) **Units of Exposure and Dose**.

(a) As used in these rules, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58E-4 coulomb per kilogram of air.

(b) As used in these rules, the units of dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(c) As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

| TYPE OF RADIATION | Quality Factor (Q) | Absorbed Dose Equal to a Unit Dose Equivalent[a] |
|---|---|---|
| X, gamma, or beta radiation and high-speed electrons | 1 | 1 |
| Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge | 20 | 0.05 |
| Neutrons of unknown energy | 10 | 0.1 |
| High-energy protons | 10 | 0.1 |

[a]Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(d) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 420-3-26-.01(13)(c) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

| | Neutron Energy (MeV) | Quality Factor[a] (Q) | Fluence per Unit Dose Equivalent[b] (neutrons $cm^{-2}$ $rem^{-1}$) | Fluence per Unit Dose Equivalent[b] (neutrons $cm^{-2}$ $Sv^{-1}$) |
|---|---|---|---|---|
| (thermal) | 2.5E-8 | 2 | 980E+6 | 980E+8 |
| | 1E-7 | 2 | 980E+6 | 980E+8 |
| | 1E-6 | 2 | 810E+6 | 810E+8 |
| | 1E-5 | 2 | 810E+6 | 810E+8 |
| | 1E-4 | 2 | 840E+6 | 840E+8 |
| | 1E-3 | 2 | 980E+6 | 980E+8 |
| | 1E-2 | 2.5 | 1010E+6 | 1010E+8 |
| | 1E-1 | 7.5 | 170E+6 | 170E+8 |
| | 5E-1 | 11 | 39E+6 | 39E+8 |
| | 1 | 11 | 27E+6 | 27E+8 |
| | 2.5 | 9 | 29E+6 | 29E+8 |
| | 5 | 8 | 23E+6 | 23E+8 |
| | 7 | 7 | 24E+6 | 24E+8 |
| | 10 | 6.5 | 24E+6 | 24E+8 |
| | 14 | 7.5 | 17E+6 | 17E+8 |
| | 20 | 8 | 16E+6 | 16E+8 |
| | 40 | 7 | 14E+6 | 14E+8 |
| | 60 | 5.5 | 16E+6 | 16E+8 |
| | 1E+2 | 4 | 20E+6 | 20E+8 |
| | 2E+2 | 3.5 | 19E+6 | 19E+8 |
| | 3E+2 | 3.5 | 16E+6 | 16E+8 |
| | 4E+2 | 3.5 | 14E+6 | 14E+8 |

[a]Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b]Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

(14) **Units of Activity**. For purposes of these rules, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(a) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

(b) One curie (Ci) = 3.7E+10 disintegrations or transformations per second (dps or tps) = 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm).

Authority: §§ 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, also 22-2-1, 22-2-2, 22-2-5, and 22-2-6, Code of Alabama, 1975.

History: New 6-15-66; Revised 3-18-70; Repromulgated 8-21-74; Revised 5-21-75, 9-15-76,1-18-78; Recodified 6-11-78; Revised and repromulgated 10-21-81; Revised and repromulgated 12-21-83; Revised and repromulgated 1-31-90. Revised and repromulgated April 22, 1994. Revised and repromulgated June 27, 2001 (Effective August 6, 2001).

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