



STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

February 10, 2000

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OSP

Paul Lohaus
Director
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D. C.

Dear Mr. Lohaus:

Enclosed are copies of proposed revisions to Alabama Regulations for Control of Radiation. The proposed revisions incorporate NRC changes as enumerated in SP-99-056, dated August 12, 1999, with the exception of changes to 10 CFR 35. The revisions include all Category A, B, C, and most D designated changes verbatim with NRC changes. With these revisions, Alabama Radiation Protection Rules should be compatible with all NRC rule changes through August 12, 1999.

The major revision to the rules involves the industrial radiography rules.

I have enclosed a hard copy of the rule changes with additions underscored and deletions indicated by ~~strikethrough~~. Also enclosed is a rationale for the revisions which cross references the changes with NRC rules, including the page number on which the changes can be found. In addition, I have enclosed a disk in WordPerfect 9 with the changes and rationale including all changes and additions highlighted.

These changes will be presented to the State Committee of Public Health of February 16, 2000. It is anticipated that the Committee will authorize publication of the revisions for public comment. The public comment period will expire on April 4, 2000.

Please advise me if you have any comments regarding these revisions. We are committed to our agreement to maintain rules which are compatible with those of NRC.

Please contact me if you have questions or comments.

Sincerely,

Kirksey E. Whatley

PROPOSED RULE CHANGE TO RULE 420-3-26-.02

"LICENSING"

RATIONALE FOR CHANGES

Page	ARCR Reference	NRC Reference	Rationale
34	420-3-26-.02(10)(g)	34.11	The change revises and clarifies existing licensing documents for industrial radiography in accordance with revised 420-3-26-.04. NRC compatibility issue.
40	420-3-26-.02(10)(k)5.	NA	Editorial change to correct spelling error. Change "Mc)Ck" to "Mock".
49	420-3-26-.02(10)(r)	NA	Editorial change to correct typographical error. Change "care" to "Care".
55	420-3-26-.02(12)(b)	30.34(b)	Clarifies conditions under which a license can be transferred to other persons. NRC compatibility issue.
57	420-3-26-.02(13)	30.36	Add " <i>and Decommissioning of Sites and Separate Buildings or Outdoor Areas</i> " to the title of the rule. NRC compatibility issue.
59	420-3-26-.02(13)(d)4.(i)	30.36(g)(4)(i)	Words " <i>planned decommissioning activities</i> " are changed to reflect more accurately what the decommissioning plan must include. NRC compatibility issue.
59	420-3-26-.02(13)(d)4.(ii)	NA	Word "decommission" is changed to "decommissioning".
61	420-3-26-.02(13)(j)2.	30.36(j)(2)	Wording change makes rule identical to NRC. Provides reference to decommissioning criteria. NRC compatibility issue.
62	420-3-26-.02(13)(k)3.(i)	30.36(k)(3)(i)	Reference for release criteria (420-3-26-.03(50) and (60)) is added to Rule. NRC compatibility issue.

62	420-3-26-.02(13)(k)3.(ii)	30.36(k)(3)(ii)	Clarifies that additional information may be submitted prior to decommissioning for consideration by the Agency. NRC compatibility issue.
62	420-3-26-.02(13)(k)4.	30.36(k)(4)	Clarifies that certain records must have been received by the Agency prior to termination. NRC compatibility issue.
62	420-3-26-.02(13)(k)2.	30.36(k)(2)	Adds the words "if present" after the word "contamination".
62.	420-3-26-.02(13)(l)	30.36(d)	Added rule requires that within 60 days of certain occurrences, licensees must begin decommissioning activities or submit a plan. Requirements for plan approval are identified. NRC compatibility issue.
63	420-3-26-.02(13)(m)	30.36(e)	Added rule requires licensees to maintain financial assurances while decommissioning. Allows the amount of assurance to be increased/decreased depending on activities. NRC compatibility issue.
63	420-3-26-.02(13)(n)	30.36(f)	Added rule allows Agency to extend decommissioning time under certain conditions. NRC compatibility issue.
67	420-3-26-.02(20)(a)3.	NA	Corrects typographical error. Changes "cf" to "of".
72	420-3-26-.02(26)(a)	NA	Change corrects incorrect reference. Changes reference from Schedule B of 420-3-26-.02 to "Appendix F to Rule 420-3-26-.03."
74	420-3-26-.02(26)(g)	30.35(e)	Requires certification of financial assurance and submission of signed original of financial instrument. NRC compatibility issue.
76	420-3-26-.02(26)(h)5.	30.35(f)(5)	Rule added to provide arrangements for governmental entities.
76	420-3-26-.02(26)(i)	30.35(g)	Changes the words "license" to "site" and "terminated" to released" and specifies records important to decommissioning. NRC compatibility issue.
77	420-3-26-.02(26)(i)3.(iv)	NA	Corrects word usage error. Changes "contaminate" to "decontaminate". Also provides reference to criteria tat must be met.

75	420-3-26-.02(26)(h)2.	30.35(f)(2)	Rule is revised to include funding guarantee procedures for other licensees. NRC compatibility issue.
83	420-3-26-.02(29)	NA	Changes heading to "Reporting Requirements:."
86	420-3-26-.02(30)	30.51	Rule which requires that licensees maintain certain records is added. NRC compatibility issue.
102	Appendix A to 420-3-26-.02	Appendix A to 10 CFR 30	Appendix A is <u>revised</u> to include criteria as stated in Appendix A to 10 CFR 30. NRC compatibility issue.
105	Appendix B to 420-3-26-.02	Appendix C to 10 CFR 30	Appendix B is added. NRC compatibility issue.
107	Appendix C to 420-3-26-.02	Appendix D to 10 CFR 30	Appendix C is added. NRC compatibility issue.
109	Appendix D to 420-3-26-.02	Appendix E to 10 CFR 30	Appendix D is added. NRC compatibility issue.

420-3-26-.02

LICENSING (Amended)**(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 420-3-26-.02, all 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.

- (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.

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,

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..

- (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 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 microcurie 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);

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

- (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;
 - (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 millicurie of tritium per balance part.
- 4. Automobile shift quadrants containing not more than 25 millicuries of 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 microcuries 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

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.

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.

(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

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

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 32⁵

⁵ See footnote 4.

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

- (a) General Licenses provided in this Rule 420-3-26-.02 are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.
- (b) Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document.

(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 420-3-26-.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)1. 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)1.:
- (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)1., 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 110⁶
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(12), 420-3-26-.02(18), 420-3-26-.02(19), 420-3-26-.02(21), Rule 420-3-26-.03 and Rule 420-3-26-.10 of these rules.⁷

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

⁶ See footnote 4.

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

eliminators 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 measuring, Gauging, or Controlling Devices.

1. A general license is hereby issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use, or transfer in accordance with the provisions of 420-3-26-.02(7)(b)2., 3., and 4., radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light, or an ionizing atmosphere.
2. The general license in 420-3-26-.02(7)(b)1. applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to 420-3-26-.02(10)(f) or in accordance with the specifications contained in a specific license issued by the U. S. Nuclear Regulatory Commission, Licensing State, or an Agreement State, and which will be possessed and used at a single physical location. Devices which are portable, or which are incorporated as part of a mobile system, and are to be used at multiple physical locations are subject to the specific licensing provisions of 420-3-26-.02(8) and 420-3-26-.02(9).
3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 420-3-26-.02(7)(b)1. :
 - (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 krypton only need not be tested for leakage of radioactive material, and
 - (II) Devices containing tritium only 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 420-3-26-.02 (7) (b) 3. (ii) 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 an applicable specific license from the Agency, Licensing State, the U. S. Nuclear Regulatory commission, or an Agreement State to perform such activities;
- (iv) Shall maintain records showing compliance with the requirements of 420-3-26-.02(7)(b)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performances of, and the names of persons performing, testing, installing, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 420-3-26-.02(7)(b)3.(ii) shall be maintained for 5 years after the record is made. Records of tests of the on/off mechanism and indicator required by 420-3-26-.02(7)(b)3. (ii) shall be maintained for 1 year after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by 420-3-26-.02(7)(b)3.(iii) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed;
- (v) Shall, upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or

indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, Licensing State, the U. S. Nuclear Regulatory Commission, or an Agreement State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency, a report containing a brief description of the event and the remedial action taken;

- (vi) Shall not abandon the device containing radioactive material;
- (vii) Except as provided in 420-3-26-.02(7)(b)3.(viii), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U. S. Nuclear Regulatory Commission, Licensing State, or an Agreement State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;
- (viii) Shall transfer the device to another general licensee only:
 - (I) Where the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this rule and any safety documents identified by the label on the device and within 30 days of the transfer, report to the Agency the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or
 - (II) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

- (ix) Shall comply with the provisions of 420-3-26-.03(51) and 420-3-26-.03(52) of these rules for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Rules 420-3-26-.03 and 420-3-26-.10 of these rules.
 - (x) Shall within ten (10) days after the receipt of the device, notify the Agency, in writing, of the type of device and the name and address of the supplier. Devices that contain only tritium (H-3) gas are exempted from the notification requirements of this section.
- 4. The general license in 420-3-26-.02(7)(b)l. does not authorize the manufacture of devices containing radioactive material.
 - 5. The general license provided in 420-3-26-.02(7)(b)l. 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) of these rules.

(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 32⁸ of the regulations of the U. S. Nuclear Regulatory Commission.

⁸ See footnote 4.

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-.03(23) and 420-3-26-.03(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(ii), 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 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 70⁹, 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.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE

⁹ See footnote 4.

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,

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.

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

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), 420-3-26-.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 tests¹¹, in accordance with the provisions of subparagraphs 2., 3., 4., 5., and 6. of this paragraph, the following radioactive materials in prepackaged units:
 - (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

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.

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(h)l. at any one location of storage or use a total amount of iodine 125, iodine 131, iron 59, cobalt 57, and/or selenium 75 in excess of 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 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(8); 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 duplication 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:

Wholebody; head and trunk; active
blood-forming organs;

15 rems

gonads; or lens of eye

Hands and forearms; feet and ankles, 200 rems
localized areas of skin averaged over areas
no larger than 1 square centimeter

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.

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.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)

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 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 calendar quarter 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. Each person licensed under 420-3-26-.02(10)(f) to distribute devices to generally licensed persons shall:
 - (i) Furnish a copy of the general license contained in 420-3-26-.02(7)(b) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 420-3-26-.02(7)(b).
 - (ii) Furnish a copy of the general license contained in the U. S. Nuclear Regulatory Commission's, Licensing State's, or Agreement State's regulation equivalent to 420-3-26-.02(7)(b), or alternatively, furnish a copy of the general license contained in 420-3-26-.02(7)(b) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U. S. Nuclear Regulatory Commission, Licensing State, or the Agreement State. If a copy of the general license in 420-3-26-.02(7)(b) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U. S. Nuclear Regulatory Commission, Licensing State, or the Agreement State under requirements substantially the same as those in 420-3-26-.02(7)(b).
 - (iii) Report to the Agency all transfers of such devices to persons for use under the general license in 420-3-26-.02(7)(b). Such report shall identify each general licensee by name and address, and individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred and the quantity and type of radioactive material

contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under 4203-26-.02(7)(b) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.

(iv) Reports to Other Agencies.

- (I)** Report to the U. S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U. S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.¹³
- (II)** Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 420-3-26-.02 (10)(f) for use under a general license in that State's regulations equivalent to 420-3-26-.02(7) (b).
- (III)** Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.
- (IV)** If no transfers have been made to U. S. Nuclear Regulatory Commission licensees during the reporting

¹³

See footnote 4.

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 State during the reporting period, this information shall be reported to the responsible State agency upon request of the agency.
- (v) Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 420-3-26-.02(7)(b), or equivalent regulations of the U. S. Nuclear Regulatory Commission or another state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of 420-3-26-.02(10)(f)4.
- (g) **Use of Sealed Sources in Industrial Radiography¹⁴.** 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:
 - ~~1. The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the Agency a schedule or description of such program which specifies the:~~
 - ~~(i) Initial training;~~
 - ~~(ii) Periodic training;~~
 - ~~(iii) On-the-job training;~~
 - ~~(iv) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Agency rules and licensing requirements, and the operating and emergency procedures of the applicant; and~~

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.

~~(v) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of the operating and emergency procedures of the applicant.~~

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.

~~2. The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as described in 420-3-26-.04(15); and,~~

~~3. The applicant will have an internal inspection system adequate to assure that Agency rules, Agency license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspection at intervals not to exceed three months and the retention of records of such inspections for three years.~~

~~4. The applicant submits to the Agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program; and,~~

~~5. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including;~~

~~(i) Instrumentation to be used;~~

~~(ii) Method of performing tests, e.g., points on equipment to be smeared and method of taking smear; and,~~

~~(iii) Pertinent experience of the person who will perform the test.~~

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

(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 problems.

(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

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

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, 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~~ 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 quarter 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 420-3-26-.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).
 - (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

¹⁶

See footnote 4.

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,

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.

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;

- (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)1. 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 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 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,

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

- (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;
 - (II) Registered or licensed with the State of Alabama as a drug manufacturer;
 - (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 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 words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee 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(2)(d).
- (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)(d).
 - (II) This individual meets the requirements specified in 420-3-26-.07(80) 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 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 an 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 of 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).

(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) ~~Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provision of the Act.~~
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.
- (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 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.

(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 planned decommissioning activities; 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 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 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); and 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 of decommissioning activities, records of disposals, and records of required surveys have been received by the Agency.~~

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

(I) 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 licensee 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.

(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~~ 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, of the transporting vehicle, and incident reporting.¹⁹
- (c) Persons who transport radioactive material pursuant to the general licenses in 420-3-26-.02(22)(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 carrier²⁰ for transport 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 radioac-

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 to a carrier for transport.

tive 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 designee²¹, 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;
 - (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

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

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

²² Identified in 10 CFR 71, Appendix A effective September 6, 1983. Available as shown in footnote 4.

estimated to occur. A copy of the notification shall be retained by the licensee for 1 year.

- (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 governors 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 byproduct or source radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in ~~Schedule B to 420-3-26-.02~~ Appendix F to rule 420-3-26-.03 shall submit a decommissioning funding plan as described in 420-3-26-.02(26)(g). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in ~~Schedule B~~ Appendix F.
- (b) Each applicant for a specific license authorizing the possession and use of more than 100 millicuries of source material in a readily dispersible form shall submit a decommissioning funding plan as described in 420-3-26-.02 (26)(g).
- (c) Each applicant for a specific license authorizing the possession and use of byproduct or source 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)(h). 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 (h) 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 (h) 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 \$750,000 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).
- (e) Table of required amounts of financial assurance for decommissioning by quantity of material. For quantities:
1. Greater than 10^4 but less than or equal to 10^5 times \$750,000
The applicable quantities of Schedule B of
420-3-26-.02 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)

2. Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Schedule B of 420-3-26-.02 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) \$150,000
3. Greater than 10^{10} times the applicable quantities of Schedule B of 420-3-26-.02 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) \$75,000

(f) Each application for a specific license authorizing the possession and use of quantities of source material greater than 10 millicuries but less than 100 millicuries in a readily dispersible form 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 of \$150,000 using one of the methods described in 420-3-26-.02(26) (h) .

(g) 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)(h), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. 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)(h).

(h) Financial assurance for decommissioning must be provided by one 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 funds, 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 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 ~~420-3-26-02(26)~~. 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 A 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 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)(h)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.
- (i) 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 license site is terminated 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 of relevant information 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 a 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(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 contaminate decontaminate the area to meet the criteria for decommissioning in 420-3-26-.03(60) ~~unrestricted release~~ levels 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 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, Division 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.

Records, Inspections, Tests, and Reports Reporting Requirements

(29) Reporting Requirements.

- (a) **Immediate Report.** Each licensee shall notify the Agency as soon as possible but no later than 24 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(11). 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 by 420-3-26-.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.1.

Author: Kirksey E. Whatley, Director, ~~Division~~ Office of Radiation Control, Bureau of Health Care Standards, 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 Repromulgated 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 effective (effective date of these rules)

NOTE:

**Pages 88 through 101 contain
tables. There are no changes on these
pages.**

**These pages will remain a part of the
rules.**

APPENDIX A

Criteria Relating to Use of Financial Tests and Self-Guarantees 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 ~~furnishing its own~~ 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 for the self guarantee and establishes the terms for ~~a self-guarantee~~ obtaining the parent company guarantee.

II. Financial Test:

To pass the financial test, ~~a the parent company~~ must meet ~~all of the following the~~ criteria of either paragraph 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

~~(1)(ii)~~ Tangible net worth at least ~~10~~ 6 times the total current decommissioning cost estimates for the total of all facilities or parts thereof (or the current prescribed amount required if a certification is used); and all decommissioning activities for which the company is responsible for as self-guaranteeing licensee and as parent-guarantor.

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

~~(2)(iv)~~ Assets located in the United States amounting to at least 90 percent of the total assets or at least ~~10~~ 6 times the total current decommissioning cost estimates for all facilities or parts thereof (or the current prescribed 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 current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.~~

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

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

~~(2)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.

~~(3)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.

~~C. 2.~~ If the licensee parent company no longer meets the requirements of Section H. 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 Self-Guarantee:

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

- A. The parent company guarantee will remain in force unless the guarantor 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 both the licensee and the Agency, as evidenced by the return receipt.
- B. If the The licensee shall 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.
- D. 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.
- E. 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.

- F. 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 on 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 alternative 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.

PROPOSED RULE CHANGES TO RULE 420-3-26-.03

"STANDARDS FOR PROTECTION AGAINST RADIATION"

RATIONALE FOR CHANGES

Page	ARCR Reference	NRC Reference	Rationale
1	420-3-26.03(2)	20.1001	Clarifies that exposure limits do not include exposures received from patients administered radioactive material and released from confinement. NRC compatibility issue.
2	420-3-26-.03(3)(h)	20.1003	Expands the definition of background radiation to include radiation from nuclear accidents such as Chernobyl.
2	420-3-26-.03(3)(i)	20.1003	Corrects definition of "bioassay".
3	420-3-26-.03(3)(n)1.	20.1003	Adds the definition of "constraint". NRC compatibility issue.
3	420-3-26-.03(3)(o)1.	20.1003	Adds definition of "critical group". NRC compatibility issue.
3	420-3-26-.03(3)(o)	20.1003	Changes the definition to require that a written declaration be given to the licensee rather than the employer, unless the employer is also the licensee. NRC compatibility issue.
3	420-3-26-.03(3)(p)1.	20.1003	Adds the definition of "decommission". NRC compatibility issue.
4	420-3-26-.03(3)(s)1.	20.1003	Adds the definition of "distinguishable from background". NRC compatibility issue.
4	420-3-26-.03(3)(z)	20.1003	The term "eye equivalent" is changed to "lens equivalent". NRC compatibility issue.

4	420-3-26-.03(3)(aa)	20.1003	Definition is revised to clarify that "high radiation area" results from radiation sources external to the body. NRC compatibility issue.
5	420-3-26-.03(3)(dd)	20.1003	Definition changed to include "individual monitoring equipment" and the word "thermoluminescent" is changed to "thermoluminescence".
6	420-3-26-.03(3)(qq)	20.1003	Change clarifies that occupational dose not include exposure from patients administered radioactive material and released from confinement. NRC compatibility issue.
6	420-3-26-.03(3)(tt)	20.1003	Change clarifies that public dose not include exposure from patients administered radioactive material and released from confinement. NRC compatibility issue.
7 & 8	420-3-26-.03(3)(yy)	20.1003	Currently there are two definitions of "reference man" in the Rule. The definition, as listed in 420-3-26-.03(3)(yy) is deleted and the definition as listed in 420-3-26-.03(3)(zz), which is the current NRC definition, is retained..
8	420-3-26-.03(3)(aaa)1.	20.1003	Adds the definition of "residual radioactivity". NRC compatibility issue.
9	420-3-26-.03(3)(iii)	20.1003	Change clarifies that very high radiation area involves sources external to the body. NRC compatibility issue.
10	420-3-26-.03(3)(ppp)	20.1003	Adds definition of "lens dose equivalent". NRC compatibility issue.
11	420-3-26-.03(5)(b)	20.1101(b)	Change the word "practicable" to "practical".
11	420-3-26-.03(5)(d)	20.1101(d)	Adds conditions for implementing ALARA with respect to air emissions. Radon-222 and all daughters produced after the release of the radon are excluded from this rule.
12	420-3-26-.03(6)(a)2.(i) and (c)1.	20.1201(c)	Changes the word "eye" to "lens". NRC compatibility issue.
12	420-3-26-.03(6)(d)	20.1201	Reference to rule 420-3-26-.03(46) is appropriately repositioned within the body of the text.

16	420-3-26-.03(9)(h)2.	NA	Change corrects reference to rule "420-3-26-.03(6)(a)1.(i)" to the proper reference, "420-3-26-.03(6)(a)1.(ii).
18	420-3-26-.03(11)(a)	20.1206(a)	Revised to clarify what is intended by the term "higher exposure" as used in the current rule.
19	420-3-26-.03(13)	20.1208	Change adds the word "equivalent" (dose equivalent) to the title. NRC compatibility issue.
19	420-3-26-.03(13)(a), (c), (c)2., and (d)	20.1208(a), (c), (c)(2), and (d)	The phrase, "dose to the embryo/fetus" is changed to "dose equivalent to the embryo/fetus" to make clear that it applies to dose equivalent. NRC compatibility issue.
20	420-3-26-.03(14)(a)1. and 2.	20.1301(a)	Changed to state that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released from confinement in accordance with the rules. Exclusion of dose from background radiation and voluntary participation in medical research is added. NRC compatibility issue.
24	420-3-26-.03(17)(a)2.(i) and (iii)	20.1501	Revised for clarification. NRC compatibility issue.
24&25	420-3-26-.03(18)(a)2., 3., and 4.	20.1502	Monitoring requirements for minors and pregnant women are revised. For minors the dose limits apply for an entire year. For a declared pregnant woman, the dose limit applies only for the 9-month gestation period. Monitoring requirement for declared pregnant woman is added. Numbering is adjusted. NRC compatibility issue.
27	420-3-26-.03(19)(g)	NA	The word "licensees" is deleted as the rule applies only to registrants. Sentence added to emphasize that the rule applies only when machines are not activated.
35	420-3-26-.03(29)(b)	NA	Corrects a reference error The reference to 420-3-26-.07(27) is corrected to read 420-3-26-.07(29).
40 & 41	420-3-26-.03(38)	20.2006	Appendix D has previously been replaced by Appendix G is no longer needed. Reference to Appendix is therefore removed.

41 &42	420-3-26-.03(40)	20.2101	Permits licensees to add SI units to special units and replaces "eye dose equivalent" with "lens dose equivalent". NRC compatibility issue.
44	420-3-26-.03(46)(a)4.	20.2106	Rule is revised by adding references that require licensees to take certain measurements that are specified. NRC compatibility issue.
48	420-3-26-.03(53)	20.2203	The word "constraint" is added to the title.
49	420-3-26-.03(53)(a)2.(vi)	20.2203(a)(2)(vi)	Rule added to clarify that constraint applies only to release of airborne effluents to the environment and thus, dose to the nearest resident, offsite business or school, is to be constrained. NRC compatibility issue.
49	420-3-26-.03(53)(b)1.(iv)	20.2203(b)(1)(iv)	Rule is added to include ALARA constraints. NRC compatibility issue.
50	420-3-26-.03(53)(b)2.	20.2203(b)(2)	Rule is revised to require the name, social security number, and date of birth only for occupationally overexposed individuals and not for members of the public who have received doses in excess of the public limits, including the constraint. NRC compatibility issue.
51 & 52	420-3-26-.03(59)	20.1401	Provides criteria that applies to decommissioning of facilities licensed under Rule 420-3.26-.02, "Licensing". NRC compatibility issue.
52	420-3-26-.03(60)	20.1402	Describes the criteria under which a site will be considered acceptable for unrestricted use so the license can be terminated. The principal criteria is that the residual radioactivity that is distinguishable from background radiation does not result in a TEDE to an average member of the critical group in excess of 25 mrem(.025 mSV) per year. NRC compatibility issue.
52, 53, & 54	420-3-26-.03(61)	20.1403	Describes the criteria under which a site will be considered for restricted use so the license can be terminated. The criteria include ALARA considerations, legally enforceable institutional controls, sufficient financial assurance, and submission of a decommissioning plan. NRC compatibility issue.

54 & 55	420-3-26-.03(62)	20.1404	Provides alternate criteria for a licensee, greater than those cited in 420-3-26-.03(60) and (61), for the Agency to terminate a license. NRC compatibility issue.
55 & 56	420-3-26-.03(63)	20.1405	Describes Agency actions pursuant to the receipt of a decommissioning pla, such as notification and solicitation of comments from local and State agencies, the publication of notices, and soliciting comments from affected parties. NRC compatibility issue.
56	420-3-26-.03(64)	20.1406	Requires applicants to describe, through design and operation, to minimize contamination of the facility and the environment and the generation of radioactive waste. NRC compatibility issue.
281 thru 284	Appendix D to Rule 420-3-26-.03	NA	Appendix D is an obsolete rule having been replaced with Appendix C in prior rule revision. The rule is being removed from the rules to avoid confusion. Appendix D has remained in the rules for a specified period of time as licensees could use either appendix. Now, however, Appendix D is no longer valid.

STANDARDS FOR PROTECTION AGAINST RADIATION "Amended"

GENERAL PROVISIONS

(1) Purpose.

- (a) This Rule, 420-3-26-.03, establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These rules are issued pursuant to Act No. 582, Regular Session, 1963, as amended.
- (b) The requirements of this Rule are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this Rule. However, nothing in this Rule shall be construed as limiting actions that may be necessary to protect health and safety.

- (2) **Scope.** Except as specifically provided in other parts of these rules, this Rule applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this Rule do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 420-3-26-.07(29), or to voluntary participation in medical research programs.

(3) Definitions. As used in this Rule:

- (a) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).
- (b) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).
- (c) "Adult" means an individual 18 or more years of age.
- (d) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
- (e) "Airborne radioactivity area" means a room, enclosure, or area in which airborne

radioactive materials, composed wholly or partly of licensed material, exist in concentrations:

1. In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of this Rule.
2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours the individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

- (f) "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits 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 the 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 interests.
- (g) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.
- (h) "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, or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency.
- (i) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, quantities the location 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.
- (j) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or

Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

- (k) "Collective dose" is 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.
- (l) "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.
- (m) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).
- (n)1. "Constraint (dose commitment)" means a value above which specified licensee actions are required.
- (n) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.
- (o)1. "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.
- (o) "Declared pregnant woman" means a woman who has voluntarily informed her employer the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.
- (p)1. "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits (1) release of the property for unrestricted use and termination of the license or (2) release of the property under restricted conditions and termination of the license.
- (p) "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm. (1000 mg/cm²).
- (q) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

- (r) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).
- (s)1. "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.
- (s) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.
- (t) "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).
- (u) "Embryo/fetus" means the developing human organism from conception until the time of birth.
- (v) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials or machines which produce radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.
- (w) "Exposure" means being exposed to ionizing radiation or to radioactive material.
- (x) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.
- (y) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.
- (z) "Eye Lens dose equivalent" (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).
- (aa) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

- (bb) "Individual" means any human being.
- (cc) "Individual monitoring" means:
1. The assessment of dose equivalent by the use of devices designed to be worn by an individual;
 2. The assessment of committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or
 3. The assessment of dose equivalent by the use of survey data.
- (dd) "Individual monitoring devices" (individual monitoring equipment) 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 thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.
- (ee) "Inhalation class" [see "Class"].
- (ff) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
- (gg) "License" means a license issued by the Agency in accordance with the rules adopted by the Agency
- (hh) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Agency.
- (ii) "Licensee" means any person who is licensed by the Agency in accordance with the rules and the Act.
- (jj) "Limits (dose limits)" means the permissible upper bounds of radiation doses.
- (kk) "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 source that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.
- (ll) "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.

- (mm) "Minor" means an individual less than 18 years of age.
- (oo) "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.
- (pp) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.
- (qq) "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 exposure to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), from voluntary participation in medical research programs, or as a member of the public.
- (rr) "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. 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.
- (ss) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.
- (tt) "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, from exposure to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), or dose from voluntary participation in medical research programs.
- (uu) "Quality factor" means the modifying factor listed in the table below that is used to derive dose equivalent from absorbed dose:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

<u>TYPE OF RADIATION</u>	<u>Quality Factor (Q)</u>	<u>Absorbed Dose Equal to a Unit Dose Equivalent*</u>
X, gamma, or beta radiation and high-speed electrons	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

*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

- (vv) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.
- (ww) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.
- (xx) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (5 millirem) (0.05 Msv) in one hour at 30 centimeters from the radiation source or from the surface that the radiation penetrates.
- ~~(yy) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."~~
- ~~(yy) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize~~

results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

- (zz) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.
- (aaa)1. "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources, used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of this rule.
- (aaa) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
- (bbb) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.
- (ccc) "Shallow-dose equivalent (H_s), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of one square centimeter.
- (ddd) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.
- (eee) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, "probabilistic effect" is an equivalent term.
- (fff) "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 materials present.

- (ggg) "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).
- (hhh) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.
- (iii) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rad (5 Grays) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.¹
- (iii) "Week" means 7 consecutive days starting on Sunday.
- (kkk) "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

^b For the purpose of weighting the external whole body dose, for adding it to the

¹ At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

- (III) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.
 - (mmm) "Working level (WL)" is any combination of short lived radon daughters in one 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.
 - (nnn) "Working level month (WLM)" means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year equals approximately 170 hours per month).
 - (ooo) "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.
 - (ppp) "Lens dose equivalent" LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm^2).
- (4) **Implementation.**
- (a) Any existing license or registration condition that is more restrictive than this Rule remains in force until there is an amendment or renewal of the license or registration.
 - (b) If a license or registration condition exempts a licensee or registrant from a provision of this Rule in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this Rule.
 - (c) If a license or registration condition cites provisions of this Rule in effect prior to January 1, 1994, which do not correspond to any provisions of this Rule, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

(5) Radiation Protection Programs.

- (a) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this Rule. See 420-3-26-.03(41) for recordkeeping requirements relating to these programs.
- (b) The licensee or registrant shall use, to the extent practicable practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).
- (c) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.
- (d) To implement the ALARA requirements of 420-3-26-.03(5)(b) and notwithstanding the requirements of 420-3-26-.03(14), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and daughters of radon, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 millirem (0.1 mSv) per year from those emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall file a report with the Agency as provided by 420-3-26-.03(53) and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

(6) Occupational Dose Limits for Adults.

- (a) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 420-3-26-.03(11), to the following dose limits:
 - 1. An annual limit, which is the more limiting of:
 - (i) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or
 - (ii) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).
 - 2. The annual limits to the lens of the eye, to the skin, and to the extremities which are:

- (i) ~~An eye~~ A lens dose equivalent of 0.15 Sv (15 rem), and
 - (ii) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.
- (b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 420-3-26-.03(11)(e)1. and 2.
- (c) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:
 - 1. The deep dose equivalent, eye lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or
 - 2. When a protective apron is worn and monitoring is conducted as specified in 420-3-26-.03(18)(c), the effective dose equivalent for external radiation shall be determined as follows:
 - (i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in 420-3-26-.03(6)(a), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or
 - (ii) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.
- (d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose (see 420-3-26-.03(46)) and to demonstrate compliance with the occupational dose limits. See ~~420-3-26-.03(46)~~.
- (e) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium

intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

- (f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 420-3-26-.03(10)(e).

(7) Compliance with Requirements for Summation of External and Internal Doses.

- (a) If the licensee or registrant is required to monitor pursuant to both 420-3-26-.03(18)(a) and (b), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 420-3-26-.03(18)(a) or only pursuant to 420-3-26-.03(18)(b), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 420-3-26-.03(7)(b),(c), and (d). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.
- (b) **Intake by Inhalation.** If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:
 - 1. The sum of the fractions of the inhalation ALI for each radionuclide, or
 - 2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
 - 3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factor, w_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} (i.e. $w_T H_{T,50}$ per unit intake for any organ or tissue).
- (c) **Intake by Oral Ingestion.** If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.
- (d) **Intake through Wounds or Absorption through Skin.** The licensee shall evaluate

and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to 420-3-26-.03(7)(d).

(8) Determination of External Dose from Airborne Radioactive Material.

- (a) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.
- (b) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(9) Determination of Internal Exposure.

- (a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 420-3-26-.03(18), take suitable and timely measurements of:
 - 1. Concentrations of radioactive materials in air in work areas; or
 - 2. Quantities of radionuclides in the body; or
 - 3. Quantities of radionuclides excreted from the body; or
 - 4. Combinations of these measurements.
- (b) Unless respiratory protective equipment is used, as provided in 420-3-26-.03(24), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.
- (c) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:
 - 1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;

and

2. Upon prior approval of the Agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
 3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.
- (d) If the licensee chooses to assess intakes of Class Y material using the measurements given in 420-3-26-.03(9)(a)2. and 3., the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by 420-3-26-.03(52) or 420-3-26-.03(53). This delay permits the licensee to make additional measurements basic to the assessments.
- (e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:
1. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or
 2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.
- (f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
- (g) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:
1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 420-3-26-.03(6) and in complying with the monitoring requirements in 420-3-26-.03(17)(b) and (c), and
 2. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and
 3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.
- (h) When determining the committed effective dose equivalent, the following information

may be considered:

1. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
2. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in ~~420-3-26-.03(6)(a)1.(i)~~ 420-3-26-.03(6)(a)1.(ii) is met.

(10) Determination of Prior Occupational Dose.

- (a) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 420-3-26-.03(18), the licensee or registrant shall:
 1. Determine the occupational radiation dose received during the current year; and
 2. Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- (b) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
 1. The internal and external doses from all previous planned special exposures; and
 2. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and
 3. All lifetime cumulative occupational radiation dose.
- (c) In complying with the requirements of 420-3-26-.03(10)(a), a licensee or registrant may:
 1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual

received during the current year; and

2. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form Y or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and
 3. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
- (d)
1. The licensee or registrant shall record the exposure history as required by 420-3-26-.03(10)(a), on Agency Form Y, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Agency Form Y or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form Y or equivalent indicating the periods of time for which data are not available.
 2. Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this Rule in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on Agency Form Y or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.
- (e)
- If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:
1. In establishing administrative controls pursuant to 420-3-26-.03(6)(f) for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

2. That the individual is not available for planned special exposures.
- (f) The licensee or registrant shall retain the records on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.
- (11) **Planned Special Exposures.** A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 420-3-26-.03(6) provided that each of the following conditions is satisfied:
- (a) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure dose estimated to result from the planned special exposure are unavailable or impractical.
 - (b) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.
 - (c) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:
 1. Informed of the purpose of the planned operation; and
 2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
 3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.
 - (d) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 420-3-26-.03(6)(b) during the lifetime of the individual for each individual involved.
 - (e) Subject to 420-3-26-.03(6)(b), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:
 1. The numerical values of any of the dose limits in 420-3-26-.03(6)(a) in any year; and
 2. Five times the annual dose limits in 420-3-26-.03(6)(a) during the individual's lifetime.

- (f) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 420-3-26-.03(45) and submits a written report in accordance with 420-3-26-.03(54).
 - (g) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 420-3-26-.03(6)(a) but shall be included in evaluations required by 420-3-26-.03(11)(d) and (e).
- (12) **Occupational Dose Limits for Minors.** The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 420-3-26-.03(6).
- (13) **Dose Equivalent to an Embryo/Fetus.**
- (a) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See 420-3-26-.03(46) for recordkeeping requirements.
 - (b) The licensee or registrant shall make efforts to avoid substantial variation* above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 420-3-26-.03(13)(a).
 - (c) The dose equivalent to an embryo/fetus shall be taken as the sum of:
 - 1. The deep dose equivalent to the declared pregnant woman; and
 - 2. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
 - (d) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with 420-3-26-.03(13)(a) if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

*The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

(14) Dose Limits for Individual Members of the Public.

- (a) Each licensee or registrant shall conduct operations so that:
 - 1. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposures to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 420-3-26-.03(35),** and
 - 2. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 420-3-26-.07(29), does not exceed 0.02 mSv (0.002 rem) in any one hour.
- (b) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.
- (c) A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:
 - 1. Demonstration of the need for and the expected duration of operations in excess of the limit in 420-3-26-.03(14)(a); and
 - 2. The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and
 - 3. The procedures to be followed to maintain the dose ALARA.
- (d) In addition to the requirements of this Rule, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

**Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994 and met the previous requirements of 5 mSv (0.5 rem) in a year.

- (e) The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

(15) Compliance with Dose Limits for Individual Members of the Public.

- (a) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 420-3-26-.03(14).
- (b) A licensee or registrant shall show compliance with the annual dose limit in 420-3-26-.03(14) by:
 - 1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
 - 2. Demonstrating that:
 - (i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and
 - (ii) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.
- (c) Upon approval from the Agency, the licensee may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

(16) Testing for Leakage or Contamination of Sealed Sources.

- (a) The licensee in possession of any sealed source shall assure that:
 - 1. Each sealed source, except as specified in 420-3-26-.03(16)(b), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee.

2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.
 3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.
 4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee shall assure that the sealed source is tested for leakage or contamination before further use.
 5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.
 6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μ Ci) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.
 7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of a radium daughter which has a half-life greater than 4 days.
- (b) A licensee need not perform test for leakage or contamination on the following sealed sources:
1. Sealed sources containing only radioactive material with a half-life of less than 30 days;
 2. Sealed sources containing only radioactive material as a gas;
 3. Sealed sources containing 3.7 MBq (100 μ Ci) or less of beta or photon-emitting material or 370 kBq (10 μ Ci) or less of alpha-emitting material;

4. Sealed sources containing only hydrogen-3;
 5. Seeds of iridium-192 encased in nylon ribbon; and
 6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.
- (c) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.
- (d) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.
- (e) The following shall be considered evidence that a sealed source is leaking:
1. The presence of 185 Bq (0.005 μ Ci) or more of removable contamination on any test sample.
 2. Leakage of 37 Bq (0.001 μ Ci) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.
 3. The presence of removable contamination resulting from the decay of 185 Bq (0.005 μ Ci) or more of radium.
- (f) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Rule.
- (g) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 420-3-26-.03(58).

SURVEYS AND MONITORING

(17) General.

- (a) Each licensee or registrant shall make, or cause to be made, surveys that:
1. Are necessary for the licensee or registrant to comply with this Rule; and

2. Are necessary under the circumstances to evaluate:
 - (i) The magnitude and extent of Rradiation levels; and
 - (ii) Concentrations or quantities of radioactive material; and
 - (iii) The potential radiological hazards ~~that could be present.~~
 - (b) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.
 - (c) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 420-3-26-.03(6), with other applicable provisions of these, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:
 1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
 2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
 - (d) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.
- (18) Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.**

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this Rule. As a minimum:

- (a) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
 1. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 420-3-26-.03(6)(a); and
 2. Minors and ~~declared pregnant women~~ likely to receive, in 1 year from radiation

sources external to the body, a deep dose equivalent in excess of ~~10 percent of any of the applicable limits in 420-3-26-.03(12) or 420-3-26-.03(13)~~ 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the ~~skin~~ skin or to the extremities in excess of 0.5 rem (5 mSv); and

3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

~~3.(4)~~ Individuals entering a high or very high radiation area.

4. ~~Reserved.~~

- (b) Each licensee shall monitor, to determine compliance with 420-3-26-.03(9), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

1. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
2. Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

- (c) For individuals working with medical fluoroscopic equipment:

1. An individual monitoring device used to determine the dose to an embryo/fetus of a declared pregnant woman, pursuant to 420-3-26-.03(18)(a)2., shall be located under the protective apron at the waist. (Note: It is recognized that, in the specific work environment of medical fluoroscopic equipment, the dose to the embryo/fetus is overestimated by the individual monitoring device because of the overlying tissue of the pregnant individual. A certified expert, such as a medical physicist who is certified by the American Board of Radiology in Diagnostic Radiological Physics or in Radiological Physics should be consulted to determine the dose to the embryo/fetus for the occasions in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). Therefore, for purposes of these rules, the value to be used for determining the dose to the embryo/fetus pursuant to 420-3-26-.03(13), for occupational exposure to radiation from medical fluoroscopic equipment may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by a qualified expert.)
2. An individual monitoring device used for eye dose equivalent shall be located

at the neck, or an unshielded location closer to the eye, outside the protective apron.

3. When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 420-3-26-.03(6)(C)2., it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. (Note: The second individual monitoring device is required for a declared pregnant woman.)

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

(19) Control of Access to High Radiation Areas.

- (a) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:
 1. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or
 2. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
 3. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.
- (b) In place of the controls required by 420-3-26-.03(19)(a) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.
- (c) The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.
- (d) The licensee or registrant shall establish the controls required by 420-3-26-.03(19)(a) and (c) in a way that does not prevent individuals from leaving a high radiation area.
- (e) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

1. The packages do not remain in the area longer than 3 days; and
 2. The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.
- (f) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that personnel are in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this Rule and to operate within the ALARA provisions of the licensee's radiation protection program.
- (g) ~~The licensee or A~~ registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 420-3-26-.06 for x-rays in the healing arts, and 420-3-26-.09 for particle accelerators. Entrance or access to rooms is required to be controlled when equipment is in operation.

(20) Control of Access to Very High Radiation Areas.

- (a) In addition to the requirements in 420-3-26-.03(19), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.
- (b) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 420-3-26-.03(20)(a) if the registrant has met all the specific requirements for access and control specified in other applicable rules, such as, 420-3-26-.04 for industrial radiography, 420-3-26-.06 for x rays in the healing arts, and 420-3-26-.09 for particle accelerators.

(21) Control of Access to Very High Radiation Areas -- Irradiators.

- (a) This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

- (b) Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:
1. Each entrance or access point shall be equipped with entry control devices which:
 - (i) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and
 - (ii) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
 - (iii) Prevent operation of the source of radiation if it would produce radiation levels in the area that would result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.
 2. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 420-3-26-.03(21)(b)1.:
 - (i) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
 - (ii) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.
 3. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:
 - (i) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
 - (ii) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or

registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

4. When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.
5. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 420-3-26-.03(21)(b)3. and 4.
6. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.
7. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.
8. Each area shall be checked by a radiation measurement to ensure, that prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.
9. The entry control devices required in 420-3-26-.03(21)(b)1. shall be tested for proper functioning. See 420-3-26-.03(49) for recordkeeping requirements.
 - (i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and
 - (ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and
 - (iii) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.
10. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs

on controls, unless control devices are functioning properly.

11. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.
- (c) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 420-3-26-.03(21)(b) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 420-3-26-.03(21)(b), such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 420-3-26-.03(21)(b). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.
- (d) The entry control devices required by 420-3-26-.03(21)(b) and (c) shall be established in such a way that no individual will be prevented from leaving the area.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

- (22) **Use of Process or Other Engineering Controls.** The licensee shall use, to the extent practicable, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.
- (23) **Use of Other Controls.** When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:
 - (a) Control of access; or
 - (b) Limitation of exposure times; or

(c) Use of respiratory protection equipment; or

(d) Other controls.

(24) Use of Individual Respiratory Protection Equipment.

(a) If the licensee uses respiratory protection equipment to limit intakes pursuant to 420-3-26-.03(23):

1. Except as provided in 420-3-26-.03(24)(a)2., the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.
2. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.
3. The licensee shall implement and maintain a respiratory protection program that includes:
 - (i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and
 - (ii) Surveys and bioassays, as appropriate, to evaluate actual intakes; and
 - (iii) Testing of respirators for operability immediately prior to each use; and
 - (iv) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and
 - (v) Determination by a physician prior to initial fitting of respirators, and every 12 months thereafter, that the individual user is medically fit to use the respiratory protection equipment.

4. The licensee shall issue a written policy statement on respirator usage covering:
 - (i) The use of process or other engineering controls, instead of respirators; and
 - (ii) The routine, nonroutine, and emergency use of respirators; and
 - (iii) The length of periods of respirator use and relief from respirator use.
 5. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
 6. The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.
- (b) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 420-3-26-.03(23), provided that the following conditions, in addition to those in 420-3-26-.03(24)(a), are satisfied:
1. The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in 420-3-26-.03(23) of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.
 2. The licensee shall obtain authorization from the Agency before assigning respiratory protection factors in excess of those specified in Appendix A. The Agency may authorize a licensee to use higher protection factors on receipt of

an application that:

- (i) Describes the situation for which a need exists for higher protection factors, and
 - (ii) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.
- (c) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.
- (d) The licensee shall notify the Agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 420-3-26-.03(24)(a) or (b).

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

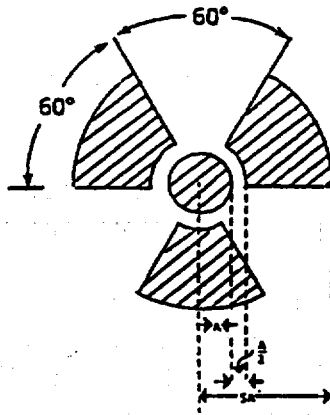
- (25) **Security of Stored Sources of Radiation.** The licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in controlled or unrestricted areas.
- (26) **Control of Sources of Radiation not in Storage.**
- (a) The licensee shall control and maintain constant surveillance of licensed radioactive material that is in a controlled or unrestricted area and that is not in storage or in a patient.
 - (b) The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

PRECAUTIONARY PROCEDURES

- (27) **Caution Signs.**
- (a) **Standard Radiation Symbol.** Unless otherwise authorized by the Agency, the symbol prescribed by 420-3-26-.03(27) shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



- (b) **Exception to Color Requirements for Standard Radiation Symbol.** Notwithstanding the requirements of 420-3-26-.03(27)(a), licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.
- (c) **Additional Information on Signs and Labels.** In addition to the contents of signs and labels prescribed in this Rule, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(28) Posting Requirements.

- (a) **Posting of Radiation Areas.** The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."
- (b) **Posting of High Radiation Areas.** The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."
- (c) **Posting of Very High Radiation Areas.** The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA." For each very high radiation area, created in a medical institution by the use of a registered medical particle accelerator, the word "Danger" may be substituted for the words "GRAVE DANGER".
- (d) **Posting of Airborne Radioactivity Areas.** The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

- (e) **Posting of Areas or Rooms in Which Licensed Radioactive Material is Used or Stored.** The licensee shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

(29) Exceptions to Posting Requirements.

- (a) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:
 - 1. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Rule; and
 - 2. The area or room is subject to the licensee's or registrant's control.
- (b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 420-3-26-.03(28) provided that the patient could be released from confinement pursuant to ~~420-3-26-.07(27)~~ 420-3-26-.07(29) of these rules.
- (c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.
- (d) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

(30) Labeling Containers and Radiation Machines.

- (a) The licensee shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.
- (b) Each licensee, prior to removal or disposal of empty uncontaminated containers to

unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

- (c) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

(31) Exemptions to Labeling Requirements. A licensee is not required to label:

- (a) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or
- (b) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or
- (c) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Rule; or
- (d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation;** or
- (e) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- (f) Installed manufacturing or process equipment, such as piping and tanks.

(32) Procedures for Receiving and Opening Packages.

- (a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 420-3-26-.03(32)(b) of these rules shall make arrangements to receive:
 - 1. The package when the carrier offers it for delivery; or
 - 2. The notification of the arrival of the package at the carrier's terminal and to take

**Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

possession of the package expeditiously.

(b) Each licensee shall:

1. Monitor the external surfaces of a labeled^{***} package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 420-3-26-.01(2)(a)103 of these rules; and
2. Monitor the external surfaces of a labeled³ package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity as defined in 420-3-26-.03(32)(b) of these rules; and
3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

Table of Exempt and Type A Quantities

Exempt Quantity Limit (in millicuries)	Type A Quantity Limit (in curies)
$A^{****}_2 \times 0.001$	A_2

- (c) The licensee shall perform the monitoring required by 420-3-26-.03(32)(b) as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.
- (d) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:
1. Removable radioactive surface contamination that exceeds 0.01 microcurie (22,200 disintegrations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package; or
 2. Radiation levels are found on the external surface of the package in excess of

^{***}Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

^{****} These quantities are defined as determined in 10 CFR Part 71, Appendix A. See footnote 3 on page 8.

200 millirem per hour, or at three feet from the external surfaces of the package in excess of 10 millirem per hour.

- (e) Each licensee shall:
 - 1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
 - 2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.
- (f) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 420-3-26-.03(32)(b), but are not exempt from the monitoring requirement in 420-3-26-.03(32)(b) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

(33) General Requirements.

- (a) A licensee shall dispose of licensed or registered material only:
 - 1. By transfer to an authorized recipient as provided in 420-3-26-.03(38) of these rules, or to the U.S. Department of Energy; or
 - 2. By decay in storage; or
 - 3. By release in effluents within the limits in 420-3-26-.03(14); or
 - 4. As authorized pursuant to 420-3-26-.03(34), 420-3-26-.3(35), 420-3-26-.03(36), or 420-3-26-.03(37).
- (b) A person shall be specifically licensed to receive waste containing licensed material from other persons for:
 - 1. Treatment prior to disposal; or
 - 2. Treatment or disposal by incineration; or
 - 3. Decay in storage; or
 - 4. Disposal at a land disposal facility licensed pursuant to 420-3-26-.02(10)(p) of these rules; or

5. Storage until transferred to a storage or disposal facility authorized to receive the waste.

(34) **Method for Obtaining Approval of Proposed Disposal Procedures.** A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed material generated in the licensee's operations. Each application shall include:

- (a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and
- (b) An analysis and evaluation of pertinent information on the nature of the environment; and
- (c) The nature and location of other potentially affected facilities; and
- (d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Rule.

(35) **Disposal by Release into Sanitary Sewerage.**

- (a) A licensee may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:
 1. The material is readily soluble, or is readily dispersible biological material, in water; and
 2. The quantity of licensed or registered radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and
 3. If more than one radionuclide is released, the following conditions must also be satisfied:
 - (i) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and
 - (ii) The sum of the fractions for each radionuclide required by 420-3-26-.03(35)(a)3.(i) does not exceed unity; and

4. The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.
- (b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 420-3-26-.03(35)(a).
- (36) **Treatment or Disposal by Incineration.** A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in 420-3-26-.03(37) or as specifically approved by the Agency pursuant to 420-3-26-.03(34).
- (37) **Disposal of Specific Wastes.**
 - (a) A licensee may dispose of the following licensed material as if it were not radioactive:
 1. 1.85 kBq (0.05 μ Ci), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and
 2. 1.85 kBq (0.05 μ Ci), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.
 - (b) A licensee shall not dispose of tissue pursuant to 420-3-26-.03(37)(a)2. in a manner that would permit its use either as food for humans or as animal feed.
 - (c) The licensee shall maintain records in accordance with 420-3-26-.03(48).
- (38) **Transfer for Disposal and Manifests**
 - (a) ~~†~~The requirements of this section and Appendices ~~D~~ and Appendix G to this rule, 420-3-26-.03, are designed to:
 - (i)1. Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this rule, who ships low-level radioactive waste either directly, or indirectly through a waste collector or waste processor, to a low-level waste land disposal facility;
 - (ii)2. Establish a manifest tracking system; and
 - (iii)3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

- ~~2. Beginning March 1, 1998, all affected licensees must use Appendix G. Prior to March 1, 1998, a LLW disposal facility operator or its regulatory authority may require the shipper to use Appendix D or Appendix G. Licensees using Appendix D shall comply with paragraph (b)1. Of this section. Licensees using Appendix G shall comply with paragraph (b)2. of this section.~~
- (b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G of this rule.
- ~~(b) 1. Each shipment of radioactive waste intended for disposal at a licensed land disposal facility must be accompanied by a shipment manifest in accordance with section I of Appendix D to this rule.~~
- ~~2. Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to this rule.~~
- (c) Each shipment manifest must include a certification by the waste generator as specified in section II of ~~Appendix D or Appendix G~~ to this rule, as appropriate. ~~See paragraph (a)2. of this section to determine the appropriate appendix.~~
- (d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of ~~Appendix D or Appendix G~~ to this rule, as appropriate. ~~See paragraph (a)2. of this section to determine the appropriate appendix.~~
- (39) **Compliance with Environmental and Health Protection Regulations.** Nothing in 420-3-26-.03(33), 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), or 420-3-26-.03(38) relieves the licensee from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 420-3-26-.03(33), 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), or 420-3-26-.03(38).

RECORDS

(40) General Provisions.

- (a) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and

subdivisions, and shall clearly indicate the units of all quantities on records required by this Rule.

(b) In the records required by this rule, the licensee may record quantities in SI units in parentheses following each of the units specified in 420-3-26-.03(40)(a) of this rule. However, all quantities must be recorded as stated in rule 420-3-26-.03(40)(a) of this rule.

(c) Notwithstanding requirements of rule 420-3-26-.03(40)(a), when recording information on shipment manifests, as required by rule 420-3-26-.03(38)(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in rule 420-3-26-.03(40)(a).

(b)(d) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Rule, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(41) Records of Radiation Protection Programs.

(a) Each licensee or registrant shall maintain records of the radiation protection program, including:

1. The provisions of the program; and
2. Audits and other reviews of program content and implementation.

(b) The licensee or registrant shall retain the records required by 420-3-26-.03(41)(a)1. until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 420-3-26-.03(41)(a)2. for 3 years after the record is made.

(42) Records of Surveys.

(a) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 420-3-26-.03(17) and 420-3-26-.03(32)(b). The licensee or registrant shall retain these records for 3 years after the record is made.

(b) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

1. Records of the results of surveys to determine the dose from external sources

of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

2. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and
3. Records showing the results of air sampling, surveys, and bioassays required pursuant to 420-3-26-.03(24)(a)3.(i) and(ii); and
4. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

- (c) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

(43) Records of Tests for Leakage or Contamination of Sealed Sources. Records of tests for leakage or contamination of sealed sources required by 420-3-26-.03(16) shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for 5 years after the records are made.

(44) Records of Prior Occupational Dose.

- (a) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 420-3-26-.03(10) on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.
- (b) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

(45) Records of Planned Special Exposures.

- (a) For each use of the provisions of 420-3-26-.03(11) for planned special exposures, the licensee or registrant shall maintain records that describe:
 1. The exceptional circumstances requiring the use of a planned special exposure; and
 2. The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

3. What actions were necessary; and
 4. Why the actions were necessary; and
 5. What precautions were taken to assure that doses were maintained ALARA; and
 6. What individual and collective doses were expected to result; and
 7. The doses actually received in the planned special exposure.
- (b) The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.
 - (c) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.
- (46) **Records of Individual Monitoring Results.**
- (a) **Recordkeeping Requirement.** Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 420-3-26-.03(18), and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:
 1. The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
 2. The estimated intake of radionuclides. See 420-3-26-.03(7); and
 3. The committed effective dose equivalent assigned to the intake of radionuclides; and
 4. The specific information used to calculate the committed effective dose equivalent pursuant to 420-3-26-.03(9)(a) and (c); and 420-3-26-.03(18); and
 5. The total effective dose equivalent when required by 420-3-26-.03(7); and
 6. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.
 - (b) **Recordkeeping Frequency.** The licensee or registrant shall make entries of the

records specified in 420-3-26-.03(46)(a) at intervals not to exceed 1 year.

- (c) **Recordkeeping Format.** The licensee or registrant shall maintain the records specified in 420-3-26-.03(46)(a) on Agency Form Z, in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by Agency Form Z.
 - (d) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.
 - (e) The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.
 - (f) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.
- (47) **Records of Dose to Individual Members of the Public.**
- (a) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 420-3-26-.03(14).
 - (b) The licensee or registrant shall retain the records required by 420-3-26-.03(3)(48)(b) until the Agency terminates each pertinent license or registration requiring the record.
- (48) **Records of Waste Disposal.**
- (a) Each licensee shall maintain records of the disposal of licensed radioactive material made pursuant to 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), and disposal by burial in soil, including burials authorized before January 1, 1994.
 - (b) The licensee shall retain the records required by 420-3-26-.03(48)(a) until the Agency terminates each pertinent license requiring the record.
- (49) **Records of Testing Entry Control Devices for Very High Radiation Areas.**
- (a) Each licensee or registrant shall maintain records of tests made pursuant to 420-3-26-.03(21)(b)9. on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.
 - (b) The licensee or registrant shall retain the records required by 420-3-26-.03(49)(a) for

3 years after the record is made.

- (50) **Form of Records.** Each record required by this Rule shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

- (51) **Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.**

- (a) **Telephone Reports.** Each licensee or registrant shall report to the Agency by telephone as follows:

1. Immediately after its occurrence becomes known to the licensee stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or
2. Within 30 days after its occurrence becomes known to the licensee lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C that is still missing.
3. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

- (b) **Written Reports.** Each licensee or registrant required to make a report pursuant to 420-3-26-.03(51)(a) shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and,
2. A description of the circumstances under which the loss or theft occurred; and
3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and
 5. Actions that have been taken, or will be taken, to recover the source of radiation; and
 6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.
- (c) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.
 - (d) The licensee or registrant shall prepare any report filed with the Agency pursuant to 420-3-26-.03(51) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(52) Notification of Incidents.

- (a) **Immediate Notification.** Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:
 1. An individual to receive:
 - (i) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or
 - (ii) An eye dose equivalent of 0.75 Sv (75 rem) or more; or
 - (iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or
 2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- (b) **Twenty-Four Hour Notification.** Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of 24 hours:
 - (i) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
 - (ii) An eye dose equivalent exceeding 0.15 Sv (15 rem); or
 - (iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or
 2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- (c) The licensee or registrant shall prepare each report filed with the Agency pursuant to 420-3-26-.03(52) so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.
- (d) Licensees or registrants shall make the reports required by 420-3-26-.03(52)(a) and (b) to the Agency by telephone, telegram, mailgram, or facsimile to the Agency.
- (e) The provisions of 420-3-26-.03(52) do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 420-3-26-.03(54).
- (53) **Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.**
- (a) **Reportable Events.** In addition to the notification required by 420-3-26-.03(52), each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:
1. Incidents for which notification is required by 420-3-26-.03(52); or
 2. Doses in excess of any of the following:
 - (i) The occupational dose limits for adults in 420-3-26-.03(6); or
 - (ii) The occupational dose limits for a minor in 420-3-26-.03(12); or
 - (iii) The limits for an embryo/fetus of a declared pregnant woman in 420-3-26-.03(13); or

- (iv) The limits for an individual member of the public in 420-3-26-.03(14); or
 - (v) Any applicable limit in the license or registration; or
 - (vi) The ALARA constraints for air emissions established under 420-3-26-.03(5)(d).
3. Levels of radiation or concentrations of radioactive material in:
- (i) A restricted area in excess of applicable limits in the license or registration; or
 - (ii) An unrestricted area in excess of 10 times the applicable limit set forth in this Rule or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 420-3-26-.03(14); or
4. For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) Contents of Reports.

1. Each report required by 420-3-26-.03(53)(a) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
- (i) Estimates of each individual's dose; and
 - (ii) The levels of radiation and concentrations of radioactive material involved; and
 - (iii) The cause of the elevated exposures, dose rates, or concentrations; and
 - (iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints generally applicable environmental standards, and associated license or registration conditions.
2. Each report filed pursuant to 420-3-26-.03(53)(a) shall include for each

occupationally overexposed individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 420-3-26-.03(13), the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

- (c) All licensees or registrants who make reports pursuant to 420-3-26-.03(53)(a) shall submit the report in writing to the Agency.

- (54) **Reports of Planned Special Exposures.** The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with 420-3-26-.03(11), informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 420-3-26-.03(45).

- (55) [Reserved].

- (56) **Reports of Individual Monitoring.**

- (a) This section applies to each person licensed or registered by the Agency to:

1. Possess or use sources of radiation for purposes of industrial radiography pursuant to 420-3-26-.02(10)(g) and 420-3-26-.04 of these rules; or
2. Receive radioactive waste from other persons for disposal pursuant to 420-3-26-.03(10)(p) of these rules; or
3. Possess or use at any time, for processing or manufacturing for distribution pursuant to 420-3-26-.02 or 420-3-26-.07 of these rules, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity ^a	
	Ci	Gbq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000

- The Agency may require as a license condition, or by rule, or order pursuant to 420-3-26-.03(60), reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.
- (b) Each licensee or registrant in a category listed in 420-3-26-.03(56) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 420-3-26-.03(18) during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Agency Form Z or equivalent or electronic media containing all the information required by Agency Form Z.
 - (c) The licensee or registrant shall file the report required by 420-3-26-.03(56)(b), covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Agency.
- (57) **Notifications and Reports to Individuals.**
- (a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 420-3-26-.10(4) of these rules.
 - (b) When a licensee or registrant is required pursuant to 420-3-26-.03(53) to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of 420-3-26-.10(4)(a) of these rules.
- (58) **Reports of Leaking or Contaminated Sealed Sources.** The licensee shall file a report within 5 days with the Agency if the test for leakage or contamination required pursuant to 420-3-26-.03(16) indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

- ~~(59) **Vacating Premises.** Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.~~

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

- (59) **General Provisions.**

- (a) The criteria in this rule apply to the decommissioning of facilities licensed under 420-3-26-.02
 - (b) After a site has been decommissioned and the license terminated in accordance with the criteria in this rule, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of this rule were not met and residual radioactivity remaining at the site could result in a significant threat to public health and safety.
 - (c) When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.
- (60) **Radiological Criteria for Unrestricted Use.** A site will be acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 millirem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.
- (61) **Criteria for License Termination Under Restricted Conditions.** A site will be considered acceptable for license termination under restricted conditions if:
- (a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 420-3-26-.03(59) would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;
 - (b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) per year.
 - (c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:
 - 1. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in rule 420-3-26-

.02(26)(h)1:

2. Surety method, insurance, or other guarantee method as described in rule 420-3-26-.02(26)(h)2;
3. A statement of intent in the case of Federal, State, or local Government licensees, as described in rule 420-3-26-.02(26)(h)4; or
4. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with rule 420-3-26-.02(13)(m) and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

1. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:
 - (i) Whether provisions for institutional controls proposed by the licensee:
 - I. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) TEDE per year;
 - II. Will be enforceable; and
 - III. Will not impose undue burdens on the local community or other affected parties.
 - (ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;
2. In seeking advice on the issues identified in rule 420-3-26-.03(60)(d)1., the licensee shall provide for:

- (i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
 - (ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
 - (iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and
- (e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:
- 1. 100 millirem (1 mSv) per year; or
 - 2. 500 millirem (5 mSv) per year provided the licensee does the following:
 - (i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem per year (1mSv per year) value of rule 420-3-26-.03(60)(e)1. Are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;
 - (ii) Makes provisions for durable institutional controls;
 - (iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of rule 420-3-26-.03(60)(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those listed in rule 420-3-26-.03(60)(d).

(62) Alternate Criteria for License Termination.

- (a) The Agency may terminate a license using alternate criteria greater than the dose criterion listed in rules 420-3-26-.03(59), 420-3-26-.03(60)(b), and 420-3-26-.03(d)1.(a), if the licensee;

1. Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than 100 millirem per year (1mSv per year), by submitting an analysis of possible sources of exposure;
 2. Has employed to the extent practical restrictions on site use in accordance with rule 420-3-26-.03(60) in minimizing exposures at the site; and
 3. Reduces doses to ALARA levels, taking into account consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.
 4. Has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with 420-3-26-.02(13)(m), and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTO how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:
 - (i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
 - (ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
 - (iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.
- (b) The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of Agency staff recommendations that will address any comments provided by Federal and other State Agencies including comments submitted by the public.
- (63) Public Notification and Public Participation. Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee, for release of a site pursuant to 420-3-26-.03(60) or 420-3-26-.03(61), or whenever the Agency deems such notice to be in the public interest, the Agency shall:

(a) Notify and solicit comments from:

- 1. Local and State government agencies in the vicinity of the site and other individuals who could be affected by the decommissioning of the site; and**
- 2. Alabama Department of Environmental Management for cases where the licensee proposes to release a site pursuant to 420-3-26-.03(62).**

(b) Publish a notice in local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to the individuals in the vicinity of the site, and solicit comments from affected parties.

(64) Minimization of Contamination. Applicants for licenses, other than renewals, after the effective date of these rules, shall describe in the application how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, generation of radioactive waste.

Authority: §§ 22-14-4, 22-14-6, 22-14-8, and 22-14-9, Code of Alabama 1975.

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

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NOTE:

The page numbers of this Rule, 420-3-26-.03, as currently adopted, are numbered 124 through 296 (pages 1 through 123 contain requirements listed in Rules 420-3-26-.01 and 420-3-26-.02). The draft of the proposed changes is numbered pages 1 through 56, and 281 through 284. The draft was numbered in this manner for easy reference using the “rationale” statement guide.

Page numbers 180 through 266, and 271 through 296, of the current Rule are not reproduced in this document as there are no proposed changes on any of these pages. The pages, however, will be reproduced, as it currently exists, and included in the final adopted version of the Rule.

APPENDIX DREQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE
FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTSI. Manifest

~~The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than 0.1% chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in Section I of Appendix E shall be clearly identified as such in the manifest. The total quantity of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 shall be shown. The manifest required by this paragraph may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this section may be legible carbon copies or legible photocopies.~~

II. Certification

~~The waste generator shall include in the shipment manifest a certification that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the Agency. An authorized representative of the waste generator shall sign and date the manifest.~~

III. Control and Tracking

- a) ~~Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in (a)(1) through (8). Any radioactive waste generator who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of (a)(4) through (8). A licensee shall:~~
- 1) ~~Prepare all wastes so that the waste is classified according to Section I of Appendix E and meets the waste characteristics requirements in Section II of Appendix E;~~

- 5) Forward a copy of the manifest to the intended recipient, at the time of shipment, or
- 2) ~~Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Section I of Appendix E;~~
- 3) ~~Conduct a quality control program to ensure compliance with Section I and II of Appendix E; the program shall include management evaluation of audits;~~
- 4) ~~Prepare shipping manifests to meet the requirements of Section I and II;~~
- ~~deliver to a collector at the time the waste is collected; obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;~~
- 6) ~~Include one copy of the manifest with the shipment;~~
- 7) ~~Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material; and~~
- 8) ~~For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with Section III. (c).~~
- b) ~~Any waste collector licensee who handles only prepackaged waste shall.~~
- 1) ~~Acknowledge receipt of the waste from the generator within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation;~~
- 2) ~~Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in Section I. The collector licensee shall certify that nothing has been done to the waste that would invalidate the generator's certification;~~
- 3) ~~Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;~~
- 4) ~~Include the new manifest with the shipment to the disposal site;~~
- 5) ~~Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material; and retain information from generator manifest until disposition is authorized by the Agency; and~~
- 6) ~~For any shipments or any portion of a shipment for which acknowledgment of receipt is not received within the times set forth in this section, conduct an investigation in accordance with Section III. (c).~~

- ~~c) Any licensed waste processor who treats or repackages wastes shall:~~
- ~~1) Acknowledge receipt of the waste from the generator within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation;~~
 - ~~2) Prepare a new manifest that meets the requirements of Section I and H. Preparation of the new manifest reflects that the processor is responsible for the waste;~~
 - ~~3) Prepare all wastes so that the waste is classified according to Section I of Appendix E and meets the waste characteristics requirements in Section H of Appendix E;~~
 - ~~4) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Section I and III of Appendix E;~~
 - ~~5) Conduct a quality control program to ensure compliance with Section I and H of Appendix E. The program shall include management evaluation of audits;~~
 - ~~6) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;~~
 - ~~7) Include the new manifest with the shipment;~~
 - ~~8) Retain copies of original manifests and new manifests and documentation of acknowledgment of receipt as the record of transfer of licensed material; and~~
 - ~~9) For any shipment or portion of a shipment for which acknowledgment is not received within the times set forth in this section, conduct an investigation in accordance with Section III.(e).~~
- ~~d) The land disposal facility operator shall:~~
- ~~1) Acknowledge receipt of the waste within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;~~
 - ~~2) Maintain copies of all completed manifests or equivalent documentation until the Agency authorizes their disposition; and~~

- ~~3) Notify the shipper, that is, the generator, the collector, or processor, and the Agency when any shipment or portion of a shipment has not arrived within 60 days after the advance manifest was received.~~
- ~~e) Any shipment or portion of a shipment for which acknowledgment is not received within the times set forth in this section shall:~~
 - ~~1) Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer, and~~
 - ~~2) Be traced and reported to whom. The investigation shall include tracing the shipment and filing a report with the Agency. Each licensee who conducts a trace investigation shall file a written report with the Agency within 2 weeks of completion of the investigation.~~