RULES
OF
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

CHAPTER 1200-02-10
LICENSING AND REGISTRATION

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1200-02-10-.01 PURPOSE. This Chapter establishes requirements for the licensing and registration of sources of radiation.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.02 SCOPE. Except as otherwise specifically provided, no person shall receive, possess, use, transfer, own, or acquire radioactive material unless authorized in a specific or general license issued pursuant to this chapter. All other sources of radiation, registered inspectors, and x-ray installations and services unless exempt from this Chapter under 1200-02-10-.03, 1200-02-10-.04, 1200-02-10-.06, 1200-02-10-.07 or 1200-02-10-.30 shall be registered with the Division in accordance with the requirements of 1200-02-10-.24 of this Chapter.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.03 EXEMPTIONS: SOURCE MATERIAL.

(1) Any person is exempt from this Chapter 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.

(Rule 1200-02-10-.03, continued)

(2) Any person is exempt from this Chapter to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(3) Any person is exempt from this Chapter to the extent that such person receives, possesses, uses, or transfers:

(a) Any quantities of thorium contained in: a. incandescent gas mantles; b. vacuum tubes; c. welding rods; d. electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium; e. germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium; f. rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight of thorium, uranium, or any combination of these; or g. personnel neutron dosimeters provided that each dosimeter does not contain more than 50 milligrams of thorium.

(b) Source material contained in the following products: a. glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material; b. piezoelectric ceramic 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; d. 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.

(c) Photographic film, negatives, and prints containing uranium or thorium

(d) Any finished product or part fabricated of, or containing tungsten or magnesium-thorium alloys, provided 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.

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

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

2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: “DEPLETED URANIUM”[1]. [Depleting uranium means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present.];

3. Each counterweight is durably and legibly labeled or marked with the identification of manufacturer and the statement: “UNAUTHORIZED ALTERATIONS PROHIBITED”[1]; and

[1] *The requirements specified in 2. and 3. of this 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 regulations.*

(Rule 1200-02-10-.03, continued)

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

(f) Uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and which is encased in mild steel or equally fire resistant metal ~~or~~ of minimum wall thickness of 1/8 inch.

(g) 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:

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

2. The receipt, possession, use or transfer of thorium contained in contact lenses or in spectacles or in eye pieces in binoculars or other optical instruments.

(h) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains no more than 0.005 microcurie of uranium.

(i) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

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

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

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

Authority: *T.C.A. §68-23-101 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.04 EXEMPTIONS: RADIOACTIVE MATERIALS OTHER THAN SOURCE MATERIAL.

(1) Exempt concentrations.

(a) Except as provided in 1200-02-10-.04(1)(b), any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule RHS 8-4.

(b) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 1200-02-10-.04(1)(a) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State except in accordance with a license issued pursuant to 1200-02-10-.13(8) or the general license provided in 1200-02-10-.10 and 1200-02-10-.29.

(Rule 1200-02-10-.04, continued)

(2) Exempt products. Except for persons who apply radioactive materials to or persons who incorporate radioactive material into the products listed in this paragraph, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns or acquires the following products[2];

(a) Time pieces or hands or dials containing not more than the following quantities of radioactive material and not exceeding the following specified levels of radiation:

1. 25 millicuries of tritium per timepiece;

2. 5 millicuries of tritium per hand;

3. 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);

4. 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;

5. 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;

6. 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered part of the dial);

7. The levels of radiation from hands and dials containing radioactive materials 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.

8. One (1) microcuries of radium-226 per timepiece in timepieces acquired prior to the effective date of this regulation.

(b) 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.

(c) 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.

(d) Automobile shift quadrants containing not more than 25 millicuries of tritium.

(e) 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.

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

(f) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

(g) Electron tubes[3] containing not more than one of the following specified quantities of radioactive material per tube:

1. 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

2. 1 microcurie of cobalt-60;

3. 5 microcuries of nickel-63;

4. 30 microcuries of krypton-85;

5. 5 microcuries of cesium-137;

6. 30 microcuries of promethium-147;

provided, the levels of radiation from each electron tube containing radioactive material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.

(h) Resins containing scandium-46 and designed for sand consolidation in oil wells.

1. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells.

2. 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 specifications contained in a specific license issued by the Division 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 (Code of Federal Regulations) Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

3. This exemption does not authorize the manufacture of any resins containing scandium-46.

(i) Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred[2] in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.26 of 10 CFR Part 32 or a licensing state pursuant to regulations equivalent to ~~1200-2-10-.23(15)~~ 1200-02-

[3] *"Electron tubes", as used in this subparagraph, include spark gap tubes, power tubes, gas tubes, including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.*

(Rule 1200-02-10-.04, continued)

10-.13(15) that authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

2. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under 1200-02-10-.04(2)(i)1., provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 1200-02-10-.13(15).

3. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under ~~1200-2-1-.04(2)(i)1.~~ 1200-02-10-.04(2)(i)1, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 1200-02-10-.13(15).

(j) Self luminous products containing radioactive material.

1. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton-85, promethium-147 in self luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

2. The exemption in 1200-02-10-.04(2)(j)1. does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

3. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns self luminous products containing less than 0.1 microcurie of radium-226 which were acquired prior to the effective date of this regulation.

(k) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material; provided that:

1. Each source contains no more than one exempt quantity set forth in Schedule RHS 8-3;

2. Each instrument contains no more than 10 exempt quantities. For purposes of this subparagraph (k), an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule RHS 8-3, provided that the sum of such fractions shall not exceed unity; and

3. For purposes of this subparagraph (k), 0.05 microcuries of americium-241 is considered an exempt quantity under Schedule RHS 8-3.

(l) 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 per hour (11.4 liters per hour).

(Rule 1200-02-10-.04, continued)

(3) Exempt quantities.

(a) Except as provided in (c) and (d) of this paragraph, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule RHS 8-3; however, these quantities shall not be administered in any form to human beings internally or externally for any purpose.

(b) Any person who possesses radioactive material received or acquired under the general license formerly provided in subparagraph RHS 7.203 A.2. is exempt from the requirements for a license set forth in this Chapter to the extent that such person possesses, uses, transfers, or owns such radioactive material. Such exemption does not apply for radium-226.

(c) This paragraph (3) 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.

(d) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule RHS 8-3, 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, any Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the Department pursuant to 1200-02-10-.13(14) which license states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph (3) or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State.[2.]

(4) Capsules containing carbon-14 urea for 'in vivo' diagnostic use for humans.

(a) Except as provided in subparagraphs (4)(b) and (c) below, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires capsules containing 1 microcurie (37 kilobecquerels) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for 'in vivo' diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license under Chapter 1200-02-10.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 10 CFR 32.21.

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

Authority: *T.C.A. §§4-5-201 et seq., 68-23-101 et seq., 68-23-206, 68-202-201 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed June 5, 1991; effective September 28, 1991. Amendment filed November 17, 2005; effective January 31, 2006. Amendment filed December 21, 2009; effective December 21, 2010.*

(Rule 1200-02-10-.04, continued)

1200-02-10-.05 RESERVED.

1200-02-10-.06 EXEMPTIONS: U.S. DEPARTMENT OF ENERGY AND U.S. NUCLEAR REGULATORY COMMISSION CONTRACTORS. Any contractor or subcontractor of the U.S. Department of Energy (DOE) or the U.S. Nuclear Regulatory Commission (NRC) of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) Prime contractors performing work for DOE at U.S. Government-owned or controlled sites including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruption of such transportation;

(2) Prime contractors of DOE performing research in, or development, manufacture, storage, testing or transportation of atomic weapons or components thereof;

(3) Prime contractors of DOE using or operating nuclear reactors or other nuclear devices in the U.S. Government-owned vehicle or vessel; and

(4) Any other prime contractor or subcontractor of DOE or NRC when the State and NRC jointly determine (1) that, under the terms of the contract or subcontract, there is assurance that the work thereunder can be accomplished with protection of the public health and safety and (2) that, the exemption of such contractor or subcontractor is authorized by law.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.07 OTHER EXEMPTIONS.

(1) The following machines and equipment are exempt from these regulations:

(a) Domestic television receivers, providing the *exposure* rate at 5 centimeters from any outer surface is less than 0.5 milliroentgen per hour.

(b) Other electrical equipment that produces radiation incidental to its operation for other purposes, providing the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding is removed does not exceed 0.5 rem per year. The production testing or factory servicing for such equipment shall not be exempt.

(c) Radiation producing machines while in transit or storage incident thereto.

(d) Radiation machines which are totally unusable except for salvage parts.

(2) Equipment described in paragraph (1) of this Rule shall not be exempt if it is used or handled in such a manner that any individual might receive a dose of radiation in excess of the limits specified in these regulations.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.08 TYPES OF LICENSES. Licenses for radioactive materials are of two types:

(1) Licenses for radioactive materials are of two types:

(Rule 1200-02-10-.08, continued)

(a) General licenses provided for in this chapter are effective without the filing of applications with the Division or the issuance of licensing documents to particular persons; however, the Division will require reporting of devices covered by the particular general license in accordance with 1200-02-10-.10(2)(c)13.

(b) Specific licenses are issued to named persons upon applications filed pursuant to this chapter.

(2) Reserved.

Authority: *T.C.A. §§4-5-201 et seq., 68-202-201 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed March 12, 2007; effective May 26, 2007.*

1200-02-10-.09 GENERAL LICENSES - SOURCE MATERIAL.

(1) A general license is hereby issued authorizing receipt, possession, use and transfer of not more than fifteen (15) pounds (6,803.89 grams) of source material at any one time:

(a) To commercial and industrial firms, research, educational and medical institutions and State and local government agencies, for research, development, educational, commercial, or operational purposes;

(b) Persons who receive, possess, use or transfer source material pursuant to the general license in this paragraph are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as authorized by the Division in a specific license.

(c) Provided, that no such person shall, pursuant to this general license, receive more than a total of 150 pounds (68,038.90 grams) of source material in any one calendar year.

(d) Persons who receive, possess, use or transfer source material pursuant to the general license issued in (1) of this Rule are exempt from the provisions of 1200-02-05 of these regulations to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this Chapter.

(2) 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.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.10 GENERAL LICENSES[4] - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL.

(1) A general license is hereby issued to receive, acquire, own, possess, use and transfer radioactive material incorporated in a device or equipment which is listed in Schedule RHS 8-5 and has been manufactured pursuant to a specific license or equivalent licensing document, issued by the Division, the U.S. Nuclear Regulatory Commission, or any

[4] *Different general licenses are issued in this Rule, each of which has its own specific conditions and requirements.*

(Rule 1200-02-10-.10, continued)

Agreement State and authorizing distribution under the general license of this paragraph or its equivalent.

(2) Certain detecting, measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere.[5]

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business and State or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of (b), (c) and (d) of this paragraph, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) 1. The general license in subparagraph (a) applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(i) A specific license issued by the Division pursuant to 1200-02-10-.13(4), or

(ii) A specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

2. The devices shall have been received from one of the above licensees or through a transfer made under part (2)(c)9.

(c) Persons who own, acquire, receive, possess, use or transfer radioactive material in a device pursuant to the general license contained in subparagraph (2)(a):

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

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

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

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

3. Shall assure that the tests required by part (2)(c)2. and other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed:

[5] *Persons possessing radioactive material in devices under the general license in 1200–2–10–.10(2) before October 2, 1978, may continue to possess, use or transfer that material in accordance with the requirements in the 1972 edition of the regulations.*

(Rule 1200-02-10-.10, continued)

(i) In accordance with the instructions provided by the labels, or

(ii) By a person holding an applicable specific license issued by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities.

4. Shall maintain records showing compliance with the requirements of parts (2)(c)2. and (c)3. The records shall show the results of tests. The records also shall show the dates of performance of and the names of persons performing testing, installation, servicing and removal from installation of the radioactive material, its shielding or containment. The licensee shall retain these records as follows:

(i) Each record of a test for leakage or radioactive material required by part (2)(c)2. shall be retained for three (3) years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(ii) Each record of a test of the on-off mechanism and indicator required by part (2)(c)2. shall be retained for three (3) years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(iii) Each record that is required by part (2)(c)3. shall be retained for three (3) years from the date of the recorded event or until the sealed source is transferred or disposed of.

5. Shall immediately suspend operation of the device if there is a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 becquerel) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license issued by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person holding an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the Division. The licensee shall within 30 days furnish to the Division at the address in Rule 1200-02-04-.07 a report containing a brief description of the event and the remedial action taken. In the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, the licensee shall within 30 days submit to the Division at the address in 1200-02-04-.07 a plan for ensuring that the premises and environs are acceptable for unrestricted use. Under these circumstances, the criteria set out in paragraph 1200-02-10-.36(2), "Radiological criteria for unrestricted use," may be applicable, as determined by the Division on a case-by-case basis;

6. Shall not abandon the device containing radioactive material;

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

8. Shall:

(i) Transfer or dispose of the device containing radioactive material only by export as provided by part (2)(c)7., by transfer to another general licensee as authorized in part (c)9. of this paragraph, or to a person authorized to

receive the device by a specific license issued by the Division under this chapter or an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under subpart (2)(c)8.(iii) below.

(ii) Shall within 30 days after the transfer of a device to a specific licensee or export furnish a report to the Division. The report shall contain:

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

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

(III) The date of the transfer.

(iii) Shall obtain written Division approval before transferring the device to any other specific licensee not specifically identified in subpart (2)(c)8.(i).

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

(i) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this paragraph (2) and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Division:

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

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

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

(IV) The name, title and phone number of the responsible individual identified by the transferee in accordance with part (2)(c)12. to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

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

10. Shall comply with the provisions of 1200-02-05-.140 and 1200-02-05-.141 for reporting radiation incidents, theft or loss of radioactive material;

11. Shall respond to written requests from the Division to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Division at the address in Rule 1200-02-04-.07 providing written justification as to why it cannot comply;

12. Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee,

(Rule 1200-02-10-.10, continued)

through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

13. Shall:

(i) Report these devices to the Division annually. Reporting shall be done by verifying, correcting and/or adding to the information provided in a request for a report received from the Division. The report information shall be submitted to the Division within 30 days of the date of the request or as otherwise indicated in the request.

(ii) In reporting devices, furnish the following information and any other information specifically requested by the Division:

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

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

(III) Name, title and telephone number of the responsible person designated as a representative of the general licensee under part (c)12;

(IV) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage. Each address for a location of use represents a separate general license;

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

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

14. Shall be subject to the bankruptcy notification requirement in paragraph 1200-02-10-.16(7) if holding devices containing radioactive material that meet the following criteria, based on the activity indicated on the label:

(i) At least 10 mCi (370MBq) of cesium-137;

(ii) At least 0.1 mCi (3.7 MBq) of strontium-90;

(iii) At least 1 mCi (37 MBq) of cobalt-60; or

(iv) At least 1 mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)).

15. Persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State with respect to devices meeting the criteria in part (2)(c)13 and (2)(c)14 of this paragraph are not subject to reporting requirements if the devices are used in areas subject to the Division's jurisdiction for a period less than 180 days in any calendar year. The Division will not request reporting information from such licensees.

(Rule 1200-02-10-.10, continued)

16. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Division, at the address in 1200-02-04-.07, within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage;

17. Shall not hold devices that are not in use for longer than two (2) years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by part (c)2. need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person and have not been tested within the required test interval, they shall be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in storage.

(d) The general license provided in this paragraph is subject to the provisions of 1200-02-10-.16(1), (2) and (3), 1200-02-10-.23(1), (2) and (3), 1200-02-10-.26 through 1200-02-10-.28 and 1200-02-10-.30.

(e) The general license in 1200-02-10-.10(2)(a) does not authorize the manufacture or import of devices containing radioactive material.

(3) Luminous safety devices for aircraft.

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

1. Each device contains not more than ten (10) curies of tritium or 300 millicuries of promethium-147; and

2. 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 Division or an Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in (a) of this paragraph (3) are exempt from the requirements of Chapter 1200-02-05, except that they shall comply with the provisions of 1200-02-05-.140 and 1200-02-05-.141.

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

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

(e) The general license provided in this paragraph is subject to the provisions of 1200-02-10-.16 through 1200-02-10-.30, as applicable.

(4) Calibration and reference sources.

(Rule 1200-02-10-.10, continued)

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

1. Any person who holds a specific license issued by the Division that authorizes the receipt, possession, use and transfer of radioactive materials; and

2. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the receipt, possessions, use and transfer of special nuclear material.

(b) 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 (d) and (e) of this paragraph (4) to any person who holds a specific license issued by the Division which authorizes him to receive, possess, use and transfer radioactive material.

(c) A general license is hereby issued to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of (d) and (e) of this paragraph to any person who holds a specific license issued by the Division which authorizes him to receive, possess, use, and transfer radioactive material.

(d) The general licenses in (a), (b) and (c) of this paragraph apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained n 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 or Section 70.39 of 10 CFR, Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Division or any Agreement State or Licensing 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.

(e) The general licenses provided in (a), (b) and (c) of this paragraph are subject to the provisions of 1200-02-10-.16, 1200-02-10-.22, 1200-02-10-.23, 1200-02-10-.26, 1200-02-10-.27, 1200-02-10-.28, 1200-02-10-.30, and Chapters 1200-02-04 and 1200-02-05 of these regulations. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to these general licenses:

1. Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, 5 microcuries of plutonium or 5 microcuries of radium-226 in such sources;

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

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

(Rule 1200-02-10-.10, continued)

CAUTION - RADIOACTIVE MATERIAL - THIS
SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)[6].
DO NOT TOUCH RADIOACTIVE
PORTION OF THIS SOURCE

_____
(name of manufacturer or importer)

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

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

_____
(name of manufacturer or importer)

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

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

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

(f) These general ~~license~~ licenses do not authorize the manufacture of calibration or reference sources containing americium–241, plutonium or radium–226.

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

(6) Ice detection devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 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 equivalent licensing document issued by the Division 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.

(b) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in (a) of this paragraph (6):

[6] *Showing only the name of the appropriate material.*

(Rule 1200-02-10-.10, continued)

1. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license or equivalent licensing document 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 these regulations;

2. 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;

3. Are exempt from the requirements of Chapter 1200-02-05 of these regulations except that such persons shall comply with the provisions of 1200-02-05-.120(1), 1200-02-05-.140, and 1200-02-05-.141.

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

(d) The general license provided in this paragraph is subject to the provisions of 1200-02-10-.16, 1200-02-10-.22, 1200-02-10-.23, 1200-02-10-.26, 1200-02-10-.27, 1200-02-10-.28, 1200-02-10-.30.

(7) Radioactive material for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of (b), (c), (d), (e) and (f) of this paragraph (7), the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

1. Iodine-125, in units not exceeding 10 microcuries each.

2. Iodine-131, in units not exceeding 10 microcuries each.

3. Carbon-14, in units not exceeding 10 microcuries each.

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

5. Iron-59, in units not exceeding 20 microcuries each.

6. Cobalt-57, in units not exceeding 10 microcuries each.

7. Selenium-75, in units not exceeding 10 microcuries each.

8. 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.

(b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by (a) of this paragraph (7) until he has filed an application for and received from the Division a copy of Form RHS 8-5I with number assigned. The general licensee shall furnish on the application the following information and such other information as may be required by that form:

1. Name and address of the licensee;

2. The location of use; and

3. A statement that the licensee has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive materials as authorized under this general license 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.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to this general license shall comply with the following:

1. The general licensee shall not possess at any one time, pursuant to this general license, at any one location of storage or use, a total amount of iodine-125, iodine-131, cobalt-57, selenium-75 and/or iron-59 in excess of 200 microcuries.

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

3. The general licensee shall use the radioactive material only for the uses authorized by (a) of this paragraph (7).

4. The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it by a license pursuant to this Chapter 1200-02-10, from the U.S. Nuclear Regulatory Commission, or an Agreement State or Licensing State nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

5. The general licensee shall dispose of the Mock Iodine - 125 reference or calibration sources described in (a) of this paragraph (7) as required by 1200-02-05-.120.

(d) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to (a) of this paragraph (7):

1. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, cobalt-57, iron-59, or Mock Iodine-125 to persons generally licensed; and

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

(i) This radioactive material 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 of a State with which

(Rule 1200-02-10-.10, continued)

the Commission has entered into an agreement for the exercise of regulatory authority.

_____
(name of manufacturer)

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians 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 a Licensing State.

_____
(name of manufacturer)

(e) Licensees possessing or using radioactive materials under this general license shall report in writing to the Director, Division of Radiological Health, at the address in Rule 1200-02-04-.07, any changes in information furnished in the application submitted under subparagraph 1200-02-10-.10(7)(b). The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using radioactive material pursuant to this general license is exempt from the requirements of Chapter 1200-02-05 with respect to radioactive materials covered by this general license, except that such person using the Mock Iodine-125 described in part (a)8 shall comply with the provisions of 1200-02-05-.120, 1200-02-05-.140, and 1200-02-05-.141.

Authority: *T.C.A. §§4-5-201 et seq., 68-202-201 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed July 18, 2002; effective October 1, 2002. Amendments filed November 17, 2005; effective January 31, 2006. Amendment filed March 12, 2007; effective May 26, 2007. Amendment filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.11 FILING OF APPLICATION FOR SPECIFIC LICENSES.

(1) Application for specific licenses shall be filed in duplicate on a form prescribed by the Division.

(2) The Division 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 Division to determine whether the application should be granted or denied or whether a license should be modified or revoked.

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

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

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

(Rule 1200-02-10-.11, continued)

(6) Applications and documents submitted to the Division may be made available for public inspection except that the Division may withhold any document or part thereof from public inspection if disclosure of its contents involves proprietary information.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.12 GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES. A license application will be approved if the Division determines that:

(1) The applicant has properly trained a sufficient number of personnel to use the material in question for the purpose required in accordance with these regulations in such a manner as to protect the public health and safety or property;

(2) The applicant's proposed equipment, facilities and procedures are in good repair and working order and designed to protect the public health and safety or property;

(3) The applicant satisfies all applicable requirements of these regulations;

(4) The applicant or an existing licensee in any of the classes specified in (a) of this paragraph and not otherwise specifically exempted by (m) of this paragraph has provided financial assurance as herein specified. (See (6) of this Rule for definitions of terms used in this paragraph.)

(a) Classes for financial assurance:

1. Major processors

2. Waste handlers

3. Ore refineries

4. Former USAEC. or USNRC licensed facilities

5. Other persons with or applicants for a specific license as determined by the Commissioner.

(b) The financial assurance shall be filed with and maintained by the Director, Division of Radiological Health (hereafter referred to as Director), in a dollar amount determined by the Commissioner as necessary to provide for the protection of public health and safety in the event of abandonment, insolvency or other inability of the licensee to perform to the satisfaction of the Commissioner. The Commissioner shall consider the following in making his determination of the financial assurance requirements for each individual applicant or licensee:

1. The probable extent of contamination through the use or possession of radioactive material at the facility or site and the probable cost of removal of such contamination to a level in conformance with prevailing national standards or guidelines. This consideration shall encompass all probable contaminating event associated with the licensee's methods or modes of operation;

2. The amount of possible off-site property damage caused by operation of the facility or site;

(Rule 1200-02-10-.12, continued)

3. The cost of removal and disposal of sources of radiation, which are or would be generated, stored, processed or otherwise present at the licensed facility or site; and

4. The costs involved in reclaiming the property on which the facility or site is located. For purposes of this part, "reclaiming" shall mean return of the property to a condition or state such that the property no longer presents a public health or safety hazard or threat to the environment.

(c) Each applicant or licensee of each facility to which it is applicable must file and maintain with the Director financial assurance for reclaiming the facility in accordance with the requirements of this subparagraph.

1. The applicant or licensee must choose from the financial assurance mechanisms as specified in (d) of this paragraph. (NOTE: See also (e), (f) and (g) of this paragraph.)

2. The applicant or licensee must file and maintain financial assurance in an amount at least equal to the current reclaiming cost estimate.

(i) Whenever the reclaiming cost estimate increases to an amount greater than the amount of financial assurance currently filed with the Director, the licensee must, within 60 days after the increase, file additional financial assurance at least equal to this increase.

(ii) Whenever the current reclaiming cost estimate decreases, and upon the written request of the licensee, the Commissioner shall, provided the decrease is validated, reduce the amount of financial assurance required for the facility to the amount of the current reclaiming cost estimate. Upon such occurrence, the Director shall, as appropriate considering the financial assurance mechanism(s) on file, either cause to be released to the licensee cash or collateral equal to this reduction or allow the licensee to substitute for the mechanism(s) on file a new mechanism(s) in the reduced amount.

3. An applicant for a license must file the financial assurance instruments(s) before the license can be issued.

4. The financial assurance must be maintained by the applicant or licensee until the Commissioner releases the licensee from the requirements of this subparagraph, as specified in this part, or until the Commissioner orders forfeiture of the financial assurance as provided in 5. of this subparagraph.

5. The Commissioner may order that any financial assurance filed by a licensee pursuant to this subparagraph be forfeited to the State if the Commissioner determines that the licensee has failed to perform reclaiming in a manner deemed acceptable by the Commissioner to assure health and safety from radiation hazards and other license requirements when required to do so. Any such forfeiture action shall follow the procedures provided in (h) of this paragraph.

(d) Mechanisms of financial assurance.

1. Surety Bond - An applicant or licensee may satisfy the requirements of (c) of this paragraph by obtaining and filing a surety bond which conforms to the requirements of this part.

(i) The surety company issuing the bond must be licensed to do business as a surety in Tennessee.

(ii) The wording of the surety bond must be identical to the wording specified in (j)1. of this paragraph.

(iii) The bond must guarantee that:

(I) Funds will be available to perform reclaiming in a manner deemed acceptable by the Commissioner to assure health and safety from radiation hazards and other requirements of the license for the facility whenever required to do so.

(II) The licensee will provide alternate financial assurance as specified in this paragraph and obtain the Director's written approval of the assurance provided within 90 days of receipt by both the licensee and the Director of a notice of cancellation of the bond from the surety.

(iv) Under the terms of the bond, the surety will become liable on the bond obligation when the licensee fails to perform as guaranteed by the bond. Following a determination by the Commissioner that the licensee has failed to so perform, under the terms of the bond the surety will perform reclamation to the satisfaction of the State as guaranteed by the bond or will forfeit the amount of the penal sum, as provided in (c)5. of this paragraph.

(v) The penal sum of the bond must be in an amount at least adequate to provide the necessary financial assurance.

(vi) Under the terms of the bond, the surety may cancel the bond by sending notice of cancellation by certified mail to the licensee and to the Director. Cancellation may not occur, however, during the 180 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Director, as evidenced by the return receipts.

(vii) The surety will not be liable for deficiencies in the performance of reclaiming after the Commissioner releases the licensee from the financial assurance requirements as provided in (c)4. of this paragraph.

2. Personal Bond Supported by a Letter of Credit - An applicant or licensee may satisfy the requirements of (c) of this paragraph by filing his personal performance guarantee accompanied by collateral in the form of an irrevocable standby letter of credit. He must guarantee funds to perform reclaiming in accordance with acceptable practice for protection of health and safety and other requirements of the license for the facility. The irrevocable standby letter of credit supporting this guarantee must conform to the following requirements:

(i) The institution issuing the letter of credit must be an entity which has the authority to issue letter of credit and whose letter-of-credit operations are regulated and examined by a Federal or State agency.

(ii) The wording of the letter of credit must be identical to the wording specified in (j)2. of this paragraph.

(Rule 1200-02-10-.12, continued)

(iii) The letter of credit must be accompanied by a letter from the licensee referring to the letter of credit by number, issuing institution and date and providing the following information: The radioactive material license number, name and address of the facility and the amount of funds assured for reclaiming of the facility by the letter of credit. (NOTE: This letter from the licensee may also contain his personal performance guarantee.)

(iv) The letter of credit must be irrevocable and issued for a period of at least one (1) year. The letter of credit must provide that the expiration date will be automatically extended for a period of at least one (1) year unless, at least 180 days before the current expiration date, the issuing institution notifies both the licensee and the Director by certified mail of a decision not to extend the expiration date. Under the terms of the letter of credit, the 180 days will begin on the date when both the licensee and the Director have received the notice, as evidenced by the return receipts.

(v) The letter of credit must be issued in an amount at least adequate to provide the necessary financial assurance.

(vi) The Commissioner may draw on the letter of credit upon forfeiture as provided in (c)5. of this paragraph. The Commissioner will also draw on the letter of credit if the licensee does not establish alternate financial assurance as specified in this paragraph and obtain written approval of such alternate assurance from the Director within 90 days after receipt by both the licensee and the Director of a notice from the issuing institution that it has decided not to extend the letter of credit beyond the current expiration date. The Director may delay the drawing if the issuing institution grants an extension of the term of the credit. During the last 30 days of any such extension the Commissioner will draw on the letter of credit if the licensee has failed to provided alternate financial assurance as specified in this paragraph and obtain written approval of such assurance from the Director.

3. Personal Bond Supported by Insurance - An applicant or licensee may satisfy the requirements of (c) of this paragraph by filing his personal performance guarantee accompanied by collateral in the form of an insurance policy. He must guarantee funds sufficient to perform reclaiming in a manner deemed acceptable by the Commissioner for protection of health and safety and other requirements of the license for the facility. The insurance policy supporting this guarantee must conform to the following requirements:

(i) The insurer must be licensed to transact the business of insurance or eligible to provide insurance as an excess or surplus lines insurer in the State of Tennessee.

(ii) The insurance policy must be accompanied by a certificate of insurance whose wording is identical to the wording specified in (j)3. of this paragraph.

(iii) The insurance policy must be for a face amount at least adequate to provide the necessary financial assurance. The term “face amount” means the total amount the insurer is obligated to pay under the policy. Actual payments by the insurer will not change the face amount, although the insurer’s future liability will be lowered by the amount of the payments.

(Rule 1200-02-10-.12, continued)

(iv) The insurance policy must guarantee that funds will be available for reclaiming the facility whenever reclaiming is necessary.

(v) Upon forfeiture of financial assurance as provided in (c)5. of this paragraph, the Commissioner will direct the insurer to pay the full face amount to the State.

(vi) The licensee must maintain the policy in full force and effect until the Commissioner releases the financial assurance mechanism as provided in this paragraph. Failure to pay the premium, without substitution of alternate financial assurance as specified in this paragraph, will constitute a significant violation of these regulations, warranting such remedy as the Commissioner deems necessary. Such violation will be deemed to begin upon receipt by the Director of a notice of future cancellation, termination or failure to renew due to nonpayment of the premium, rather than upon the date of expiration.

(vii) The policy must provide that the insurer may not cancel, terminate or fail to renew the policy except for failure to pay the premium. The automatic renewal of the policy must, at a minimum, provide the insured with the option of renewal at the face amount of the expiring policy. If there is a failure to pay the premium, the insurer may elect to cancel, terminate or fail to renew the policy by sending notice by certified mail to the licensee and the Director. Cancellation, termination or failure to renew may not occur, however, during the 180 days beginning with the date of receipt of the notice by both the Director and the licensee, as evidenced by the return receipts. Cancellation, termination or failure to renew may not occur and the policy will remain in full force and effect in the event that on or before the date of expiration:

(I) The Commissioner deems the facility abandoned;

(II) The license is terminated or revoked or renewal is denied;

(III) Closure is ordered by the Commissioner or a court of competent jurisdiction;

(IV) The licensee is named as debtor in a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code; or

(V) The premium due is paid.

(viii) Commencing on the date that liability to make payments pursuant to the policy accrues, the insurer will thereafter annually increase the face amount of the policy. Such increase must be equivalent to the face amount of the policy, less any payments made, multiplied by an amount equivalent to 85 percent of the most recent investment rate or of the equivalent coupon-issue yield announced by the U.S. Treasury for 26-week Treasury securities.

4. Personal Bond Supported by Securities - An applicant or licensee may satisfy the requirements of (c) of this paragraph by filing his personal performance guarantee accompanied by collateral in the form of securities. He must guarantee sufficient funds to perform reclaiming in accordance with acceptable practices for protection of health and safety and other requirements of the license for the facility. The securities supporting this guarantee must be fully registered as to

(Rule 1200-02-10-.12, continued)

principal and interest in such manner as to identify the State and the Division as holder of such collateral and to also identify that person filing such collateral. These securities must have a current market value at least adequate to provide the necessary financial assurance and must be included among the following types:

(i) Negotiable certificates of deposit assigned irrevocably to the State.

(I) Such certificates of deposit must be automatically renewable and must be assigned to the State in writing and recorded as such in the records of the financial institution issuing such certificate.

(II) Such certificates of deposit must also include a statement signed by an officer of the issuing financial institution which waives all rights of lien which the institution has or might have against the certificate.

(ii) Negotiable United States Treasury securities assigned irrevocably to the State.

(iii) Negotiable general obligation municipal or corporate bonds which have at least an “A” rating by Moody’s and/or Standard & Poor’s rating services and which are assigned irrevocably to the State.

5. Personal Bond Supported by Cash - An applicant or licensee may satisfy the requirements of (c) of this paragraph by filing his personal performance guarantee accompanied by cash in an amount at least adequate to provide the necessary financial assurance.

6. Financial Test and Corporate Guarantee.

(i) An applicant or licensee may satisfy the requirements of (c) of this paragraph by demonstrating that he passes a financial test as specified in this part. To pass this test the licensee must meet the criteria of either item (I) or (II) of this subpart as follows:

(I) The applicant or licensee 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;

II. Net working capital and tangible net worth each at least six (6) times the current reclaiming cost estimate;

III. Tangible net worth of at least $10 million; and

IV. Assets in the United States amounting to at least 90 percent of this total assets or at least six (6) times the current reclaiming cost estimate.

(II) The applicant or licensee must have:

(Rule 1200-02-10-.12, continued)

I. A current rating for his most recent bond issuance of AAA, AA, A or BBB as issued by Standard & Poor's, or Aaa, Aa, A or Baa as issued by Moody's;

II. Tangible net worth at least six (6) times the current reclaiming cost estimate;

III. Tangible net worth of at least $10 million; and

IV. Assets located in the United States amounting to at least 90 percent of his total assets or at least six (6) times the current reclaiming cost estimate.

(ii) The phrase "current reclaiming cost estimates" as used in (i) of this part refers to the cost estimates required to be shown in paragraphs 1-4 of the letter from the applicant's or licensee's chief financial officer.

(iii) To demonstrate that he meets this test, the applicant or licensee must submit the following items to the Director:

(I) A letter signed by the applicant's or licensee's chief financial officer and worded as specified in (j)4. of this paragraph;

(II) A copy of the independent certified public accountant's report on examination of the applicant's or licensee's financial statements for the latest completed fiscal year; and

(III) A special report from the applicant's or licensee's independent certified public accountant to the applicant or licensee stating that:

I. He has compared the data which the letter from the chief financial officer specifies as having been derived from the independently audited, year-end financial statements for the latest fiscal year with the amounts in such financial statements; and

II. In connection with that procedure, no matters came to his attention which caused him to believe that the specified data should be adjusted.

(iv) After the initial submission of items specified in (iii) of this part, the licensee must send updated information to the Director within 90 days after the close of each succeeding fiscal year. This information must consist of all three items specified in (iii) of this part.

(v) If the licensee no longer meets the requirements of (i) of this part, he must send notice to the Director of intent to establish alternate financial assurance as specified in this paragraph. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the requirements. The licensee must provide the alternate financial assurance within 120 days after the end of such fiscal year.

(vi) The Director may, based on a reasonable belief that the licensee may no longer meet the requirements of (i) of this part, require reports of financial condition at any time from the licensee in addition to those specified in (iii)

of this part. If the Director finds, on the basis of such reports or other information, that the licensee no longer meets the requirements of (i) of this part, the licensee must provide alternate financial assurance as specified in this paragraph within 30 days after notification of such a finding.

(vii) The Director may disallow use of this test on the basis of qualifications in the opinion expressed by the independent certified public accountant in his report on examination of the applicant's or licensee's financial statements. An adverse opinion or a disclaimer of opinion will be cause for disallowance. The Director will evaluate other qualifications on an individual basis. The applicant or licensee must provide alternate financial assurance as specified in this paragraph within 30 days after notification of the disallowance.

(viii) An applicant or licensee may meet the requirements of (c) of this paragraph by obtaining a written guarantee, hereafter referred to as "corporate guarantee." The guarantor must be the parent corporation of the licensee. The guarantor must meet the requirements for applicants or licensees in (i) through (vii) of this part and must comply with the terms of the corporate guarantee. The wording of the corporate guarantee must be identical to the wording specified in (j)5. of this paragraph. The corporate guarantee must accompany the items sent to the Director as specified in (iii) of this part. The terms of the corporate guarantee must provide that:

(I) If the licensee fails to perform reclaiming of a facility covered by a corporate guarantee for reclaiming in accordance with acceptable practices to protect health and safety and other license requirements whenever required to do so, the guarantor will do so or forfeit to the State monies in an amount equal to the current reclaiming cost estimate for the facility, as provided in (c)5. of this paragraph.

(II) The corporate guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and to the Director. Cancellation may not occur, however, during the 180 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Director as evidenced by the return receipts.

(III) If the licensee fails to provide alternate financial assurance as specified in this paragraph and obtain the written approval of such alternate assurance from the Director within 90 days after receipt by both the licensee and the Director of a notice of cancellation of the corporate guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(e) Use of Multiple Financial Mechanisms - In meeting the requirements of (c) of this paragraph, an applicant or licensee may utilize more than one financial assurance mechanism per facility. These mechanisms are limited to personal bonds supported by letters of credit, insurance, securities or cash. The mechanisms must be as specified in (d) of this paragraph, except that it is the combination of mechanisms, rather than the single mechanism, which must provide financial assurance for the necessary amount.

(f) Use of a Financial Mechanism for Multiple Facilities - An applicant or licensee may use a financial assurance mechanism specified in (d) of this paragraph to meet the requirements of (c) of this paragraph for more than one facility he owns or operates in Tennessee. If so, the mechanism submitted to the Director must include a list showing,

(Rule 1200-02-10-.12, continued)

for each facility, the license number, name, address and amount of funds for reclaiming care assured by the mechanism. The amount of funds available through the mechanism must be no less than the sum of funds that would be available if a separate mechanism had been filed and maintained for each facility.

(g) Substituting Alternate Financial Assurance - In meeting the requirements of (c) of this paragraph, a licensee may substitute alternate financial assurance meeting the requirements of this paragraph for the financial assurance already filed with the Director for the facility. However, the existing financial assurance shall not be released by the Commissioner until the substitute financial assurance has been received and approved by him.

(h) Procedures for Forfeiture of Financial Assurance.

1. Upon the determination of abandonment, insolvency or other inability of the licensee to perform to the satisfaction of the Commissioner, a notice of non-compliance shall be served upon the licensee. Such notice shall be hand-delivered or forwarded by certified mail. The notice of non-compliance shall specify in what respects the licensee has failed to perform as required.

2. If the Commissioner determines that the licensee has failed to perform as specified in the notice of non-compliance, or as specified in any subsequent compliance agreement which may have been reached by the licensee and the Commissioner, the Director shall cause a notice of show cause meeting to be served upon the licensee. Such notice shall be signed by the Director and either hand-delivered or forwarded by certified mail to the licensee. The notice of show cause meeting shall establish the date, time and location of a meeting scheduled to provide the licensee with the opportunity to show cause why the Director should not pursue forfeiture of the financial assurance filed to guarantee such performance.

3. If no mutual compliance agreement is reached at the show cause meeting, or, upon the Commissioner’s determination that the licensee has failed to perform as specified in such agreement that was reached, the Director shall request the Commissioner to order forfeiture of the financial assurance filed to guarantee such performance.

4. The Commissioner shall order forfeiture of the financial assurance upon his validation of the Director’s determinations and upon his determination that the procedures of this subparagraph have been followed. The Commissioner may, however, at his discretion, provide opportunity for the licensee to be heard before himself before issuing such order. Upon issuance a copy of the order shall be hand-delivered or forwarded by certified mail to the licensee. Any such order issued by the Commissioner shall become effective 30 days after the receipt by the licensee.

5. If necessary, upon the effective date of the order of forfeiture, the Commissioner shall give notice to the State Attorney General who shall collect the forfeiture.

6. All funds from forfeited financial assurances shall be deposited in the State’s radiation reclamation trust fund account for use by the Commissioner as set forth in Section 68-23-405 of the Act.

(i) Incapacity of Applicants or Licensees, Guarantors, or Financial Institutions.

(Rule 1200-02-10-.12, continued)

1. An applicant or licensee must notify the Director by certified mail of the commencement of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming the applicant or licensee as debtor, within ten (10) days after commencement of the proceeding. A guarantor of a corporate guarantee as specified in (d)6. of this paragraph must make such a notification if he is named as debtor, as required under the terms of the corporate guarantee.

2. An applicant or licensee who fulfills the requirements of this paragraph by obtaining a surety bond, letter of credit or insurance policy will be deemed to be without the required financial assurance in the event of bankruptcy of the issuing institution or a suspension or revocation of the authority of the institution issuing the surety bond, letter of credit or insurance policy to issue such instruments. The applicant or licensee must establish other financial assurance within 30 days after such an event.

(j) Wording of the Instruments.

1. A surety bond guaranteeing funds for reclaiming as specified in (d)1. of this aragraph, must be worded as follows except that the instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

SURETY BOND

Date bond executed: _____
Effective date: _____
Principal: (legal name and business address of applicant or licensee)
Type of organization: (insert “individual,” “joint venture,” “partnership” or “corporation”)
State of incorporation: _____
Surety(ies): (Name(s) and business address(es))
License number, name, address and reclaiming cost for each facility guaranteed by this bond (list amounts separately):
$_____
Total penal sum of bond: $_____
Surety’s bond number: _____

KNOW ALL PERSONS BY THESE PRESENTS, that we, the Principal and Surety(ies) hereto are firmly bound to the Tennessee Department of Environment and Conservation (hereinafter called Department), in the above penal sum for the payment of which we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally; provided that, where the Surety(ies) are corporations acting as co-sureties, we, the Sureties, bind ourselves in such sum “jointly and severally” only for the purpose of allowing a joint action or actions against any or all of us, and for all other purposes each Surety binds itself, jointly and severally with the Principal, for the payment of such sum only as is set forth opposite the name of such Surety, but if no limit of liability is indicated, the limit of liability shall be the full amount of the penal sum.

WHEREAS said Principal is required, under the Tennessee Radiological Health Act, as amended, to have a license in order to receive, possess, store and use radioactive material at the facility identified above, and

WHEREAS said Principal is required to provide financial assurance for reclaiming as a condition of the license;

(Rule 1200-02-10-.12, continued)

NOW, THEREFORE, the conditions of this obligation are such that if the Principal shall faithfully perform reclaiming, whenever required to do so, of each facility for which this bond guarantees funds for reclaiming, to the satisfaction of the Commissioner, Tennessee Department of Environment and Conservation in accordance with acceptable practices for protection of health and safety pursuant to all applicable laws, statutes, rules and regulations, as such laws, statutes, rules and regulations may be amended,

OR, if the Principal shall provide alternate financial assurance as specified in 1200-02-10-.12(4), and obtain the written approval of such assurance from the Director, Division of Radiological Health (hereinafter called Director), within 90 days after the date notice of cancellation is received by both the Principal and the Director from the Surety(ies), then this obligation shall be null and void, otherwise it is to remain in full force and effect.

The Surety(ies) shall become liable on this bond obligation only when the Principal has failed to fulfill the conditions described above.

Upon notification by the Director that the Principal has been found in violation of the reclaiming requirements of the Division, for a facility for which this bond guarantees funds for performance of reclaiming, the Surety(ies) shall forfeit the reclaiming cost amount guaranteed for the facility to the Department as directed by the Director.

Upon notification by the Director that the Principal has filed to provide alternate financial assurance as specified in 1200-02-10-.12(4), and obtain written approval of such assurance from the Director during the 30 days following receipt by both the Principal and the Director of a notice of cancellation of the bond, the Surety(ies) shall forfeit funds in the amount guaranteed for the facility(ies) to the Department as directed by the Director.

The Surety(ies) hereby waive(s) notification of amendments to licenses, applicable laws, statutes, rules and regulations and agree(s) that no such amendment shall in any way alleviate its (their) obligation on this bond.

The liability of the Surety(ies) shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the aggregate to the penal sum of the bond, but in no event shall the obligation of the Surety(ies) hereunder exceed the amount of said penal sum.

The Surety(ies) may cancel the bond by sending notice of cancellation by certified mail to the Principal and to the Director, provided, however, that cancellation shall not occur during the 180 days beginning on the date of receipt of the notice of cancellation by both the Principal and the Director, as evidenced by the return receipts.

The Principal may terminate this bond by sending written notice to the Surety(ies), provided, however, that no such notice shall become effective until the Surety(ies) receive(s) written authorization for termination of the bond by the Director.

IN WITNESS WHEREOF, the Principal and Surety(ies) have executed this SURETY BOND and have affixed their seals on the date set forth above.

The persons whose signatures appear below hereby certify that they are authorized to execute this surety bond on behalf of the Principal and Surety(ies) and that the wording of this surety bond is identical to the wording specified in

(Rule 1200-02-10-.12, continued)

1200-02-10-.12(4)(j)1. as such regulation was constituted on the date this bond was executed.

PRINCIPAL

(Signature(s))
(Name(s))
(Title(s))
(Corporate seal)
CORPORATE SURETY(IES)
(Name and address)
State of incorporation: _____
Liability limit: $_____
(Signature(s))
(Name(s) and title(s))
Corporate seal:
(For every co-surety, provide signature(s), corporate seal and other information in the same manner as for Surety above.)
Bond premium: $_____

2. A letter of credit, as specified in (d)2. of this paragraph, must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

IRREVOCABLE STANDBY LETTER OF CREDIT

Director
Division of Radiological Health
Tennessee Department of Environment and Conservation

Dear Sir or Madam:

We hereby establish our Irrevocable Standby Letter of Credit No. _____ in your favor, at the request and for the account of (applicant's or licensee's name and address) up to the aggregate amount of (in words) U.S. dollars $ _____, available upon presentation of:

1) your sight draft, bearing reference to this letter of credit No. _____, and

2) your signed statement reading as follows: "I certify that the amount of the draft is payable pursuant to regulations issued under authority of the Tennessee Radiological Health Act, as amended."

This letter of credit is effective as of (date) and shall expire on (date at least one (1) year later), but such expiration date shall be automatically extended for a period of (at least one (1) year) on (date) and on each successive expiration date, unless, at least 180 days before the current expiration date, we notify both you and (applicant's or licensee's name) by certified mail that we have decided not to extend this letter of credit beyond the current expiration date. In the event you are so notified, any unused portion of the credit shall be available upon presentation of your sight draft for 180 days after the date of receipt by both you and (licensee's name), as shown on the signed return receipts.

Whenever this letter of credit is drawn on under and in compliance with the terms of this credit, we shall duly honor such draft upon presentation to us, and we shall

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forfeit the amount of the draft to the State of Tennessee in accordance with your instructions.

We certify that the wording of this letter of credit is identical to the wording specified in 1200-02-10-.12(4)(j)2 as such regulation was constituted on the date shown immediately below.

(Signature(s) and title(s) of official(s) of issuing institution) (Date)

This credit is subject to (insert "the most recent edition of the Uniform Customs and Practice for Documentary Credits, published by the International Chamber of Commerce," or "the Uniform Commercial Code").

3. A Certificate of insurance, as specified in (d)3. of this paragraph must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

CERTIFICATE OF INSURANCE FOR RECLAIMING

Name and Address of Insurer
(herein called the "Insurer"): _____

Name and Address of Insured
(herein called the "Insured") : _____

Facilities Covered: (List for each facility: The license number, name, address and the amount of insurance for reclaiming (these amounts for all facilities covered must total the face amount shown below))

Face Amount: $ _____

Policy Number: _____

Effective Date: _____

The Insurer hereby certifies that it has issued to the Insured the policy of insurance identified above to provide financial assurance for reclaiming the facilities identified above. The Insurer further warrants that such policy conforms in all respects with the requirements of 1200-02-10-.12(4)(j)3, as applicable and as such regulations were constituted on the date shown immediately below. It is agreed that any provision of the policy inconsistent with such regulation is hereby amended to eliminate such inconsistency.

Whenever requested by the Director, Division of Radiological Health, Tennessee Department of Environment and Conservation, the Insurer agrees to furnish to the Director, Division of Radiological Health a duplicate original of the policy listed above, including all endorsements thereon.

I hereby certify that the wording of this certificate is identical to the wording specified in 1200-02-10-.12(4)(j)3 as such regulation was constituted on the date shown immediately below.

(Authorized signature for Insurer)

(Name of person signing)

(Rule 1200-02-10-.12, continued)

(Title of person signing)

Signature of witness or notary: _____

(Date)

4. A letter from the chief financial officer, as specified in (d)6 of this paragraph must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

LETTER FROM CHIEF FINANCIAL OFFICER

(Address to Director, Division of Radiological Health)

I am the chief financial officer of (name and address of firm). This letter is in support of this firm's use of the financial test to demonstrate financial assurance, as specified in 1200-02-10-.12(4).

(Fill out the following four paragraphs regarding facilities and associated cost estimates. If your firm has no facilities that belong in a particular paragraph, write "None" in the space indicated. For each facility, include its license number, name, address and current reclaiming cost estimates.)

1. This firm is the licensee at the following facility for which financial assurance for reclaiming is demonstrated through the financial test specified in 1200-02-10-.12(4). The current reclaiming cost estimate covered by the test is: $ _____.

2. This firm guarantees, through the corporate guarantee specified in 1200-02-10-.12(4), the reclaiming of the following facility owned or operated by a subsidiary of this firm. The current cost estimates for reclaiming so guaranteed is: $ _____.

3. In other states, this firm, as licensee or guarantor, is demonstrating financial assurance for reclaiming of the following facilities through the use of a test equivalent or substantially equivalent to the financial test specified in 1200-02-10-.12(4). The current reclaiming cost estimates covered by such a test are shown for each facility: $ _____.

4. This firm is the licensee of the following facilities receiving, possessing, using or storing radioactive material for which financial assurance for reclaiming is <u>not</u> demonstrated either to the Division, another State, or the U.S. Nuclear Regulatory Commission through the financial test or any other financial assurance mechanisms specified in 1200-02-10-.12(4) or equivalent or substantially equivalent mechanisms. The current reclaiming cost estimates not covered by such financial assurance are shown for each facility: $ _____.

   This firm (insert "is required" or "is not required") to file a Form 10K with the Securities and Exchange Commission (SEC) for the latest fiscal year.

   The fiscal year of this firm ends on (month, day). The figures for the following items marked with an asterisk are derived from this firm's independently audited, year-end financial statement for the latest completed fiscal year, ending (date).

(Rule 1200-02-10-.12, continued)

(Fill in Alternative I if the criteria of (d)6(i)(I) of this paragraph are used. Fill in Alternative II is the criteria of (d)6(i)(II) of this paragraph are used).

ALTERNATIVE I

1.	Sum of current reclaiming cost estimates (total of all cost estimates shown in the four paragraphs above)	$ _____
*2.	Total liabilities (if any portion of the reclaiming cost estimate is included in total liabilities, you may deduct the amount of that portion from this line and add that amount to lines 3 and 4)	$ _____
*3.	Tangible net worth	$ _____
*4.	Net worth	$ _____
*5	Current assets	$ _____
*6	Current liabilities	$ _____
*7	Net working capital (line 5 minus line 6)	$ _____
*8.	The sum of net income plus depreciation, depletion, and amortization	$ _____
*9.	Total assets in U.S. (required only if less than 90% of firm's assets are located in the U.S.)	$ _____

		YES	NO
10.	Is line 3 at least $10 million?	_____	_____
11.	Is line 3 at least 6 times line 1?	_____	_____
12.	Is line 7 at least 6 times line 1?	_____	_____
*13.	Are at least 90% of firm's assets located in the U.S.? If not, complete line 14	_____	_____
14.	Is line 9 at least 6 times line 1?	_____	_____
15.	Is line 2 divided by line 4 less than 2.0?	_____	_____
16.	Is line 8 divided by line 2 greater than 0.1?	_____	_____
17.	Is line 5 divided by line 6 greater than 1.5?	_____	_____

ALTERNATIVE II

1.	Sum of current reclaiming cost estimates (total of all cost estimates shown in the four paragraphs above)	$ _____

(Rule 1200-02-10-.12, continued)

2.	Current bond rating of most recent issuance of this firm and name of rating service		_____
3.	Date of issuance of bond		_____
4.	Date of maturity of bond		_____
*5.	Tangible net worth	$	_____
*6	Total assets in U.S. (required only if less than 90% of firm's assets are located in the U.S.)	$	_____

		YES	NO
7.	Is line 5 at least $10 million?	_____	_____
8.	Is line 5 at least 6 times line 1?	_____	_____
9.	Are at least 90% of firm's assets located in the U.S.? If not, complete line 10.	_____	_____
10.	Is line 6 at least 6 times line 1?	_____	_____

I hereby certify that the wording of this letter is identical to the wording specified in 1200-02-10-.12(4)(j)4 as such regulations were in effect on the date shown immediately below.

(Signature)
(Name)
(Title)
(Date)

5. A corporate guarantee, as specified in (d)6 of this paragraph, must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

CORPORATE GUARANTEE FOR RECLAIMING

Guarantee made this (date) by (name of guaranteeing entity), a business corporation organized under the laws of the State of (insert name of State), herein referred to as guarantor, to the Tennessee Department of Environment and Conservation (Department), obligee, on behalf of our subsidiary (applicant or licensee) of (business address).

Recitals

1. Guarantor meets or exceeds the financial test criteria and agrees to comply with the reporting requirements for guarantors as specified in 1200-02-10-.12(4)(d)6.

2. (Applicant or licensee) owns or operates and is licensed by the Department to receive, possess, store and use radioactive material at the facility covered by this guarantee: (List for the facility: license number, name and address).

3. For value received from (licensee), guarantor guarantees to the Department that in the event that (licensee) fails to perform reclaiming of

(Rule 1200-02-10-.12, continued)

the above facility in a manner deemed acceptable by the Commissioner to assure health and safety from radiation hazards and other license requirements, the guarantor shall do so or forfeit to the State of Tennessee, as specified in 1200-02-10-.12(4) monies in an amount equal to the current reclaiming cost estimates as specified in 1200-02-10-.12(4).

4. Guarantor agrees that if, at the end of any fiscal year before termination of this guarantee, the guarantor fails to meet the financial test criteria, guarantor shall send within 30 days, by certified mail, notice to the Director of the Department's Division of Radiological Health (Division Director) and to (licensee) that he intends to provide alternate financial assurance as specified in 1200-02-10-.12(4), in the name of (licensee). Within 90 days after the end of such fiscal year, the guarantor shall establish such financial assurance unless (licensee) has done so.

5. The guarantor agrees to notify the Division Director, by certified mail, of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming guarantor as debtor, within ten (10) days after commencement of this proceeding.

6. Guarantor agrees that within 30 days after being notified by the Division Director of a determination that guarantor no longer meets the financial test criteria or that he is disallowed from continuing as a guarantor for reclaiming he shall establish alternate financial assurance as specified in 1200-02-10-.12(4) in the name of (licensee) unless (licensee) has done so.

7. Guarantor agrees to remain bound under this guarantee notwithstanding any or all of the following: amendment or modification of the license, the extension or reduction of the time of performance of reclaiming or any other modification or alteration of an obligation of the licensee pursuant to these regulations.

8. Guarantor agrees to remain bound under this guarantee for so long as (licensee) must comply with the applicable financial assurance requirements of 1200-02-10-.12(4) for the above-listed facility, except that guarantor may cancel this guarantee by sending notice by certified mail to the Division Director and to (licensee), such cancellation to become effective no earlier than 180 days after receipt of such notice by both the Department and (licensee), as evidenced by the return receipts.

9. Guarantor agrees that if (licensee) fails to provide alternate financial assurance as specified in 1200-02-10-.12(4), and obtain written approval of such assurance from the Division Director within 30 days after a notice of cancellation by the guarantor is received by the Division Director from guarantor, guarantor shall provide such alternate financial assurance in the name of (licensee).

10. Guarantor expressly waives notice of acceptance of this guarantee by the Department or by (licensee). Guarantor also expressly waives notice of amendments or modification of the facility license.

I hereby certify that the wording of this guarantee is identical to the wording specified in 1200-02-10-.12(4)(j)5 as such regulations were in effect on the date first above written.

Effective Date: _____

(Name of guarantor)

(Authorized signature for guarantor)

(Name of person signing)

(Title of person signing)

Signature of witness or notary: _____

(k) Persons licensed at the time these financial assurance regulations become effective and upon notice by the Department must, within a period of ninety (90) days following such notice, provide the required financial assurance.

(l) The Department may reevaluate, at any time, the adequacy of existing financial assurance and may require their adjustment by either increasing or decreasing the amount of financial assurance required so that adequate funds will be available.

(m) Except that the following persons are exempt from the requirements of this paragraph:

1. State and local government agencies.

2. Educational institutions accredited by the Southern Association of Colleges and Schools.

3. Licensees of the State Licensing Board for the Healing Arts and those medical facilities possessing or utilizing radioactive materials for medical purposes when supervised by such licensees.

4. Veterinarians possessing or utilizing radioactive materials in their veterinary practice.

5. Persons possessing or utilizing radioactive materials for *in vitro* medical purposes.

6. Persons possessing or utilizing only generally licensed quantities of radioactive materials.

(5) The applicant or an existing licensee, for whom financial assurance is required and where it is intended that the licensed facility will eventually cease to operate while containing, storing or possessing radioactive sources on the premises and will require continuing and perpetual care or surveillance over the facility to protect public health, safety or welfare, shall deposit sums to a Perpetual Care Trust Fund maintained by the Commissioner in the name of the State.

(a) The Commissioner shall consider the following in making his determination of the Perpetual Care Trust Fund deposits for each individual applicant or licensee.

1. The nature of the licensed radioactive material; including its radiotoxicity, half-life, chemical and physical form and containment;

2. Size and type of facility to be decommissioned; and

3. The anticipated cost to the State of perpetual care and surveillance.

(Rule 1200-02-10-.12, continued)

(b) The Department may reevaluate at any time the adequacy of a licensee's contributions to the existing Perpetual Care Trust Fund and may adjust by increasing or decreasing the rate of contribution or the specified amount required of a licensee so that the fund may be adequate in amount to meet perpetual care requirements of that licensee.

(6) Definitions of terms used in paragraph (4) of this Rule

(a) *Current reclaiming cost estimate* means the most recent of the estimates prepared in accordance with (c)1, 2, and 3 of paragraph (4) of this Rule.

(b) *Director* means the Director of the Division of Radiological Health of the Department of Environment and Conservation.

(c) *Parent corporation* means a corporation which directly owns at least 50 percent of the voting stock of the corporation which is the facility owner or operator; the latter corporation is deemed a "subsidiary" of the parent corporation.

(d) The following terms are used in the specifications for the financial tests for financial assurance for reclaiming. The definitions are intended to assist in the understanding of these regulations and are not intended to limit the meanings of terms in a way that conflicts with generally accepted accounting practices.

1. *Assets* means all existing and all probable future economic benefits obtained or controlled by a particular entity.

2. *Current assets* means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.

3. *Current liabilities* means obligations whose liquidation is reasonably expected to require the use of existing resources properly classifiable as current assets or the creation of other current liabilities.

4. *Independently audited* refers to an audit performed by an independent certified public accountant in accordance with generally accepted auditing standards.

5. *Liabilities* means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.

6. *Net working capital* means current assets minus current liabilities.

7. *Net worth* means total assets minus total liabilities and is equivalent to owner's equity.

8. *Tangible net worth* means the tangible assets that remain after deducting liabilities; such assets would not include intangibles such as goodwill and rights to patents of royalties.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed October 22, 1987; effective December 6, 1987.*

1200-02-10-.13 SPECIAL REQUIREMENTS FOR ISSUANCE OF SPECIFIC LICENSES.

(Rule 1200-02-10-.13, continued)

(1) Reserved ~~Human use of radioactive materials in institutions. In addition to the requirements set forth in 1200-2-10-.12, a specific license for human use of radioactive material in institutions will be issued only if:~~

~~(a) The applicant has appointed a radiation safety committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. Membership of the committee must include at least the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the institution's management, and the Radiation Safety Officer;~~

~~(b) The applicant possesses facilities for the clinical care of patients;~~

~~(c) The physician designated on the application as the individual user has experience in the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients as outlined in 1200-2-10-.33; and~~

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

(2) Reserved ~~Human use of radioactive materials by individual physicians.~~

~~(a) In addition to the requirements set forth in 1200-2-10-.12, a specific license for the human use of radioactive materials will be issued to an individual physician or group of physicians only if:~~

~~1. The application is for use in the applicant's practice in an office outside a medical institution;~~

~~2. The applicant has access to a hospital possessing facilities to hospitalize and monitor the applicant's radioactive patients whenever it is clinically indicated; and~~

~~3. The applicant has experience in the handling and administration of radioisotopes, and, where applicable, the clinical management of radioactive patients, as outlined in 1200-2-10-.33.~~

~~(b) The Department 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:~~

~~1. 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.~~

(Rule 1200-02-10-.13, continued)

2. ~~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~~

3. ~~The medical institution does not hold a radioactive material license under 1200-2-10-.13(1).~~

(3) Reserved ~~Human use of sealed sources. In addition to the requirements set forth in 1200-2-10-.12, a specific license for human use of sealed sources will be issued only if the applicant, or if the application is made by an institution, the individual user (1) has training as outlined in 1200-2-10-.33 in the therapeutic use of the sealed source considered (teletherapy unit, beta applicator, etc.) and (2) is a physician.~~

(4) Multiple quantities of types of radioactive material for use in research and development. In addition to the requirements set forth in 1200-02-10-.12, a specific license for multiple quantities or types of radioactive material for use in research and development will be issued only if:

(a) 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 use; and

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

(5) Manufacture, distribution or initial distribution of devices to persons generally licensed under 1200-02-10-.10(2). In addition to the requirements set forth in 1200-02-10-.12, a specific license to distribute certain devices of the types enumerated in 1200-02-10-.10(2) to persons generally licensed under 1200-02-10-.10(2) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be issued only if:

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

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

2. Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and no person will receive in one year a dose in excess of ten percent (10%) of the limits specified in 1200-02-05-.50; and

3. Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Table RHS 7-1;

(Rule 1200-02-10-.13, continued)

TABLE RHS 7-1 TABLE OF ORGAN DOSES

Part of Body	rem	mSv / Sv
Whole body; head and trunk; active blood forming organs; gonads; or lens of eye	15	150 mSv
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200	2 Sv
Other organs	50	500 mSv

(b) Each device bears a durable, legible clearly visible label or labels approved by the Division that contain(s) in a clearly identified and separate statement:

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

2. The requirements, 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 the radioactive material by isotope, quantity of radioactivity and date of determination of the quantity; and

3. The information called for in one of the following statements in the same or similar form:

(i) The receipt, possession, use, and transfer of this device, Model _____,[10] Serial No. _____,[10] are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

(Name of manufacturer or distributor)

(ii) The receipt, possession, use and transfer of this device Model _____,[7] Serial No. _____,[7] are subject to a general license or the equivalent and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

[7] *If specified elsewhere in labeling affixed to the device, the model, serial number and manufacturer or distributor may be omitted from this label*

CAUTION - RADIOACTIVE MATERIAL

_____

(Name of manufacturer or distributor)

(c) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "CAUTION - RADIOACTIVE MATERIAL," and, if practicable, the radiation symbol described in 1200-02-05-.110 and the name of the manufacturer or initial distributor.

(d) Each device meeting the criteria of ~~10 CFR 31.5(c)(13)(i)~~ 1200-02-10-.10 bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "CAUTION – RADIOACTIVE MATERIAL," and, if practicable, the radiation symbol described in 1200–02–05–.110.

(e) In the event the applicant desires that the device be tested at intervals longer than six (6) 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 information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material or failure of the on-off mechanism indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Division will consider information that includes, but is not limited to:

1. Primary containment (source capsule);

2. Protection of primary containment;

3. Method of sealing containment;

4. Containment construction materials;

5. Form of contained radioactive material;

6. Maximum temperature withstood during prototype tests;

7. Maximum pressure withstood during prototype tests;

8. Maximum quantity of contained radioactive material;

9. Radiotoxicity of contained radioactive material; and
10. Operating experience with identical devices or similarly designed and constructed devices;

(f) In the event the applicant desires that the general licensee under 1200-02-10-.10(2) or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or

(Rule 1200-02-10-.13, continued)

activities and the basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license, will not cause that individual to receive in one year a dose in excess of ten percent (10%) of the limits specified in 1200-02-05-.50;

(g) Before radioactive material may be transferred in a device for use under a general license, each person licensed under 1200-02-10-.13(5) shall furnish the following information to each person to whom he directly or through an intermediate person transfers radioactive material in a device. In the case of a transfer through an intermediate person, the information shall be provided to the intended user and to the intermediate person prior to initial transfer to the intermediate person.

	For use under the general license contained in 1200-02-10-.10(2)	For use under equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State
1.	A copy of the general license contained in 1200-02-10-.10(2). If parts 1200-02-10-.10(2)(c)2. through 4. or 1200-02-10-.10(2)(c)13. do not apply to the particular device, those parts may be omitted;	A copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulations equivalent to 1200-02-10-.10(2). Alternatively, he may furnish a copy of the general license contained in 1200-02-10-.10(2). If a copy of the general license in 1200-02-10-.10(2) 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, Agreement State or Licensing State under requirements substantially the same as those in 1200-02-10-.10(2); If paragraphs (c)(2) through (4) or (c)(13), or sections of the Agreement State or Licensing State regulations equivalent to these paragraphs, do not apply to the particular device, these paragraphs may be omitted.
2.	A copy of 1200-02-10-.26, 1200-02-05-.140 and 1200-02-05-.141	A copy of 10 CFR §§31.2, 30.51, 20.2201, and 20.2202 or the Agreement State or Licensing State regulations equivalent to these NRC regulations
3.	A list of services that may only be performed by a specific licensee;	
4.	Information on acceptable disposal options including estimated costs of disposal;	
5.	A statement that regulatory agencies may issue citations and civil penalties for improper disposal;	

(Rule 1200-02-10-.13, continued)

6. The name or title, address, and phone number of the person at the appropriate regulatory agency from whom additional information may be obtained;

(h) An alternative approach to informing customers may be proposed by the licensee for approval by the Division.

(i) Each device that is transferred one year after the effective date of this rule or later shall meet the labeling requirements in subparagraphs 1200-02-10-.13(5)(b), (c) and (d).

(j) Each person licensed under 1200-02-10-.13(5) to distribute devices to generally licensed persons shall:

1. Report to the Division, at its offices located at the address in Rule 1200-02-04-.07, all transfers of such devices to persons for use under the general license in 1200-02-10-.10(2).

2. 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.

3. Report to the responsible Agreement or Licensing State agency all transfers of devices manufactured and distributed pursuant to 1200-02-10-.13(5) for use under a general license in that state's regulations equivalent to 1200-02-10-.10(2).

4. Reports required by parts (5)(j)1., 2., and 3. shall identify:

(i) Each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

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

(iii) The date of transfer;

(iv) The type, model number and serial number of the device transferred; and

(v) The quantity and type of radioactive material contained in the device.

5. 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 the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

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

(Rule 1200-02-10-.13, continued)

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

8. The report shall cover each calendar quarter, shall be filed within 30 days of the end of the calendar quarter, and shall clearly indicate the period covered by the report.

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

10. If no transfers have been made to or from persons generally licensed under 1200-02-10-.10(2) during the reporting period, the report shall so indicate.

11. Keep records showing the name, address of use, and responsible individual 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 1200-02-10-.10(2) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records shall show the date of each transfer, the model number, serial number and the isotope and quantity of radioactivity in each device transferred, the identity of any intermediate person(s), and compliance with the report requirements of this subparagraph. The records required by this part (5)(j)11. shall be maintained for a period of three (3) years from the date of the recorded event.

(6) *The use of sealed sources in industrial radiography.* In addition to the requirements set forth in 1200-02-10-.12, a specific license for use of sealed sources in industrial radiography will be issued only if:

(a) The applicant will have a program for training radiographers and radiographer's assistants and submits to the Division for approval a schedule or description of such program which specifies the:

1. Initial training:

(i) This initial training will consist of a complete training program as outlined in 1200-02-08-.07; or

(ii) Resumes of prior training and experience of individuals that show fulfillment of the requirements of 1200-02-08-.07(7)(a) and (b) and the program for the initial training of such individuals in the licensee's or registrant's specific industrial radiography program as outlined in 1200-02-08-.07(7)(c), (d) and (e);

2. Periodic training;

3. On-the-job training;

4. Means to be used by the applicant to determine the radiographer's knowledge and understanding of and ability to comply with Division regulations and licensing requirements and the operating and emergency procedures of the applicant; and

5. Means to be used by the applicant to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(b) The applicant has established and submits to the Division for approval written operating and emergency procedures as described in 1200-02-08-.05(2);

(c) The applicant will have an internal inspection system to assure that Division regulations, 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 inspections at intervals not to exceed three (3) months and the retention of records of such inspections for inspection by the Division.

(d) The applicant submits to the Division a description of his overall organizational structure pertaining to the radiography program, including specified delegations of authority and responsibility for operation of the program; and

(e) The applicant who desires to conduct his own leak tests must establish procedures to be followed in testing sealed sources for possible leakage and contamination and submit to the Division for approval a description of such procedures including:

1. Instrumentation to be used;

2. Method of performing tests, *e.g.*, points on equipment to be smeared and method of taking smear; and

3. Pertinent experience of the person who will perform the test.

(7) *Multiple quantities or types of radioactive materiel for use in processing.* In addition to the requirements set forth in 1200-02-10-.12, 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[8]:

(a) The applicant's staff has experience in the use of radioisotopes for processing and distribution; and

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

(8) *Introduction of radioactive material into products in exempt concentrations.* In addition to the requirements set forth in 1200-02-10-.12, 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 1200-02-10-.04(1)(a) will be issued only if:

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

[8] *Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by product 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, DC 20555.*

(Rule 1200-02-10-.13, continued)

(b) The applicant provides assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule RHS 8-4, that reconcentration of the radioactive material in concentrations exceeding those in Schedule RHS 8-4 is not likely, that lower concentrations cannot be used, 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. Each person licensed under this paragraph (8), shall file an annual report with the Division which shall identify 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 at the time of introduction, the type and quantity of radioactive material introduced into each product or material, and the initial concentrations of radioactive material in the product or material at the tie of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to this paragraph (8) during the reporting period, the report shall so indicate. The report shall be submitted within 30 days after the end of each calendar year.

(9) *Radioactive material in luminous safety devices for use in aircraft.* In addition to the requirements set forth in 1200-02-10-.12, a specific license to manufacture, assemble, repair, or distribute to persons generally licensed under 1200-02-10-.10(3) luminous safety devices containing radioactive materials for use in aircraft will be issued only if the requirements of Sections 32.53, 32.54, 32.55,32.56 and 32.101 of 10 CFR Part 32 or their equivalent are met.

(10) Manufacture, preparation or transfer for commercial distribution of radiopharmaceuticals containing radioactive material for medical use ~~under group licenses~~.

(a) ~~In addition to the requirements set forth in 1200-2-10-.12, a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 1200-2-10-.14 for uses listed in Group I, Group II, Group IV, or Group V or 1200-2-10-.14(6) will be issued only if:~~ An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons authorized pursuant to 1200-02-07 will be approved if:

1. ~~The requested site for manufacture and/or distribution of radiopharmaceuticals is located within Tennessee;~~ the applicant satisfies the general requirements specified in 1200-02-10-.12;

2. 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;~~ the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug;

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

(iii) Licensed as a pharmacy by the Tennessee Board of Pharmacy.

3. The applicant submits information on the radionuclide; chemical and physical form; packaging including maximum activity per vial, syringe, generator or other container of the radioactive drug; and shielding provided by the packaging of the radioactive material for safe handling and storage of radiopharmaceuticals by ~~group~~ medical use licensees; and

(Rule 1200-02-10-.13, continued)

4. 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 shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half–life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by subpart (a)2(iii) of this paragraph:

1. May prepare ~~radioactive drugs~~ radiopharmaceuticals for medical use, as defined in subparagraph ~~1200–2–4–.04(o)~~ 1200-02-07-.05, provided that the ~~radioactive drug~~ radiopharmaceuticals are prepared by either an authorized nuclear pharmacist, as specified in parts 2 and ~~3~~ 4 of this subparagraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in 1200-02-07-.19.

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in subparagraph ~~1200–2–4–.04(1)(e),~~ 1200-02-07-.05(4),

(ii) This individual meets the requirements specified in ~~part 1200–2–10–.35(1)(a)2~~ 1200-02-07-.25(2) and 1200-02-07-.27, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with part 4 of this subparagraph.

3. The actions authorized in parts 1 and 2 of this subparagraph are permitted in spite of more restrictive language in license conditions.

4. May designate a pharmacist (as defined in ~~subparagraph 1200–2–4–.04(1)(e)~~ paragraph 1200-02-07-.05(23)) as an authorized nuclear pharmacist if the individual is identified as of {April 18, 2002}, as an 'authorized user' on a nuclear pharmacy license issued by the Division under this chapter.

5. Shall provide to the Division a copy of each individual's:

(i) Certification by ~~the Board of Pharmaceutical Specialties,~~ a specialty board whose certification process has been recognized by the Division, U.S. Nuclear Regulatory Commission or an Agreement State ~~license~~ as specified in 1200-02-07-.25(1) with the written attestation signed by a preceptor as required by 1200-02-07-.25(2)(b); or

(Rule 1200-02-10-.13, continued)

(ii) The Division, U.S. Nuclear Regulatory Commission or other Agreement State license; or

(iii) The permit issued by a licensee of broad scope; and

(iv) State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to subparts 2(i) and (iii) of this subparagraph, the individual to work as an authorized nuclear pharmacist.

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

1. 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

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

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

(11) Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. In addition to the requirements set forth in 1200-02-10-.12, a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to ~~1200-2-10-.14~~ 1200-02-07 will be issued only if[9]:

(a) The requested site for manufacture and/or distribution of generators or reagent kits is located within this State;

(b) The applicant submits evidence that:

1. 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 United States Food and Drug Administration (FDA), a biologic product license issued by FDA or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA; or

2. 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;

(c) 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 kit;

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[9] *Although the Department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have reagent kits approved by the Department for use by persons licensed pursuant to ~~1200-2-10-.14 for Group III~~ 1200-02-07 may submit the pertinent information specified in this paragraph (10).*

(Rule 1200-02-10-.13, continued)

(d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity and date of assay;

(e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

1. 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

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Division pursuant to ~~1200-2-10-.14, Group III~~ 1200-02-07 of these regulations, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; and

(f) The labels, leaflets or brochures required by (d) and (e) of this paragraph are in addition to the labeling required by the FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(12) Manufacture and distribution of sources or devices containing radioactive material for medical uses. In addition to the requirements set forth in 1200-02-10-.12, ~~a specific license to manufacture and distribute sources or devices containing radioactive material to persons licensed pursuant to 1200-2-10-.14 for use as a calibration or reference source or for uses listed in Group VI of 1200-2-10-.14(6) will be issued only if:~~ an application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under 1200-02-07 of these regulations for use as a calibration, transmission, or reference source or for the uses listed in 1200-02-07-.51, 1200-02-07-.61, 1200-02-07-.63, and 1200-02-07-.81 will be approved if:

(a) The ~~requested site for manufacture and/or distribution of sources and devices is located within this State;~~ applicant satisfies the general requirements in 1200-02-10-.12 of these regulations.

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

1. The radioactive material contained, its chemical and physical form and amount;

2. Details of design and construction of the source or device;

3. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered;

4. For devices containing radioactive material, the radiation profile of a prototype device;

5. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

6. Procedures and standards for calibrating sources and devices;

7. Legend and methods for labeling sources and devices as to their radioactive content; and

8. Instructions for handling and storing the source or device for radiation safety; these instructions are to be included on a durable label attached to the source or

(Rule 1200-02-10-.13, continued)

device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the ~~(name of source or device) is licensed by the Division for distribution to persons licensed pursuant to 1200-2-10-.14, Group VI, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; provided that such labeling for sources that do not require long term storage (e.g., gold seeds) may be on a leaflet or brochure that accompanies the source; and~~ Division has approved distribution of the (name of the source or device) to persons licensed to use radioactive material identified in 1200-02-07-.31, 1200-02-07-.51, 1200-02-07-.61, and 1200-02-07-.63 as appropriate, and to persons who hold an equivalent license issued by the U.S. NRC or an Agreement State.

(d) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six (6) months, the applicant shall include in his application information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source. In determining the acceptable interval for test of leakage of radioactive material, the Division will consider information that includes, but is not limited to:

1. Primary containment (source capsule);

2. Protection of primary containment;

3. Method of sealing containment;

4. Containment construction materials;

5. Form of contained radioactive material;

6. Maximum temperature withstood during prototype tests;

7. Maximum pressure withstood during prototype tests;

8. Maximum quantity of contained radioactive material;

9. Radiotoxicity of contained radioactive material; and

10. Operating experience with identical sources or devices or similarly designed and constructed devices;

(13) *Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.* In addition to the requirements set forth in 1200-02-10-.12, a specific license to manufacture or distribute radioactive material for use under the general license of 1200-02-10-.10(7) will be issued only if:

(a) The radioactive material is to be prepared for distribution in prepackaged units of:

1. Iodine-125 in units not exceeding 10 microcuries each.

(Rule 1200-02-10-.13, continued)

2. Iodine-131 in units not exceeding 10 microcuries each.

3. Carbon-14 in units not exceeding 10 microcuries each.

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

5. Iron-59 in units not exceeding 20 microcuries each.

6. Cobalt-57 in units not exceeding 10 microcuries each.

7. Selenium-75 in units not exceeding 10 microcuries each.

8. Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(b) Each prepackaged unit bears a durable, clearly visible label:

1. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-131, iodine-125, cobalt-57, selenium-75, or carbon-14; 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

2. Displaying the radiation caution symbol and the words, “Caution, Radioactive Material” and “Not for Internal or External Use in Humans or Animals.”

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

1. 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 of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
(Name of Manufacturer)

2. 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 a Licensing State.

_____
(Name of Manufacturer)

(Rule 1200-02-10-.13, continued)

(d) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 1200-02-05-.120.

(14) Distribution of radioactive material in exempt quantities[10].

(a) An application for a specific license to distribute NARM to persons exempt from these regulations pursuant to 1200-02-10-.04(3) will be approved if:

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

2. 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

3. The applicant submits copies of prototype labels and brochures and the Division approves such labels and brochures.

(b) The license issued under 1200-02-10-.13(14)(a) is subject to the following conditions:

1. No more than ten (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.

2. Each exempt quantity shall be separately and individually packaged. No more that 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 1200-02-10-.04(3). 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.

3. 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.”

4. In addition to the labeling information required by 1200-02-10-.13(14)(b)3, the label affixed to the immediate container, or an accompanying brochure, shall:

(i) State that the contents are exempt from Licensing State requirements;

(ii) Bear the words “Radioactive Material - Not for Human Use -Incorporation into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products

[10] *See footnote 2 of this Chapter.*

(Rule 1200-02-10-.13, continued)

Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined"; and

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

(c) Each person licensed under 1200-02-10-.13(14) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 1200-02-10-.04(3) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Division. 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 1200-02-10-.13(14) during the reporting period, the report shall so indicate.

(15) *Incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors.* An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 1200-02-10-.04(2)(i) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

(16) *Manufacture of calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 1200-02-10-.10(4).* In addition to the requirements set forth in 1200-02-10-.12, a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 1200-02-10-.10(4) will be issued only if the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent are met.

(17) Emergency preparedness.

(a) Emergency preparedness for possession of radioactive material other than uranium and plutonium.

1. In addition to the requirements set forth in 1200-02-10-.12, all specific licenses issued, or for which an initial application or an application to amend is submitted, to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Table RHS 7-2 must contain either:

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

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

2. One or more of the following factors may be used to support an evaluation submitted under (a)1(i) of this paragraph:

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

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

(Rule 1200-02-10-.13, continued)

(iii) The release fraction in the respirable size range would be lower than the release fraction shown in Table RHS 7-2 due to the chemical or physical form of the material;

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

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Table RHS 7-2;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in Table RHS 7-2; or

(vii) Other factors appropriate for the specific facility.

Table RHS 7-2 Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Radioactive material [1]	Release fraction	Quantity (curies)	Radioactive material [1]	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000	Iron-59	0.01	7,000
Americium-241	0.001	2	Krypton-85	1.0	6,000,000
Americium-242	0.001	2	Lead-210	0.01	8
Americium-243	0.001	2	Manganese-56	0.01	60,000
Antimony-124	0.01	4,000	Mercury-203	0.01	10,000
Antimony-126	0.01	6,000	Molybdenum-99	0.01	30,000
Barium-133	0.01	10,000	Neptunium-237	0.001	2
Barium-140	0.01	30,000	Nickel-63	0.01	20,000
Bismuth-207	0.01	5,000	Niobium-94	0.01	300
Bismuth-210	0.01	600	Phosphorus-32	0.5	100
Cadmium-109	0.01	1,000	Phosphorus-33	0.5	1,000
Cadmium-113	0.01	80	Polonium-210	0.01	10
Calcium-45	0.01	20,000	Potassium-42	0.01	9,000
Californium-252	0.001	9 (20 mg)	Promethium-145	0.01	4,000
Carbon-14	0.01	50,000	Promethium-147	0.01	4,000
	Non CO		Ruthenium-106	0.01	200
Cerium-141	0.01	10,000	Samarium-151	0.01	4,000
Cerium-144	0.01	300	Scandium-46	0.01	3,000
Cesium-134	0.01	2,000	Selenium-75	0.01	10,000
Cesium-137	0.01	3,000	Silver-110m	0.01	1,000
Chlorine-36	0.5	100	Sodium-22	0.01	9,000
Chromium-51	0.01	300,000	Sodium-24	0.01	10,000
Cobalt-60	0.001	5,000	Strontium-89	0.01	3,000
Copper-64	0.01	200,000	Strontium-90	0.01	90
Curium-242	0.001	60	Sulfur-35	0.5	900
Curium-243	0.001	3	Technetium-99	0.01	10,000
Curium-244	0.001	4	Technetium-99m	0.01	400,000
Curium-245	0.001	2	Tellurium-127m	0.01	5,000
Europium-152	0.01	500	Tellurium-129m	0.01	5,000
Europium-154	0.01	400	Terbium-160	0.01	4,000
Europium-155	0.01	3,000	Thulium-170	0.01	4,000
Germanium-68	0.01	2,000	Tin-113	0.01	10,000
Gadolinium-153	0.01	5,000	Tin-123	0.01	3,000
Gold-198	0.01	30,000	Tin-126	0.01	1,000
Hafnium-172	0.01	400	Titanium-44	0.01	100
Hafnium-181	0.01	7,000	Vanadium-48	0.01	7,000
Holmium-166m	0.01	100	Xenon-133	1.0	900,000
Hydrogen-3	0.5	20,000	Yttrium-91	0.01	2,000
Iodine-125	0.5	10	Zinc-65	0.01	5,000
Iodine-131	0.5	10	Zirconium-93	0.01	400
Indium-114m	0.01	1,000	Zirconium-95	0.01	5,000
Iridium-192	0.001	40,000	Any other beta-gamma emitter	0.01	10,000
Iron-55	0.01	40,000	Mixed fission products	0.01	1,000

(Rule 1200-02-10-.13, continued)

Mixed corrosion products	0.01	10,000	Packaged mixed waste, beta-gamma[2]	0.001	10,000
Contaminated equipment beta-gamma	0.001	10,000	Any other alpha emitter	0.001	2
Irradiated material, any form other than			Contaminated equipment, alpha	0.0001	20
solid noncombustible	0.01	1,000	Packaged waste, alpha[2]	0.0001	20
Irradiated material, solid noncombustible	0.001	10,000	Combinations of radioactive materials listed above [1]		
Mixed radioactive waste, beta-gamma	0.01	1,000			

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Table RHS 7-2 exceeds one.

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

(b) Emergency preparedness for possession of uranium hexafluoride.

1. In addition to the requirements set forth in 1200-02-10-.12, all specific licenses to possess uranium hexafluoride in excess of 50 kilograms in a single container or 1000 kilograms total must contain either:

   (i) An evaluation showing that the maximum intake of uranium by a member of the public due to a release would not exceed 2 milligrams; or

   (ii) An emergency plan for responding to the radiological hazards of an accidental release of source material and to any associated chemical hazards directly incident thereto.

2. One or more of the following factors may be used to support an evaluation submitted under (b)1(i) of this paragraph:

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

   (ii) Facility design or engineered safety features in the facility would reduce the amount of the release; or

   (iii) Other factors appropriate for the specific facility.

(c) Emergency preparedness for possession of plutonium.

1. In addition to the requirements set forth in 1200-02-02-.12, all specific licenses to possess plutonium in excess of 2 curies in unsealed form or on foils or plated sources must contain either:

   (i) An evaluation showing that the maximum dose to a member of the public offsite due to a release of plutonium would not exceed 1 rem effective dose equivalent, or

   (ii) An emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards directly incident thereto.

2. One or more of the following factors may be used to support an evaluation submitted under (c)1(i) of this paragraph:

   (i) The plutonium is physically separated so that only a portion could be involved in an accident;

   (ii) All or part of the plutonium is not subject to release during an accident because of the way it is stored or packaged;

(Rule 1200-02-10-.13, continued)

(iii) In the case of fires or explosions, the release fraction would be lower than 0.001 due to the chemical or physical form of the material;

(iv) The solubility of the material released would reduce the dose received;

(v) The facility design or engineered safety features in the facility would cause the release fraction to be lower than 0.001;

(vi) Operating restrictions or procedures would prevent a release large enough to cause a member of the public offsite to receive a dose exceeding 1 rem effective dose equivalent; or

(vii) Other factors appropriate for the specific facility.

(d) An emergency plan for responding to a release of radioactive material submitted under (a)1.(ii), (b)1.(ii) or (c)1.(ii) of this paragraph 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 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 radioactive materials 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 onsite, 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 material.

7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Division of Radiological Health; 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 offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated, injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Division of Radiological Health immediately after notification of the offsite response organizations and not later that one hour after the licensee declares an emergency. [11]

[11] *These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right–to–Know Act of 1986, Title III, Public Law ~~99-4~~ ~~99~~ 99–499 or other state or federal reporting requirements.*

(Rule 1200-02-10-.13, continued)

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 offsite response organizations and to the Division of Radiological Health.

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

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

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

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, Public Law 99-499, if applicable to the applicant's activities at the proposed place of the use of the source material.

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

(f) Licensees required to submit emergency plans by this paragraph shall follow the emergency plan approved by the Division of Radiological Health. The licensee may change the plan without Division of Radiological Health approval if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Division of Radiological Health and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without application to and prior approval by the Division of Radiological Health.

Authority: *T.C.A. §§4-5-201 et seq., 68-202-201 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed March 31, 1992; effective May*

(Rule 1200-02-10-.13, continued)

15, 1992. Amendment filed July 18, 2002; effective October 1, 2002. Amendments filed November 17, 2005; effective January 31, 2006. Amendment filed March 12, 2007; effective May 26, 2007. Amendments filed December 21, 2009; effective March 21, 2010.

1200-02-10-.14 REPEALED ~~SPECIFIC LICENSES FOR CERTAIN GROUPS OF MEDICAL USES OF RADIOACTIVE MATERIAL.~~

~~(1) Subject to provisions of (2), (3), (4), and (5) of this rule, an application for a specific license pursuant to 1200-2-10-.13(1), (2), or (3) for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of (6) of this rule will be approved for all of the uses within the group or groups that include the use or uses specified in the application if:~~

~~(a) The applicant satisfies the requirements of 1200-2-10-.13(1), (2), or (3);~~

~~(b) The applicant, or the physician designated in the application as the individual user, has clinical experience as outlined in Rule 1200-2-10-.33 in the types of uses included in the group or groups;~~

~~(c) The applicant or the physician designated in the application as the individual user and all other personnel who will be involved in the preparation and use of the radioactive material have training and experience in the handling of radioactive material in the uses included in the group or groups;~~

~~(d) The applicant will have radiation detection and measuring instrumentation for conducting the procedures involved in the uses included in the group or groups; and~~

~~(e) The applicant has radiation safety operating procedures for handling and disposal of the radioactive material involved in the uses included in the group or groups.~~

~~(2) Any licensee who is authorized to use radioactive material pursuant to one or more groups in (1) and (6) of this rule is subject to the following conditions:~~

~~(a) For Groups I, II, IV and V no licensee shall receive, posses or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged and distributed in accordance with:~~

~~1. A specific license issued to the manufacturer by the Division pursuant to 1200-2-10-.13(10); or~~

~~2. A specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission pursuant to §32.72 of 10 CFR Part 32, an Agreement State or a Licensing State pursuant to equivalent licensing requirements;~~

~~(b) For Group III~~

~~1. No licensee shall receive, possess or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:~~

~~(i) Reagent kits not containing radioactive material that are approved by the Division, U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State for use by persons licensed pursuant to this rule for Group III or equivalent regulations;~~

(Rule 1200-02-10-.13, continued)

(ii) Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged and distributed in accordance with a specific license issued by the Division pursuant to 1200-2-10-.13(11), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to §32.73 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulation.

2. Any licensee who uses generators or reagent kits shall:

(i) Elute the generator or process radioactive material with the reagent kit in accordance with instructions approved by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit;

(ii) Before administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;

(iii) Prohibit the administration to patients of technetium-99m containing more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m, or more than five (5) microcuries of molybdenum-99 per administered dose, at the time of administration; and

(iv) Maintain records of the molybdenum-99 test conducted on each elution for inspection by the Division.

(c) For Group VI

1. No licensee shall receive, possess or use radioactive material except as contained in a sealed source or device that has been manufactured, labeled, packaged and distributed in accordance with:

(i) A specific license issued by the Division pursuant to 1200-2-10-.13(12);

(ii) A specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission pursuant to §32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an Agreement State or Licensing State pursuant to equivalent regulation.

2. Any licensee who possesses and uses sources or devices containing radioactive material shall:

(i) Cause each sealed source or device containing more than one hundred (100) microcuries of radioactive material with a half-life greater than 30 days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination and/or leakage at intervals not to exceed six (6) months or at such other intervals as are approved by the Division, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State and described by the manufacturer on the label attached to the source, device or permanent container thereof, or in a leaflet or brochure that accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnished a certificate that the

source or device has been so tested within six (6) months prior to the transfer;

(ii) Assure that the test required by 1200-2-10-.14(2)(c)2(i) shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Division;

(iii) If the test required by 1200-2-10-.14(2)(c)2.(i), reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours, immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Division regulations. A report shall be filed with the Division, at the address in Rule 1200-2-4-.07, within five (5) days of the test ; the report shall describe the equipment involved, the test results, and the corrective action taken;

(iv) Follow the radiation safety and handling instructions approved by the Division, the U.S. Nuclear Regulatory Commission, or another Agreement State and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in a leaflet or brochure that accompanies the source or device, and maintain such instruction in a legible and available form;

(v) Maintain a written accountability of the issue from storage and return to storage of all sealed sources. This record shall include but is not limited to the following information: dates, number of sealed sources, location of use, quantity of radioactive material in each sealed source and signature of individual(s) involved in each removal from and each return to storage;

(vi) Conduct a physical inventory at least quarterly to account for all sealed sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Division and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of inventory;

(vii) Assure that sealed sources or standard medical applicator cells containing cobalt-60 as wire are not opened while in the licensee's possession unless specifically authorized by a license issued by this Division;

(viii) Release of individuals treated with temporary implants.

(I) Immediately after removing the last temporary implant source from an individual, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care an individual treated by temporary implant until all sources have been removed.

(Rule 1200-02-10-.13, continued)

(II) A licensee shall retain a record of surveys for three (3) years. Each record shall include the date of the survey, the name of the individual, the dose rate from the individual expressed as millirem per hour and measured at 1 meter from the individual, the survey instrument used, and the initials of the individual who made the survey; and

(ix) Comply with the provisions of 1200-2-7-.03(3) and (4).

(d) For Groups I, II, and III any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

1. Chemical and physical form;

2. Route of administration; and

3. Dosage range.

(e) For groups IV, V and VI. Release of individuals containing radiopharmaceuticals or permanent implants.

1. The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

2. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(i) Guidance on the interruption or discontinuation of breast-feeding and

(ii) Information on the consequences of failure to follow the guidance.

3. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three (3) years after the date of release, if the total effective dose equivalent is calculated by:

(i) Using the retained activity rather than the activity administered,

(ii) Using an occupancy factor less than 0.25 at 1 meter,

(iii) Using the biological or effective half-life, or

(iv) Considering the shielding by tissue.

4. The licensee shall maintain a record, for three (3) years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

(Rule 1200-02-10-.13, continued)

~~(3) Any licensee who is licensed pursuant to 1200-2-10-.14(1) for one or more of the medical use groups in this rule is authorized, subject to the provisions of paragraphs (3) and (4), to receive, possess and use for calibration and reference standards:~~

~~(a) Any radioactive material listed in Group I, Group II or Group III of (6) of this rule with a half-life not longer than 100 days in amounts not to exceed 15 millicuries total;~~

~~(b) Any radioactive material listed in Group I, Group II or Group III of (6) of this rule with a half-life greater than 100 days in amounts not to exceed 200 microcuries total;~~

~~(c) Technetium-99m in amounts not to exceed 30 millicuries;~~

~~(d) Any radioactive material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged and distributed in accordance with:~~

~~1. A specific license issued by the Division pursuant to 1200-2-10-.13(12);~~

~~2. A specific license issued by the U.S. Nuclear Regulatory Commission pursuant to §32.74 of 10 CFR Part 32; or~~

~~3. A specific license issued to the manufacturer by an Agreement State or Licensing State pursuant to equivalent regulations.~~

~~(4) Any licensee who possesses sealed sources as calibration or reference sources pursuant to 1200-2-10-.14(3) shall:~~

~~(a) Cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than thirty days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be used until tested, provided, however, that no leak tests are required when:~~

~~1. The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material; or~~

~~2. The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within six (6) months prior to the date of use or transfer;~~

~~(b) Assure that the leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Division;~~

~~(c) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Division regulations. A report shall be filed within five (5) days of the test with the Division describing the equipment involved, the test results and the corrective action taken.~~

~~(5) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to 1200-2-10-.14(3)(d) shall:~~

(a) Follow the radiation safety and handling instructions approved by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and available form; and

(b) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Division and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

(6) Groups of medical uses of radioactive material.

(a) Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include uses involving imaging and tumor localization.

1. Iodine-123 as sodium iodide;

2. Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid or sodium iothalamate;

3. Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate;

4. Cobalt-57 as labeled cyanocobalamin;

5. Cobalt-58 as labeled cyanocobalamin;

6. Cobalt-60 as labeled cyanocobalamin;

7. Chromium-51 as sodium chromate or labeled human serum albumin;

8. Potassium-42 as chloride;

9. Sodium-24 as chloride;

10. Iron-59 as citrate;

11. Technetium-99m as pertechnetate; and

12. Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

(b) Group II. Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies.

1. Iodine-131 as sodium iodide, iodinated human serum albumin, macro-aggregated iodinated human serum albumin, colloidal (micro-aggregated) iodinated human serum albumin, rose bengal or sodium iodohippurate;

2. Iodine-125 as sodium iodide or fibrinogen;

(Rule 1200-02-10-.13, continued)

3. Iodine-123 as sodium iodide;

4. Chromium-51 as human serum albumin;

5. Fluorine-18 in solution;

6. Gallium-67 as citrate;

7. Gold-198 in colloidal form;

8. Mercury-197 as chlormerodrin;

9. Mercury-203 as chlormerodrin;

10. Selenium-75 as selenomethionine;

11. Strontium-85 as nitrate;

12. Strontium-87m as chloride;

13. Technetium-99m as pertechnetate, sulfur colloid or macro-aggregated human serum albumin;

14. Thallium-201 as chloride;

15. Ytterbium-169 as pentatate sodium;

16. Indium-113m as chloride;

17. Any radiopharmaceutical prepared from a reagent kit listed in (c)3. of this paragraph; and

18. Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging or localizing for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

(c) Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals for certain diagnostic studies.

1. Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate;

2. Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (c)3. and (c)5. of this subparagraph;

3. Reagent kits for preparation of technetium-99m labeled:

(i) Sulfur colloid;

(ii) Pentatate sodium;

(iii) Etidronate sodium;

(iv) Human serum albumin;

(v) Human serum albumin microspheres;

(vi) Polyphosphates;

(vii) Macroaggregated human serum albumin;

(viii) Medronate sodium;

(ix) Stannous pyrophosphate;

(x) Gluceptate sodium;

(xi) Oxidronate sodium;

(xii) Disofenin;

(xiii) Succimer.

4. Tin-113/indium-113m generators for the elution of indium-113m as chloride; and

5. Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

(d) Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety:

1. Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction;

2. Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases;

3. Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

4. Any therapeutic material in a radiopharmaceutical for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

(e) Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety:

1. Gold-198 as colloid for intracavitary treatment of malignant effusions;

2. Iodine-131 as iodide for treatment of thyroid carcinoma;

3. Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

(f) Group VI. Use of sealed sources and devices containing radioactive material for certain medical uses:

(Rule 1200-02-10-.13, continued)

~~1. Americium-241 as a sealed source in a device for bone mineral analysis;~~

~~2. Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

~~3. Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

~~4. Gold-198 as seeds for interstitial treatment of cancer;~~

~~5. Iodine-125 as a sealed source in a device for bone mineral analysis;~~

~~6. Iridium-192 as seeds encased in a nylon ribbon for interstitial treatment of cancer;~~

~~7. Strontium-90 sealed in an applicator for treatment of superficial eye condition;~~

~~8. Radon-222 as seeds for interstitial treatment of cancer;~~

~~9. Radium-226 encased in needles, applicator cells, and plaques for topical, interstitial and intracavitary treatment of cancer; and~~

~~10. Iodine-125 as seeds for interstitial treatment of cancer.~~

Authority: *T.C.A. §§4-5-201 et seq., 68-23-101 et seq., 68-202-201 et seq., 68-202-203, and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed July 18, 2002; effective October 1, 2002. Amendment filed November 17, 2005; effective January 31, 2006. Repeal filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.15 ISSUANCE OF SPECIFIC LICENSES.

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

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

(a) Protect the public health and safety or property;

(b) Require such reports and the keeping of such records, and to provide for such inspection of activities under the license as may be necessary to evaluate activities conducted under the license; and

(c) Prevent loss or theft of material subject to this Chapter.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.16 SPECIFIC TERMS AND CONDITIONS OF LICENSES.

(1) Each license issued pursuant to this Chapter shall be subject to all provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Division.

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

(3) Each person licensed by the Division pursuant to this Chapter shall confine has use and possession of the material licensed to the locations and purposes authorized in the license.

(4) Each licensee authorized under 1200-02-10-.13(5) to distribute certain devices to generally licensed persons shall:

(a) Report to the Division within 30 days after the end of each calendar quarter all transfers of such devices to persons generally licensed under 1200-02-10-.10(2) or, if no transfers have been made during the reporting period, the report shall so indicate. For all transfers the 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 Division and the general licensee, the type and model number of device transferred and the quantity and type of radioactive material contained in the device; and

(b) Furnish to each general licensee in this State to whom he transfers such device a copy of the general license contained in 1200-02-10-.10(2).

(5) Each specific licensee shall notify the Division in writing when the licensee decides to permanently discontinue all activities involving radioactive materials authorized under the license.

(6) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generator shall test the generator eluates for molybdenum-99 breakthrough in accordance with ~~1200-2-10-.14(2)(b)2~~ 1200-02-07-.41.

(7) Each specific licensee and each general licensee meeting the criteria of part ~~1200-2-10-.10(2)(b)14~~ 1200-02-10-.10(2)(c)14 shall:

(a) Provide the Division written notification, at the address in Rule 1200-02-04-.07, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.):

1. By or against the licensee;

2. By or against 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

3. By or against an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee;

(b) Include in the notification required in (7)(a) of this rule the bankruptcy court in which the petition for bankruptcy was filed; and

(c) Include in the notification required in (7)(a) of this rule the date of the filing of the petition.

(8) When temporary job-sites are authorized on a specific license, radioactive material may be used at temporary job-sites, in areas not under exclusive federal jurisdiction, throughout the State of Tennessee.

(Rule 1200-02-10-.16, continued)

Authority: *T.C.A. §68-202-101 et seq., 68-202-203, 68-202-206 and 4-5-202.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed May 5, 1988; effective August 29, 1988. Amendment filed July 18, 2002; effective October 1, 2002. Amendment filed November 17, 2005; effective January 31, 2006. Amendment filed March 12, 2007; effective May 26, 2007. Amendments filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.17 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDINGS OR OUTDOOR AREAS.

(1) Expiration of specific licenses. Except as provided in 1200-02-10-.17(2), each specific license shall expire at the end of the day, in the month and year stated therein.

(2) Termination of specific licenses:

(a) Specific licenses shall continue in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Division 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 Division requirements.

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

1. The licensee has properly disposed of radioactive material;

2. The licensee has made reasonable effort to eliminate residual radioactive contamination, if present;

3. The premises are suitable for release in accordance with Division requirements. The licensee may demonstrate suitability for release by:

(i) Performance of the radiation survey described in 1200-02-10-.17(3)(d)2, or

(ii) Submission of other information that the Division determines is acceptable;

4. The licensee has complied with any requests for information from the Division; and

5. The licensee has submitted a written request for license termination to the Division.

(3) Decommissioning of sites or separate buildings or outdoor areas:

(a) Each specific licensee shall notify the Division in writing, at the address in 1200-02-04-.07, within 60 days of any of the following occurrences:

1. The license has expired pursuant to 1200-02-10-.17(2);

2. The licensee has decided to permanently cease principal activities, as defined in this rule:

(i) At the entire site, or

(ii) 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 Division requirements;

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

4. No principal activities have been conducted for 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 Division requirements.

(b) Each specific licensee:

1. If not required by 1200-02-10-.17(3)(g) to submit a decommissioning plan, shall begin decommissioning its site or any separate building or outdoor area that contains residual radioactivity within 60 days of any occurrence listed in 1200-02-10-.17(3)(a).

2. If required by 1200-02-10-.17(3)(g) to submit a decommissioning plan, shall:

(i) Submit a decommissioning plan within 12 months of notification of any occurrence listed in 1200-02-10-.17(3)(a), and

(ii) Begin decommissioning upon Division approval of that plan.

(c) Coincident with the notification required by 1200-02-10-.17(3)(a), the specific licensee shall maintain in effect all financial assurances that were established, pursuant to 1200-02-10-.12(3) in conjunction with a license issuance or renewal, or that are required by this rule.

1. The Division will determine if the licensee shall increase, or may decrease, the amount of the financial assurance to cover the detailed cost estimate for decommissioning established pursuant to 1200-02-10-.17(3)(i)5.

2. The licensee may with Division approval reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site.

(d) As the final steps in decommissioning, specific licensees shall:

1. Certify the disposition of all licensed material, including accumulated wastes; and

2. Demonstrate that the premises are suitable for release in accordance with Division requirements.

(i) The licensee shall:

(I) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, o

(II) Submit other information that the Division determines is acceptable.

(Rule 1200-02-10-.17, continued)

(ii) The licensee shall, as appropriate:

(I) Report levels of gamma radiation in units of microroentgens (millisieverts) per hour at 1 meter from surfaces, and

(II) Report levels of radioactivity, including alpha and beta, in units of

I. Disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters — removable and fixed — for surfaces,

II. Microcuries (megabecquerels) per milliliter for water, and

III. Picocuries (becquerels) per gram for solids such as soils or concrete, and

(III) Specify the survey instrument(s) used and certify that each instrument was properly calibrated and tested at the time of the survey.

(e) Except as provided in 1200-02-10-.17(3)(k)(3), specific licensees shall complete decommissioning of the site or separate building or outdoor area so that the site, building or outdoor area is suitable for release in accordance with Division requirements as soon as practicable but no later than 24 months following the initiation of decommissioning.

(f) Except as provided in 1200-02-10-.17(3)(k)(3), when decommissioning involves the entire site, the specific licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(g) A specific licensee shall submit a decommissioning plan if:

1. Required to do so by license condition; or

2. The Division determines that the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Division and that these procedures could increase potential health and safety impacts to workers or to the public. Some examples are procedures

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

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

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

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

(h) Specific licensees shall not carry out procedures with potential health and safety impacts before Division approval of the decommissioning plan.

(Rule 1200-02-10-.17, continued)

(i) The proposed decommissioning plan for the site or separate building or outdoor area shall include:

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

2. A description of planned decommissioning activities;

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

4. A description of the planned final radiation survey;

5. A detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for financial assurance, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

6. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 1200-02-10-.17(3)(k)(3).

(j) The Division will approve the proposed decommissioning plan if the information in the plan demonstrates that the licensee:

1. Will complete decommissioning as soon as practicable; and

2. Will adequately protect the health and safety of workers and the public.

(k) Requests for extensions:

1. A licensee may request a delay in initiating decommissioning.

(i) The Division may grant this delay, if the Division determines that this delay is not detrimental to the public health and safety and is otherwise in the public interest.

(ii) The request for a delay shall be submitted no later than 30 days before notification pursuant to 1200-02-10-.17(3)(a).

(iii) The schedule for decommissioning set forth in 1200-02-10-.17(3)(b) shall not start until the Division has made a determination on the request.

2. A licensee may request an alternative schedule for the submittal of a decommissioning plan. The Division may approve the alternative schedule, if the Division determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

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

(i) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(Rule 1200-02-10-.17, continued)

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

(iii) Whether allowing short-lived radionuclides to decay will achieve a significant volume reduction in wastes requiring disposal;

(iv) Whether allowing short-lived radionuclides to decay will achieve a significant reduction in radiation exposure to workers;

(v) Other site-specific factors that the Division may determine are beyond the control of the licensee.

Authority: *T.C.A. §§4-5-201 et seq., 68-202-201 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed March 12, 2007; effective May 26, 2007.*

1200-02-10-.18 RENEWAL OF LICENSE.

(1) Applications for renewal of specific licenses shall be filed in accordance with 1200-02-10-.11.

(2) 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 the application has been finally determined by the ~~Divisionepartment~~ Division.

Authority: *T.C.A. §68-23-101 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.19 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE. Applications for amendment of a license shall be filed in accordance with 1200-02-10-.11 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.20 DIVISION ACTION ON APPLICATION TO RENEW OR AMEND. In considering an application by a licensee to renew or amend his license, the Division will apply the criteria set forth in 1200-02-10-.12 and 1200-02-10-.13, as applicable.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.21 INALIENABILITY OF LICENSES. No license issued or granted under this Chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this Chapter 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 Division 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.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

(Rule 1200-02-10-.21, continued)

1200-02-10-.22 TRANSFER OF MATERIAL.

(1) No licensee shall transfer radioactive material except as authorized pursuant to this Rule.

(2) Any licensee may transfer radioactive material:

(a) To the Division provided such transfer is accepted by the Division in writing;

(b) To the U.S. Department of Energy;

(c) To any person exempt from the regulations in this Chapter to the extent permitted under such exemption;

(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Division, the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State; or

(e) As otherwise authorized by the Division in writing.

(3) Before transferring sources of radiation to a specific licensee of the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with or report to the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the source of radiation, the transferor of the source of radiation shall verify that the transferee's authorization is for the receipt of the type, form, and quantity of the source of radiation to be transferred.

(4) The following methods for the verification required in 1200-02-10-.22(3) are acceptable:

(a) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(b) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of the source of radiation to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(c) For emergency shipments the transferor may accept oral certification containing all of the information specified in 1200-02-10-.22(4)(b) provided that written certification is forwarded to the transferor within ten (10) days following the oral communication;

(d) The transferor may obtain other information compiled by a reporting service from official records of the Division, the U.S. Nuclear Regulatory Commission or the licensing agency of any state as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(e) When none of the methods of verification described in 1200-02-10-.22(4)(a) through (d) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Division, the U.S. Nuclear Regulatory Commission, or the licensing agency of any state that the transferee is authorized to receive the source of radiation.

(Rule 1200-02-10-.22, continued)

Authority: *T.C.A. §§4-5-201 et seq., 68-202-201 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed March 12, 2007; effective May 26, 2007.*

1200-02-10-.23 MODIFICATION, REVOCATION, AND TERMINATION OF LICENSES.

(1) The terms and conditions of all licenses may 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 or regulations issued by the Department.

(2) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act~~, or of the Act~~, or of the license, or of any rule or regulation of the Department. This action will be taken pursuant to Tennessee Code Annotated Chapter 23.

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

Authority: *T.C.A. §68-23-101 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.24 REGISTRATION.

(1) The owner or person having possession of any radiation machine or accelerator, except those specifically exempted in 1200-02-10-.07, shall register such sources within ten (10) days after acquisition of such machine. The owner or possessor of any accelerator shall substitute an application for certified registration required in Chapter 1200-02-09. The application for certified registration must be received by the Department within ten (10) days after acquisition of the accelerator; however, an accelerator may not be energized until registered pursuant to Chapter 1200-02-09. In addition, every person who provides inspections as provided for in 1200-02-10-.27(4) and every person who assembles, installs, or services radiation machines shall register with the Division of Radiological Health, Tennessee Department of Environment and Conservation. Registration under this rule shall be on Department Form RHS 8-4, Form RHS 8-4a or Form RHS 8-4b, as appropriate, as furnished by the Department and may be obtained from the Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532. A registration fee in accordance with the Classification and Fee Schedule in 1200-02-10-.24(3) shall be due upon receipt of an invoice from the Division of Radiological Health following the submittal of the completed registration form. The check for the fee shall be made payable to “Treasurer, State of Tennessee.”

(2) An annual registration fee will be due the first working day following January 1 of each year as long as the radiation machine or service is subject to registration. Each registrant shall submit the annual fee payable to, “Treasurer, State of Tennessee,” in the appropriate dollar amount in accordance with the Classification and Fee Schedule in 1200-02-10-.24(3) to the Division of Radiological Health. Payment shall be accompanied by a copy of the fee invoice properly completed. The invoice for the annual fee will be dated January 17 and will require payment by March 17 of the indicated year. At the time of the annual payment a registrant of only Class II radiation machines may request specific times or list restricted hours during normal work hours for inspections pursuant to 1200-02-10-.27 by personnel of the Division of Radiological Health, Tennessee Department of Environment and Conservation.

(Rule 1200-02-10-.24, continued)

(3) Classification and fee schedule. For purposes of inspections and payment of fees the classification and fee schedule shall be as follows:

(a) Radiation Machines

CLASS I	
Dental Radiation Machines:	$ 65.00 per tube
All diagnostic equipment used exclusively for dental diagnostic procedures.	
CLASS II	
Priority Two Medical Radiation Machines:	$ 150.00 per tube
All medical diagnostic x-ray equipment, not in Class III, used exclusively for medical or veterinary diagnostic procedures.	
CLASS III	
Priority One Medical Radiation Machines:	$ 200.00 per tube
All diagnostic x-ray equipment used in radiologists' offices, orthopedic surgeons' offices or hospitals exclusively for medical diagnostic procedures.	
CLASS IV	
Therapy Medical Radiation Machines:	$ 300.00 per tube
All x-ray equipment with energies less than 0.9 MeV used for the purpose of medical or veterinary radiation therapy.	
CLASS V	
Priority Two Industrial and Educational Radiation Machines:	$ 600.00 per tube
Closed-beam analytical radiation machines, gauges or industrial radiation machines used in shielded room or cabinet radiography.	
CLASS VI	
Priority One Industrial and Educational Radiation Machines:	$ 900.00 per tube
All x-ray machines used for industrial radiography and all open-beam analytical x-ray machines and all radiation machines not specifically included in Class I, II, III, IV, V or VII.	
CLASS VII	

(Rule 1200-02-10-.24, continued)

	Accelerators: All devices defined as accelerators as per "State Regulations for Protection Against Radiation."	$ 2,000.00 annual fee, plus an initial fee of $ 375.00 per maximum nominal rated MeV for initial certified registration review (initial review fee not to exceed $ 150,000.00)
(b)	A person providing inspection services as permitted by paragraph 1200-02-10-.27(4), except as provided by subparagraph 1200-02-10-.24(3)(f), shall pay an annual registration fee of six hundred dollars.	$ 600.00
(c)	A person providing assembly/installation/servicing, except as provided by subparagraph 1200-02-10-.24(3)(f), shall pay an annual registration fee of six hundred dollars.	$ 600.00

(d) A registrant may qualify to pay a registration fee equal to eighteen percent (18%) of that listed in this paragraph (3), subject to the following conditions:

1. All tubes subject to registration are inspected in accordance with paragraphs 1200-02-10-.27(3), (4) and (5).

   (i) For purposes of the eighteen percent (18%) fee, the first inspection performed on an x-ray tube on or after January 1, 2003, will establish a baseline date for that tube.

      (I) Each subsequent inspection of a tube shall be performed within 30 days of the appropriate anniversary of the baseline date, according to the schedule set out in 1200-02-10-.27(3)(a).

      (II) An inspection performed more than 30 days before or after the appropriate baseline date shall establish a new baseline date for that tube.

      (III) An inspection performed more than 30 days after a baseline date shall not qualify the registrant for the eighteen percent (18%) fee.

      (IV) An inspection performed more than 30 days before a baseline date and meeting all other requirements found in paragraphs 1200-02-10-.27(3), (4) and (5) shall qualify the registrant for the eighteen percent (18%) fee.

   (ii) Reserved.

2. Each newly acquired tube subject to registration is inspected within six (6) months of ownership or possession.

3. An individual who satisfies the requirements in paragraph 1200-02-10-.27(4) performs all inspections.

4. The registrant submits to the Division, at L&C Annex, 3rd Floor, 401 Church Street, Nashville, TN 37243-1532:

(Rule 1200-02-10-.24, continued)

(i) Copies of the appropriate State evaluation forms within 60 days after the inspection.

(ii) Copies of applicable service reports to document correction of any deficiencies noted within 60 days after the inspection.

(iii) A signed "X-Ray Inspection Notification and Certification of Compliance" form within 60 days of the inspection.

5. Inspections found by the Division to be unsatisfactory under this subparagraph or under paragraph 1200-02-10-.27(4) or (5) shall not qualify for the 18 percent (18%).

(i) The registrant shall correct and re-submit the report(s) and documentation of an inspection found to be unsatisfactory within 30 days of the date of notification by the Division. Failure to correct and re-submit the report(s) and documentation of an unsatisfactory inspection will subject the registrant to the Division's normal enforcement actions, penalties and assessments.

(ii) The 30-day correction period shall not establish a new baseline. It shall not

(I) Qualify an existing tube for reduced fee for the following calendar year, or

(II) Qualify a newly acquired tube for reduced fee for the current calendar year.

(e) Reserved.

(f) A person providing inspection services, as permitted by paragraph 1200-02-10-.27(4), or a person providing assembly/installation/servicing, who is a staff member of the facility registered pursuant to Tennessee Code Annotated (T.C.A.) §68-202-101 et seq. and these Regulations, and who performs such inspection services or assembly/installation/servicing only for that registrant, shall not be subject to subparagraphs (b) and (c) above.

(4) Any failure to pay an invoiced amount by the date specified on the invoice, unless qualified by 1200-02-10-.24(3)(d) above, shall be deemed to constitute a violation of *Tennessee Code Annotated* §68-203-101 *et seq*.

(5) Whenever there is a change in information such as address, ownership, possessor, or location of use from that declared on the last previous registration, the completion of a new Form RHS 8-4 shall be required within 10 days of the change.

(6) Each registrant, or his estate, who permanently discontinues the use of or transfers all of his radiation machines at an installation shall notify the Division in writing within sixty (60) days of such action. In the event of a transfer, the notification shall include the name and address of the transferee.

(6) No person shall state or imply that any activity under such a registration has been approved by the Division.

Authority: *T.C.A. §§4-5-201 et seq., 68-23-101 et seq., 68-202-101 et seq., and 68-202-201 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective*

(Rule 1200-02-10-.24, continued)

October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed January 26, 1993; effective March 12, 1993. Amendment filed October 1, 2001; effective December 15, 2001. Amendment filed October 17, 2001; effective December 31, 2001. Amendment filed September 4, 2003; effective November 18, 2003. Amendment filed November 17, 2005; effective January 31, 2006.

1200-02-10-.25 REPORTS.

(1) Any person who sells, leases, transfers, assembles, reassembles, or lends radiation machines, except those exempted from registration by 1200-02-10-.07 shall report to the Division, within thirty (30) days after the end of each calendar quarter, the name and address of persons to whom they have transferred such items and the date of transfer. Persons routinely engaged in the sale, transfer, leasing, lending, assembling, or reassembling of x-ray equipment shall report each calendar quarter, including a report for calendar quarters in which no radiation machine transfer occurs. Such reports shall be held proprietary by the Division.

(2) Each out-of-state person who brings radiation machines into the State, except those exempted in 1200-02-10-.07, for any temporary use shall:

(a) Notify the Division in writing at least three (3) days prior to engaging in such use. Such notification shall indicate the location, period, and type of proposed use within the State. If, for a specific case, the 3-day period would impose an undue hardship, he may, upon application to the Division obtain permission to proceed sooner;

(b) Register the radiation machines with this Division on Form RHS 8-4 prior to entry into the State; and

(c) Comply with all applicable regulations of the Division including the payment of the fee for the Class, as appropriate, contained in 1200-02-10-.24(3).

Authority: *T.C.A. §§68-23-101 et seq., 68-203-202 et seq., and 4-5-201.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed January 26, 1993; effective March 12, 1993.*

1200-02-10-.26 RECORDS.

~~Each licensee and registrant shall keep records showing the receipt, transfer and disposal of all sources of radiation.~~

(1) 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:

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

(b) The licensee who transferred the material shall retain each record of transfer for three years after each transfer, unless a specific requirement in another part of these rules dictate otherwise.

(c) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Division terminates each license that authorizes disposal of the material.

(2) A licensee shall retain each record that is required by these rules or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not

(Rule 1200-02-10-.26, continued)

otherwise specified by rule or license condition, the record must be retained until the Division terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3) 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. A licensee shall maintain adequate safeguards against tampering with and loss of records.

(4) 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 Division:

(a) Records of disposal of licensed material made under 1200-02-05-.121 (including burials authorized before January 28, 1981), 1200-02-05-.122, 1200-02-05-.123, 1200-02-05-.124; and

(b) Records required by 1200-02-05-.132(2)(d).

(5) If licensed activities are transferred or assigned in accordance with 1200-02-10-.16(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(a) Records of disposal of licensed material made under 1200-02-05-.121 (including burials authorized before January 28, 1981), 1200-02-05-.122, 1200-02-05-.123, 1200-02-05-.124; and

(b) Records required by 1200-02-05-.132(2)(d).

Authority: *T.C.A. §4-5-201 et seq., 68-23-101 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.27 INSPECTIONS.

(1) Each licensee or registrant shall afford the Division at all reasonable times opportunity to inspect sources of radiation, premises, facilities and activities subject of these regulations and records maintained pursuant to these regulations.

(a) Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of the regulations, license, and Certified Registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

1. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Act, these regulations, or license or Certified Registration condition, or any unnecessary exposure to radiation or radioactive material under the licensee's or registrant's control. Any such notice in writing shall comply with (2) of this Rule.

(Rule 1200-02-10-.27, continued)

2. The licensee or registrant or licensee's or registrant's representative may accompany Division inspectors during other phases of an inspection.

3. The provision of 1200-02-10-.27(1)(a)1. shall not be interpreted as authorization to disregard instructions pursuant to 1200-02-04-.12.

(b) If at the time of inspection, an individual has been authorized by the workers to represent them during inspections by the Division, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

1. Different representative of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspectors.

2. Any worker's representative shall be an employee of the licensee or registrant and should be a worker as defined in 1200-02-04-.04(1)(rrr) and shall have received instructions as specified in 1200-02-04-.12.

3. In addition to the licensee's or registrant's representative and with the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Division inspectors during the inspection of physical working conditions.

4. The workers' representative for any area containing proprietary information shall be an individual previously authorized by the licensee or registrant to enter that area.

5. Notwithstanding the other provisions of this Rule, Division inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection.

(2) Requests by Workers for Inspection.

(a) Any worker or representative of workers who believes that a violation of the Act, these regulations, conditions of a Certified Registration, or license conditions exists or has occurred in activities subject to these regulations with regard to radiological working conditions in which the worker is engaged, may request an inspection by registering a complaint of the alleged violation with the Commissioner, Tennessee Department of Environment and conservation; Director, Division of Radiological Health; or Division inspectors.

1. Any such complaint shall be in writing, shall set forth the specific grounds for the complaint and shall be signed by the worker or representative of workers.

2. A copy of the complaint shall be provided the licensee or registrant by the Division no later than at the time of inspection except that, upon request of the worker registering such complaint, his name and the name of individuals referred to therein shall not appear in such a copy or on any record published, released or made available by the Division except for good cause shown.

(Rule 1200-02-10-.27, continued)

(b) If, upon receipt of such complaint, the Division determines that the complaint meets the requirements set forth in 1200-02-10-.27(2)(a) and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection will be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this paragraph need not be limited to matters referred to in the request for an inspection.

(c) If it is determined that there are no reasonable grounds to believe that a violation exists or has occurred, the complainant shall be notified by the Division in writing.

(d) No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by these regulations.

(3) Inspections of radiation machines are to be conducted:

(a) According to Class as follows:

CLASS I - once every four (4) years

CLASSES II and V - once every two (2) years

CLASSES III, IV, VI and VII - annually

(b) By personnel of the Division of Radiological Health, Tennessee Department of Environment and Conservation, or

(c) As provided in 1200-02-10-.27(4), and

(d) According to the same criteria and to the satisfaction of the Division and provided the appropriate Division forms are completed and submitted along with any documentation required by subparagraph 1200-02-10-.24(3)(e), and

(e) By the Division of Radiological Health on a selected number of those facilities providing an inspection report as permitted by 1200-02-10-.27(4).

(4) The Division will accept, as inspections for a reduced registration fee as provided for in part 1200-02-10-.24(3)(d), inspections by individuals other than employees of the Division:

(a) Whose inspections are satisfactory to the Division;

(b) Who are registered with the Division;

(c) Who are staff inspectors, or who have paid an annual registration fee to the Division; and

(d) Who meet one set of the following criteria:

Formal Education or Certification	Plus	Experience

(Rule 1200-02-10-.27, continued)

	Formal Education or Certification	Plus	Experience
1.	Bachelor's degree in a physical science or mathematics		Four years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
2.	Bachelor's degree in a physical science or a biological science with a physical science minor and one year of graduate work in health physics		Three years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
3.	Master's degree in health physics or radiological health		Two years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
4.	Doctor's degree in health physics or radiological health		One year of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
5.	Certification by the American Board of Health Physics or by the American Board of Radiology or be a Fellow, Canadian College of Physicists in Medicine		One year of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
6.	Two (2) notarized letters of reference from persons registered to provide inspections for reduction in fees and meeting any of the above sets of criteria certifying to the individual's capabilities to perform the necessary inspections		Five years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed

(5) Inspections satisfactory to the Division. The following constitute a proper inspection and must occur:

(a) The inspection of an x-ray facility subject to registration under "State Regulations for Protection Against Radiation" shall identify the compliance status of the facility and each piece of equipment subject to registration with respect to requirements in Chapters 1200-02-04, 5, 6, 8, 9 and 10.

(b) The qualified individual performing the inspection shall record the results of the inspection on evaluation forms provided by the Division, one form for each facility plus an appropriate form, or forms, for each piece of equipment. The evaluation forms shall describe the compliance status of the facility and equipment, as it exists at the time of the inspection. The Division will accept computer-generated forms if these contain the same questions as Division forms contain.

(c) The qualified individual shall provide signed and dated evaluation and certification of compliance forms to the registrant promptly.

(Rule 1200-02-10-.27, continued)

(d) The registrant shall submit evaluation and certification of compliance forms to the Division as set out in 1200-02-10-.24(3)(d).

(e) A registrant whose inspection reveals an item of non-compliance shall correct the item promptly following notification by the qualified individual. The registrant shall provide appropriate documentation of the correction to the Division as set out in 1200-02-10-.24(3).

(f) If as a result of inadvertent error or excusable neglect a tube(s) is not inspected, the Commissioner or the Commissioner's designee may grant the 18 percent (18%) fee for all other tubes provided they ~~and~~ were timely inspected by a qualified individual.

(g) For a tube that is inoperable at the time of inspection, the qualified individual shall submit a form indicating the tube was inoperable. The tube shall be inspected within 60 days of its becoming functional.

Authority: *T.C.A. §§4-5-201 et seq., 68-202-101 et seq., 68-202-201 et seq., 68-202-203, 68-202-206 and 68-203-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed January 26, 1993; effective March 12, 1993. Amendment filed October 17, 2001; effective December 31, 2001. Amendment filed July 18, 2002; effective October 1, 2002. Amendment filed September 4, 2003; effective November 18, 2003. Amendment filed November 17, 2005; effective January 31, 2006. Amendment filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.28 TESTS. Each licensee and registrant shall perform, upon instruction from the Division, or shall permit the Division to perform, such tests as the Division may require including, but not limited to, tests of:

(1) Sources of radiation;

(2) Facilities wherein sources of radiation are used or stored;

(3) Radiation detection and monitoring instruments; and

(4) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.29 RECIPROCAL RECOGNITION OF LICENSES.

(1) Subject to these regulations, any individual in another state who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State, and issued by the agency having primary jurisdiction, where the licensee maintains an office for directing the licensed activities and at which radiation safety records are normally maintained, may possess or use the licensed radioactive material to conduct the activities authorized by such license within this State for a period not in excess of one hundred eighty (180) days in any period of twelve (12) consecutive months and will be considered, without obtaining a specific licensing document from this Division, a licensee of this State provided that:

(a) The out-of-state licensing document does not limit the activity authorized by such document to specified installations or locations;

(Rule 1200-02-10-.29, continued)

(b) The out-of-state licensee notifies the Division in writing at least three (3) days prior to each entry into this State to engage in such activity. Such notification shall indicate the location, period, type of proposed possession, use and supervisor within this State, and shall be accompanied by a copy of the pertinent licensing document or shall indicate in the notification that such licensing document has previously been submitted to this Division. If for a specific case, the three (3) day period would impose an undue hardship, the Division may authorize such person to proceed sooner upon notification by telephone of intent to conduct the proposed activity provided that the licensee shall file in writing the information required in this paragraph within three (3) days of the telephone notification;

(c) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the provisions of this Rule except by transfer to a person:

1. Specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive such material; or

2. Exempt from the requirements for a license for such material under 1200-02-10-.04(1)(a);

(d) The out-of-state licensee complies with all applicable regulations of the Division and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Division; and

(e) The Division may require the out-of-state licensee to supply such other information as the Division may request.

(2) Notwithstanding the provision of paragraph (1) above, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State authorizing the holder to manufacture, install, or service a device described in 1200-02-10-.10(2)(a) within the areas subject to the jurisdiction of the licensing body is hereby granted a general license to install and service such device in this State provided that:

(a) 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, an Agreement State or a Licensing State; and

(b) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that “Removal of this label is prohibited.”

(3) The Division 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 protect the public health and safety or property.

Authority: *T.C.A. §68-23-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986.*

1200-02-10-.30 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL.

(1) Except as authorized in a general license or a specific license issued by the Division, or as exempted in this rule, no licensee may:

(a) Deliver licensed material to a carrier for transport; or

(Rule 1200-02-10-.30, continued)

(b) Transport licensed material.

(2) An application by physicians as defined in 1200-02-04-.04(1)(nn) for an amendment to a specific license may be submitted to the Department to request specific conditions to their license to transport radioactive material in the course of their practice of medicine.

(3) A licensee who, under a general or specific license, transports licensed material outside its site of authorized use or on public highways, or who delivers licensed material to a carrier for transport, shall comply with the requirements of this rule and with the applicable requirements of the U.S. DOT regulations in 49 CFR parts 170 through 189 appropriate to the mode of transport.

(a) The licensee shall particularly note U.S. DOT regulations in the following areas:

1. Packaging: 49 CFR part 173, subparts A and B and I;

2. Marking and labeling: 49 CFR 172, subpart D, 172.400 through 172.407, 172.436 through 172.440 and subpart E;

3. Placarding: 49 CFR part 172, subpart F, especially 172.500 through 172.519, 172.556 and appendices B and C;

4. Accident reporting: 49 CFR part 171, 171.15 and 171.16;

5. Shipping papers and emergency information: 49 CFR part 172, subparts C and G;

6. Hazardous material employee training: 49 CFR part 172, subpart H; and

7. Hazardous material shipper/carrier registration: 49 CFR part 107, subpart G.

(b) The licensee shall also note U.S. DOT regulations pertaining to the following modes of transportation:

1. Rail: 49 CFR part 174, subparts A through D and K;

2. Air: 49 CFR part 175;

3. Vessel: 49 CFR part 176, subparts A through F and M; and

4. Public highway: 49 CFR part 177 and parts 390 through 397.

(4) If U.S. DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the U.S. DOT specified above in subparagraph (3)(a) to the same extent as if the shipment or transportation were subject to U.S. DOT regulations. A request for modification, waiver or exemption from those requirements, and any notification referred to in those requirements, shall be filed with, or made to, the Director of the Division of Radiological Health at the address given in Rule 1200-02-04-.07.

(5) Exemption for low-level materials.

(a) 1. A licensee is exempt from all requirements of this rule with respect to shipment or carriage of a package containing radioactive material having a specific activity not greater than 0.002 µCi/g (70 Bq/g).

(Rule 1200-02-10-.30, continued)

2. A licensee is exempt from all requirements of this rule other than paragraphs 1200-02-10-.30(3) and (4) and (10), with respect to shipment or carriage of the following packages, provided the packages contain no fissile material or the fissile material exemption standards of 10 CFR 71.53 are satisfied:

(i) A package containing no more than a Type A quantity of radioactive material;

(ii) A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCO), provided the external radiation level at 3-meters from the unshielded material or objects does not exceed 10 mSv/h (1 rem/h); or

(iii) A package transported within locations within the United States that contains only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 curies.

3. A licensee is exempt from all requirements of this rule other than paragraphs 1200-02-10-.30(3) and (4) and (10), with respect to shipment or carriage of low-specific-activity (LSA) material in group LSA-I, or surface contaminated objects (SCO's) in group SCO-I.

(6) General license: U.S. NRC-approved package.

(a) A general license is hereby issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance or other approval has been issued by the U.S. Nuclear Regulatory Commission.

(b) This general license applies only to a licensee who:

1. Has a copy of the certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2. Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G and H of 10 CFR 71;

3. Submits in writing to the Director, Division of Radiological Health, at the address given in Rule 1200-02-04-.07, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval; and

4. Has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in subpart H of 10 CFR 71.

(d) This general license applies only when the package approval authorizes use of the package under this general license.

(e) For a Type B or fissile material package, the design of which was approved by U.S. NRC before April 1, 1996, the general license is subject to the additional restrictions below in paragraph (7).

(Rule 1200-02-10-.30, continued)

(7) Previously approved package.

(a) A Type B package previously approved by U.S. NRC but not designated as B(U) or B(M) in the identification number of the U.S. NRC Certificate of Compliance, may be used under the general license above in paragraph (5) with the following additional conditions:

1. Fabrication of the packaging was satisfactorily completed by August 31, 1986, as demonstrated by application of its model number in accordance with Sec. 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in U.S. DOT regulations at 49 CFR 173.403; and

3. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

(b) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the U.S. NRC but without the designation '-85' in the identification number of the U.S. NRC Certificate of Compliance, may be used under the general license above in paragraph (5) with the following additional conditions:

1. Fabrication of the package was satisfactorily completed by April 1, 1999 as demonstrated by application of its model number in accordance with 10 CFR 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in U.S. DOT regulations at 49 CFR 173.403; and

3. A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(8) General license: U.S. DOT specification container.

(a) A general license is issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in U.S. DOT regulations at 49 CFR parts 173 and 178.

(b) This general license applies only to a licensee who:

1. Has a copy of the specification;

2. Complies with the terms and conditions of the specification and the applicable requirements of this rule; and

3. Has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in subpart H of 10 CFR 71.

(Rule 1200-02-10-.30, continued)

(c) This general license is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States, except by multilateral approval, as defined in U.S. DOT regulations at 49 CFR 173.403.

(9) General license: Use of foreign approved package.

(a) A general license is issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by U.S. DOT as meeting the applicable requirements of 49 CFR 171.12.

(b) This general license applies only to a licensee who:

1. Has a copy of the applicable certificate, the revalidation and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this rule; and

3. Has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in subpart H of 10 CFR 71.

(c) This general license applies only to shipments made to or from locations outside the United States.

(10) Preliminary determinations.

(a) Before the first use of any packaging for the shipment of licensed material:

1. The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging or impact compliance with the standards specified in 10 CFR 71.

2. Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent (50%) higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

3. The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight and a package identification number assigned by the U.S. Nuclear Regulatory Commission (U.S. NRC). Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. NRC.

(b) Reserved.

(11) Routine determinations.

(a) Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this rule and of the license. The licensee shall determine that:

1. The package is proper for the contents to be shipped in accordance with 49 CFR 173.401-435;

2. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

3. Each closure device of the packaging, including any required gasket, is properly installed, secured and free of defects;

4. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid in accordance with 10 CFR 71, Subpart F;

5. Any pressure relief device is operable and set in accordance with written procedures;

6. The package has been loaded and closed in accordance with written procedures;

7. For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

8. Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of 10 CFR 71.45;

9. The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and within the limits specified in U.S. DOT regulations in 49 CFR 173.443;

10. External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation; and

11. Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

(b) Reserved.

(12) Air transport of plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this rule or included indirectly by citation of 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

1. The plutonium is contained in a medical device designed for individual human application; or

2. The plutonium is contained in a material in which the specific activity is not greater than 0.002 μCi/g (70 Bq/g) of material and in which the radioactivity is essentially uniformly distributed; or

3. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with paragraphs 1200-02-10-.30(3) and (4); or

(Rule 1200-02-10-.30, continued)

4. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission.

(b) Nothing in subparagraph (a) of this paragraph is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

(c) For a shipment of plutonium by air that is subject to part (a)4 above, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

(13) Opening instructions. Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with subparagraph 1200-02-05-.115(5)(a) and (b).

(14) Records.

(a) Each licensee shall maintain, for a period of three (3) years after shipment, a record of each shipment of licensed material not exempt under paragraph 1200-02-10-.30(9), showing where applicable:

1. Identification of the packaging by model number and serial number;

2. Verification that there are no significant defects in the packaging, as shipped;

3. Volume and identification of coolant;

4. Type and quantity of licensed material in each package and the total quantity of each shipment;

5. For each item of irradiated fissile material:

(i) Identification by model number and serial number;

(ii) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(iii) Any abnormal or unusual condition relevant to radiation safety;

6. Date of the shipment;

7. For fissile packages and for Type B packages, any special controls exercised;

8. Name and address of the transferee;

9. Address to which the shipment was made; and

10. Results of the determinations required by paragraph 1200-02-10-.30(11) and by the conditions of the package approval.

(b) The licensee shall make available to the Division for inspection, upon reasonable notice, all records required by this rule. Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(Rule 1200-02-10-.30, continued)

(15) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by paragraph 1200-02-10-.30(11); design, fabrication and assembly records; results of reviews, inspections, tests and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification and repair activities. Inspection, test and audit records shall identify the inspector or data recorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted. The records shall be retained for three years after the life of the packaging to which they apply.

(16) Inspection and tests. In addition to the requirements in paragraph 1200-02-10-.27(1) and Rule 1200-02-10-.28, the licensee shall notify the Director, Division of Radiological Health, at the address given in Rule 1200-02-04-.07, at least 45 days before fabrication of a package to be used for the shipment of licensed material having a decay heat load in excess of 5 kW or with a maximum normal operating pressure in excess of 103 kPa (15 lbf/in^2) gauge.

(17) Reports. The licensee shall report to the Director, Division of Radiological Health, within 30 days:

(a) Any instance in which there is significant reduction in the effectiveness of any approved Type B, or fissile, packaging during use;

(b) Details of any defects with safety significance in Type B, or fissile, packaging after first use, with the means employed to repair the defects and prevent their recurrence; or

(c) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

(18) Advance notification of shipment of irradiated reactor fuel and nuclear waste.

(a) As specified in subparagraphs (b), (c) and (d) below, each licensee shall provide advance notification to the governor of Tennessee, or the governor's designee, and to the Director, Division of Radiological Health, of the shipment of licensed material through or across the boundary of the State, before 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.

(b) Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

1. The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;

2. The licensed material is being transported to or across the State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

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

(i) 3000 times the A_1 value of the radionuclides as specified in appendix A, Table A-1 for special form radioactive material;

(ii) 3000 times the A_2 value of the radionuclides as specified in appendix A, Table A-1 for normal form radioactive material; or

(Rule 1200-02-10-.30, continued)

(iii) 1000 TBq (27,000 Ci).

(c) Procedures for submitting advance notification.

1. The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the Director, Division of Radiological Health.

2. A notification delivered by mail shall be postmarked at least seven (7) days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

3. A notification delivered by messenger shall reach the office of the governor, or of the governor's designee, and of the Director, Division of Radiological Health, at least four (4) days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

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

(ii) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(iv) The licensee shall retain a copy of the notification as a record for three (3) years.

(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste shall contain the following information:

1. The name, address and telephone number of the shipper, carrier and receiver of the irradiated reactor fuel or nuclear waste shipment;

2. A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of U.S. DOT in 49 CFR 172.202 and 172.203(d);

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

4. The seven-day period during which arrival of the shipment at the State's boundaries is estimated to occur;

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

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

(e) Revision notice. A licensee who finds that schedule information previously furnished to the governor, or governor's designee, and to the Director, Division of Radiological Health, in accordance with this section, will not be met, shall telephone a responsible

(Rule 1200-02-10-.30, continued)

individual in the office of the governor of the State, or of the governor's designee, and of the Division of Radiological Health and inform those individuals of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three (3) years.

(f) Cancellation notice.

1. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State, or to the governor's designee, previously notified, and to the Director, Division of Radiological Health.

2. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three (3) years.

Authority: *T.C.A. §§4-5-201 et seq., 68-23-206, 68-23-101 et seq., and 68-202-101 et seq.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed January 8, 1990; effective May 1, 1990. Amendment filed July 18, 2002; effective October 1, 2002.*

1200-02-10-.31 FEES FOR LICENSES.

(1) A fee shall be assessed and collected on the application for and annual maintenance of licenses regarding radioactive materials, as follows:

(a) Application filing fees from applicants for licenses to use or possess radioactive materials or any other activity authorized under this Chapter that requires a license from the Department.

(b) Annual maintenance fees from licensees or persons required to possess a license under this Chapter, including reciprocal activity under 1200-02-10-.29.

(2) The application filing fees shall be the same amount as the annual maintenance fees set forth in (6) through (19) of this Rule. A radioactive material license application will not be considered for completeness unless the application filing fee has been paid in full. Within 15 days of receipt of an application, an invoice for the fee will be prepared and mailed to the applicant. The application filing fee is not refundable, except as specified in Public Chapter 417, Acts of 1991. Applicants for licenses greater than Category 8 shall pay the application fee annually until such time as the license is issued or denied. (An application filing fee shall be required when a licensee applies for a license modification to change to a higher numbered category, in which case the application fee will be the amount of the proposed new Category. The application filing fee shall serve as full payment of fees for the balance of the calendar year in which the license is issued.)

(3) If a license authorizes activities under more than one Category, the application and annual maintenance fee shall be the cumulative total for each applicable category under which the license is issued.

(4) The annual maintenance fees, based on the categories in (6) through (19) of this rule shall be payable to the Division of Radiological Health by check made payable to "Treasurer State of Tennessee" by February 17 of each year, as indicated on the annual invoice, until the license is terminated in accordance with these Regulations.

(a) Provided that the licensee has demonstrated to the satisfaction of the Department that all of the requirements concerning disposal of radioactive material and the

(Rule 1200-02-10-.31, continued)

decontamination of facilities are met, the termination of the license is administratively accomplished by using one of the following:

1. As requested by the licensee;

2. By the Department for cause; or

3. In accordance with these regulations.

(b) The failure to acquire radioactive material or the disposal of radioactive material without notifying the Department and requesting termination in writing does not constitute termination of the license.

(5) Complete Applications

(a) For the purpose of determining whether or not the Division has acted in the time frame established to process applications set forth in (5)(e), the evaluation period shall not begin until a complete application has been filed in the Division of Radiological Health ~~Nashville office~~ Central Office. All items on the application form shall be completed in sufficient detail to allow the Division to determine that the applicant's equipment, facilities and radiation protection program are adequate to protect health and minimize danger to life and property.

(b) The Division shall denote the date that all applications for radioactive material license are received in its Nashville office.

(c) Upon receipt of an application~~.~~, the Division must examine it to insure that it is complete and advise the applicant in writing of its findings via certified mail. Sixty (60) days will be allowed for the initial and each subsequent review per (c)(3) of this Rule.

1. If an application is determined to be incomplete, the Division must notify the applicant in writing via certified mail of the finding with a brief explanation of the deficiencies. The application filing fee shall be retained by the Division.

2. After receiving notice from the Division that the application was incomplete, the applicant shall have one hundred eighty (180) calendar days to correct the deficiencies. If properly corrected, the application will be processed and no additional application fee is required, except for the possibility of those above Category 8. If the deficiencies are not corrected within the 180 day correction period, the fee will be forfeited in its entirety to the Division with no further action taken on the application by the Division. If the applicant re-applies, a new application fee must be paid in full.

3. Upon receipt of a corrected application revised pursuant to part 1 or 2 of this subparagraph (c), the Division shall re-evaluate the application and notify the applicant of its finding as to whether or not the deficiencies in the application have been completed. The same procedure to notify an applicant as to whether or not the application is complete will follow the requirements specified by this subparagraph, with the exception being that the one hundred eighty (180) day correction period begins from the receipt of the initial application - not receipt of the revised application.

4. Any person possessing licensable quantities of unlicensed radioactive material during the review of an application for a license for the radioactive material, shall be in violation of l200-2-l0-.02.

(Rule 1200-02-10-.31, continued)

(d) Revisions to an application, to reflect changes in radioactive material or its use, will be accepted by the Division during the application processing period. However, notwithstanding (5)(e) of this Rule, the deadline for evaluation as to issuance of a license will restart upon each and every revision.

(e) The Division shall make a decision to issue or deny a request for a new radioactive material license, except Category 12, and notify the applicant of that decision in no more than 365 days after receipt of a complete application, unless the Division has requested technical assistance in the review of the application from the Nuclear Regulatory Commission.

(6) CATEGORY GL ---------- $ 150.00

Any person possessing radioactive material, under the terms of any general license issued under these regulations, in a form or device on which a test for leakage of radioactive material is required.

(7) CATEGORY 1 ---------- $ 300.00

A specific license for source material used exclusively for shielding radiation.

(8) CATEGORY 2 ---------- $ 600.00

(a) Reserved.

(b) The application, use or possession of radioactive material as chromatography sources or gauges not requiring assignment to another category.

(c) The application, use or possession of radioactive material for in vitro use only, total quantity not to exceed 200 microcuries.

(d) Any person who packages or containerizes, loads transport vehicles or ships radioactive materials to a licensed disposal/processing facility in Tennessee.

In addition to application and annual maintenance fees, there is also levied a fee of one and one-half cent per pound ($0.015/lb) on all items contaminated or potentially contaminated with radioactive material or on low-level radioactive waste received at a processing, storage, disposal or refurbishing facility in Tennessee.

Not withstanding the requirements of this paragraph 1200-02-10-.31(8) and Rule 1200-02-10-.32, licensees with multiple sites within the state will be levied only one fee if items are moved directly from one site to another.

The operator of the disposal/processing facility shall collect the fee of one and one-half cent per pound ($0.015/lb). For each calendar month, he shall remit the total of fees collected for the month to the Division of Radiological Health by the 25th day of the following month.

(Rule 1200-02-10-.31, continued)

(e) The application, use or possession of radioactive material for the calibration for hire of radiation detection, monitoring and measuring instruments.

(f) The performance for hire of leak tests on sealed sources of radioactive material.

(9) CATEGORY 3 ---------- $ 900.00

(a) The application, use or possession of radioactive material, unless specific to a higher numbered category, by an academic institution, but does not include licenses authorizing all radioisotopes with atomic number 3 through 83.

(b) The possession and use of radioactive material for civil defense activities.

(c) The application, use or possession of radioactive material by a medical institution or physicians for use in radiopharmaceuticals for the diagnosis or therapy of humans.

(d) Reserved.

(e) Reserved.

(f) Reserved.

(g) The application, use or possession of radioactive material for demonstration or training purposes.

(h) The application, use or possession of radioactive material for *in vitro* use only, total quantity exceeding 200 microcuries.

(i) The use of sealed sources for soil and/or construction materials testing at temporary job-sites by licensees with licensed authorization for no more than two (2) devices.

(j) The use of radioactive material as chromatography sources at temporary job-sites by licensees with licensed authorization for no more than two (2) devices.

(k) The use of gauging and measuring devices at temporary job-sites by licensees with licensed authorization for no more than two (2) devices.

(10) CATEGORY 4 ---------- $ 1,500.00

(a) The application, use or possession of radioactive material by a medical institution or physicians for interstitial, intracavitary or superficial treatment of humans using sealed sources, seeds or wires.

(b) The application, use or possession of radioactive material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-contained irradiators).

(c) The application, use or possession of radioactive material for analytical testing purposes.

(11) CATEGORY 5 ---------- $ 2,100.00

(Rule 1200-02-10-.31, continued)

(a) The use of radioactive material in research and development, manufacturing, testing, processing and assembling of products. This group includes the use of source material in the manufacture of items such as mantles, alloys, gases, liquids, metals, ceramics, glass or photographic products.

(b) The use of radioactive material in a process that incorporates that material into a product in exempt concentrations.

(c) The possession and use of radioactive material in curie quantities in a number of sources in gauges and gauging applications that require frequent changes and therefore frequent review of the program to ensure that the hazard potential does not exceed the scope of the radiation safety program.

(d) The use of a single radioactive material in the fabrication of sealed sources or ampoules.

(e) The receipt of prepackaged radioactive material waste from other persons by a nuclear waste handler for storage for less than three (3) months before transfer only to persons licensed to receive or dispose of the material.

(f) The use of sealed sources for soil and/or construction materials testing at temporary job-sites by licensees with licensed authorization for more than two (2) devices.

(g) The use of radioactive material as chromatography sources at temporary job-sites by licensees with licensed authorization for more than two (2) devices.

(h) The use of gauging and measuring devices at temporary job-sites by licensees with licensed authorization for more than two (2) devices.

(i) The application, use or possession of radioactive material by a medical institution or physicians for the treatment of humans with sealed sources contained in teletherapy devices.

(j) The application, use or possession of radioactive material by a veterinarian for the treatment of animals using sealed sources, seeds or wires.

(12) CATEGORY 6 ---------- $ 6,000.00

(a) The application, use or possession of radioactive material including source and/or special nuclear material in unsealed form in less than multicurie quantities for use in the fabrication of sealed sources without regard to amount of contained radioactivity.

(b) The manufacture of devices and/or sources that require in-depth review before approval by the Division. Each device and/or source reviewed shall be subject to this fee.

(c) The preparation, use or distribution of radiopharmaceuticals to locations other than the licensee's address for use in medical diagnosis or therapy.

(Rule 1200-02-10-.31, continued)

(d) The use of radiography (the examination of the structure of materials by nondestructive methods using radioactive material) on the licensee's premises in a permanent shielded facility or temporary job-sites.

(e) The possession and use of radioactive material by academic and medical institutions under a license authorizing all radioisotopes with atomic numbers 3 through 83.

(f) Reserved.

(g) The application of radioactive material to soil, water, air, plants and animals, if the application involves an actual or potential release in or to unrestricted areas.

(h) The possession, use and distribution of radioactive material at one or more satellite facilities, or the possession and use of radioactive material at one or more satellite facilities, by medical institutions.

(i) The application, use or possession of radioactive material by a medical institution or physicians for research using humans and/or animals.

(13) CATEGORY 7 ---------- $ 4,000.00

(a) Reserved.

(b) Reserved.

(c) The application, use or possession of radioactive material for well logging, well surveys or tracer studies.

(14) CATEGORY 8 ---------- $ 11,250.00

(a) The receipt of radioactive material waste from other persons by a nuclear waste handler, for the purpose of packaging or repackaging the material prior to transfer only to persons licensed to receive or dispose of the material.

(b) The commercial collection, laundering or dry cleaning of wearing apparel that is contaminated with radioactive material.

(15) CATEGORY 9 ---------- $ 15,000.00

(a) The possession of radioactive material or equipment contaminated or potentially contaminated with radioactive material as a result of operations involving the recovery of an element, compound or mixture from ores not subject to licensure because of the radioactive material content of the ore.

(b) Facilities that possess radioactive material as a result of operations (not directly involving radioactive decontamination activities) involving recovery of materials or other manufacturing processes (not directly manufacturing radioactive items or products).

(16) CATEGORY 10 ---------- $ 22,500.00

(a) Facilities storing radioactive material, contaminated equipment and/or potentially contaminated equipment for transfer to authorized recipients as a service to the nuclear industry.

(Rule 1200-02-10-.31, continued)

(b) Possession and refurbishment of contaminated equipment and/or potentially contaminated equipment that has been used at nuclear power plants.

(17)	CATEGORY 11	----------	$ 30,000.00

(a) The collection, transfer, sorting and/or brokerage of radioactive material as sealed source, residue, product or as material in or on equipment; and/or

The decontamination of products and/or equipment containing radioactive material and/or contaminated with radioactive material; and/or

The possession, storage and incineration of radioactive material or items contaminated with radioactive materials.

(b) On site possession and storage of radioactive material and/or equipment contaminated with radioactive material as a result of operations involving the recovery of an element, compound or mixture from ores subject to licensure because of the radioactive material content of the ore or concentration of the radioactive material during the processing of the ore.

(c) Facilities involved in the manufacture of product lines containing radioactive material in the manufactured product.

(d) Possession of radioactive material for processing. This material may exist in ores, concentrates, compounds or metals.

(e) The possession of multicurie quantities of unsealed radioactive material either as waste or for further processing and/or conversion into specific marketable products.

(f) Operations involving the fabrication of sealed sources or manufacture of compounds for distribution to other specific or general licensees.

(g) The possession and use of radioactive material in a sealed source for irradiation of materials in which the source is exposed for irradiation purposes (non self-contained irradiators).

(18)	CATEGORY 12	----------	$ 375,000.00

(a) The application for and/or operation of a low-level radioactive waste disposal facility.

(b) The maximum length of reviewing time (the period of time when there are no outstanding unanswered questions) after receipt of a new application and the appropriate fee for a Category 12 specific license and the issuance of a license is 60 months.

(19)	CATEGORY 13	----------	At least $ 150.00 not greater than $ 375,000.00

(Rule 1200-02-10-.31, continued)

The application, use or possession of radioactive material for uses or procedures not specifically included in any other category.

The fee shall be determined on a case-by-case basis.

The determination shall be based on an analysis of the hazard, the scope of the difficulty encountered in the review process and the specifics of the activity pursuant to the categories established above.

Authority: *T.C.A. §§68-1-1301, 68-23-206, 68-202-201 et seq., 68-202-203, 68-202-206, 68-203-101 et seq., 4-5-201 et seq., and Acts of 1991, Public Chapter 417.* ***Administrative History:*** *Original rule filed September 3, 1991; effective October 18, 1991. Amendment filed March 31, 1992; effective May 15, 1992. Amendment filed October 1, 2001; effective December 15, 2001. Amendments filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.32 LICENSING OF SHIPPERS OF RADIOACTIVE MATERIAL INTO OR WITHIN TENNESSEE.

(1) This Rule applies to any shipper who transports or offers for transport into or within Tennessee on public waterways, roadways, railways or other transportation facilities upon which United States Department of Transportation (USDOT) regulations are applicable, any radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities for packaging, repackaging, processing, refurbishing, storage pending disposal or disposal.

(2) All persons subject to the provisions of this Rule shall comply with all applicable provisions of the USDOT Regulations (49 CFR) of October 1, 1990, as amended, the U.S. Nuclear Regulatory Commission (NRC) Regulations (10 CFR) of November 30, 1988, as amended, and any disposal/processing facility radioactive material license requirements with special emphasis regarding the packaging, transportation, disposal, storage pending disposal or delivery of radioactive material.

(3) Definitions used in this rule.

(a) Carrier means any person who transports radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities.

(b) Disposal means isolation of radioactive waste from the biosphere.

(c) Disposal/Processing Facility means any facility located within Tennessee that accepts radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities for packaging, repackaging, processing, refurbishing, storage pending disposal or disposal.

(d) (Reserved)

(e) (Reserved)

(f) License for delivery means an authorization issued by the Division to any shipper of radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities to transport such radioactive material or offer such material for transport to a disposal/processing facility.

(g) Shipper means any person, whether a resident of Tennessee or a non–resident:

(Rule 1200-2-10-.32, continued)

1. Who transfers radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities to a carrier for transport;

2. Who transports his own radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities;

3. Who transports radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities he has packaged, repackaged, processed or stored pending disposal for another person; or

4. Who transfers radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities to another person if such materials are transported into or within the state.

~~5~~(h) Transport means the movement of radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities into or within the State of Tennessee on waterways, roadways, railways or other transportation facilities upon which USDOT regulations are applicable.

(4) Licensing for Delivery.

(a) Before any shipper transports or causes to be transported radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities to a disposal/processing facility within the State for subsequent processing, he shall obtain a license for delivery of such materials from the Division. An application for a license for delivery shall be submitted on Division Form RHS-30, together with any necessary fee, to the Division at the address in Rule 1200-02-04-.07. The check for payment of the fee is to be made payable to “Treasurer: State of Tennessee.”

(b) Before a license for delivery shall be issued, the shipper must deposit and maintain with the Division an acceptable form of financial assurance in the amount of Five Hundred Thousand Dollars ($500,000.00); or, provide to the Division satisfactory evidence of liability insurance.

1. For purposes of this paragraph, liability insurance shall mean coverage of Five Hundred Thousand Dollars ($500,000.00) per occurrence and one Million Dollars ($1,000,000.00) aggregate, or as otherwise provided by State law.

2. Any insurance carried pursuant to Section 2210 of Title 42 of the United States Code and U.S. NRC Regulations (10 CFR Part 140) of November 30, 1988, as amended shall be sufficient to meet the requirements of 1200-02-10-.32(4)(b).

3. Liability insurance shall be specific to the packaging, transportation, disposal, storage and delivery of radioactive waste.

4. Shippers maintaining liability insurance for the purpose of this paragraph may provide to the Division a certificate of insurance from their insurer indicating the policy number, limits of liability, policy date and specific coverage for packaging, transportation, disposal, storage pending disposal and delivery of radioactive materials.

(Rule 1200-2-10-.32, continued)

5. A cash or corporate surety bond previously posted will be returned to the shipper upon notification to the Division in writing of his intention to cease shipments of radioactive waste into or within the State. Such bond will be returned after the last such shipment is accepted safely at its destination.

(c) Each license for delivery application shall include a certification to the Division that the shipper will comply fully with all applicable State and Federal laws, administrative rules and regulations, licenses, or license conditions of the disposal/processing facility regarding the packaging, transportation, storage pending disposal, disposal and delivery of radioactive materials.

(d) Each license for delivery application shall include a certification that the shipper will hold the State of Tennessee harmless for all claims, actions or proceedings in law or equity arising out of radiological injury or damage to persons or property occurring during the transportation of its radioactive waste into or within the State including all costs of defending the same; *provided*, however, that nothing contained herein shall be construed as a waiver of the State's sovereign immunity; and, *further provided* that agencies of the State of Tennessee shall not be subject to the requirement of (4)(b) of this Rule.

(5) Disposal/processing facility operator.

(a) Owners and operators of disposal/processing facilities shall permanently record, and report to the Division within twenty-four (24) hours after discovery, all conditions in violation of the requirement of this Rule discovered as a result of inspections required by any license under which the facility is operated. In addition, owners and operators of disposal/processing facilities shall record all violations of these regulations and license conditions and maintain the record for inspection by the Division.

(b) Prior to the receipt of radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive materiel or from licensable activities at a disposal/processing facility in Tennessee, the owners and operators of such facility shall notify each shipper of any special requirements, if any, in effect regarding the packaging, transportation, storage pending disposal, disposal or delivery of such wastes at that facility.

(c) No owner or operator of a disposal/processing facility located within this State shall accept radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities for packaging, repackaging, processing, refurbishing, storage pending disposal or disposal unless the shipper of such waste has a valid license for delivery issued pursuant to this Rule.

(d) The owner or operator of a disposal/processing facility shall, along with the remittance of the fee collected pursuant to 1200-02-10-.31(8)(d), submit a listing containing the name and address of each shipper and the volume and poundage from each shipper for the calendar month.

(6) Penalties.

All shippers shall be subject to fees and Civil Penalties as authorized and specified in Tennessee Code Annotated 68-23-212 and other pertinent regulations of the Division.

Authority: *T.C.A. §§4-5-201 et seq., 68-23-206, 68-202-201 et seq., 68-202-203, 68-202-206 and Acts of 1991, Public Chapter 417.* ***Administrative History:*** *Original rule filed September 3, 1991; effective October 18, 1991. Amendments filed November 17, 2005; effective January 31, 2006. Amendment filed December 21, 2009; effective March 21, 2010.*

(Rule 1200-2-10-.32, continued)

1200-02-10-.33 ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF RADIOACTIVE MATERIAL.

(1) General Training. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups I, II and/or III, Rule 1200-02-10-.14, a physician should have:

(a) Training in basic radioisotope handling techniques consisting of lectures, laboratory sessions, discussion groups or supervised experience in a nuclear medicine laboratory in the following areas: (200 hours)

1. Radiation physics and instrumentation (approx. 100 hours)
2. Radiation Protection (approx. 30 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (approx. 20 hours)
4. Radiation biology (approx. 20 hours)
5. Radiopharmaceutical chemistry (approx. 30 hours)

(b) Experience with the types and quantities of radioactive material for which the application is being made, or equivalent (500 hours). For authorization for Group III (generators and reagent kits), this experience should include personal participation in five procedures to elute Tc-99m, including testing of eluate, and five procedures to prepare radiopharmaceuticals from Group III reagent kits.

(c) Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and include:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.
2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement and plotting data.
3. Follow-up of patients when required.
4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

(d) The requirements specified in 1200-02-10-.33(1)(a), (b) and (c) may be satisfied concurrently in a three month training program *IF* all three areas are integrated into the program.

(e) In lieu of the requirements in 1200-02-10-.33(1)(a), (b), and (c), certification by the American Board of Nuclear Medicine or the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology will be accepted as evidence that a physician has had adequate training and experience to use Groups I, II, and III.

(Rule 1200-02-10-.33, continued)

(2) *Training Requirements for Specific Diagnosis Procedures.* For applicant who wishes to be authorized for only one or two specific diagnostic procedures the physician named to use or directly supervise the use of radioactive material should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested.

(3) *Training Requirements for Therapy Procedures involving Radiopharmaceuticals.* To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups IV and/or, V, Rule 1200-02-10-.14, a physician should have:

(a) Training in basic radioisotope handling techniques applicable to the uses of unsealed sources for therapy procedures, including: (80 hours)

1. Radiation physics and instrumentation (approx. 25 hours)

2. Radiation Protection (approx. 25 hours)

3. Mathematics pertaining to the use and measurement of radioactivity (approx. 10 hours)

4. Radiation biology (approx. 20 hours)

(These requirements are in lieu of, not in addition to, those specified in subparagraph 1200-02-10-.33(1)(a), above.)

(b) Clinical training in specific therapy procedures;

1. For Group IV

(i) Iodine-13l for treatment of hyperthyroidism and/or cardiac conditions: Clinical experience in the diagnosis of thyroid function and active participation in the treatment of *ten patients*.

(ii) Phosphorus-32 for treatment of polycythemia vera, leukemia and/or bone metastases: Active participation in the treatment of *three patients* with any combination of these three conditions.

(iii) Colloidal phosphorus-32 intracavitary treatment: Active participation in the treatment of *three patients*.

2. For Group V

(i) Iodine 131 for treatment of thyroid carcinoma: Clinical experience in diagnosis of thyroid function, personal participation in the treatment of *ten patients* with hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of *three patients* with thyroid carcinoma.

(ii) Colloidal gold 198 for intracavitary treatment: Active participation in the treatment of *three patients*.

(4) *Training Requirements for Therapy Procedures Involving Sealed Sources.* To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group VI, Rule 1200-02-10-.14 or other sealed sources in therapy procedures, a physician should have:

(Rule 1200-02-10-.33, continued)

(a) Training in basic radioisotope handling techniques consisting of lectures, laboratory sessions, discussion groups or supervised experience in the following areas: (200 hours)

1. Radiation physics and instrumentation (approx. 110 hours)

2. Radiation protection (approx. 40 hours)

3. Mathematics pertaining to the use and measurement of radioactivity (approx. 25 hours)

4. Radiation biology (approx. 25 hours)

(b) Experience with the types and quantities of radioactive material for which the application is being made, or equivalent (500 hours). This experience should include:

1. Review of initial source calibration and periodic spot-check measurements of teletherapy units,

2. Calibration of ion chambers and survey meters,

3. Preparation of treatment plans and treatment times,

4. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources, and

5. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.

(c) Clinical training shall include active practice in therapeutic radiology with a minimum of 3 years experience of which at least one year should have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education. This training must include therapeutic treatment of patients of both sexes, all ages, various organs, etc., using sealed sources.

(d) In lieu of the requirements in 1200-02-10-.33(4)(a), (b) and (c), certification by the American Board of Radiology in Radiology or Therapeutic Radiology will be accepted as evidence that a physician has had adequate training and experience to use Group VI.

(5) *Training for Physicians Wishing to Use Strontium 90 Ophthalmic Eye Applicators Only.* To qualify as adequately trained to use or supervise the use of a Strontium 90 eye applicator only, a physician should submit:

(a) Evidence of certification by the American Board of Radiology in radiology or therapeutic radiology, or

(b) Evidence of:

1. Active practice in therapeutic radiology or ophthalmology, and -

2. Training in basic radioisotope handling techniques, including (24 hours)

(Rule 1200-02-10-.33, continued)

(i) Radiation physics and instrumentation (6 hours)

(ii) Radiation protection (6 hours)

(iii) Mathematics pertaining to the use and measurement of radioactivity (4 hours)

(iv) Radiation biology (8 hours)

3. Evidence of active participation in the treatment of *five patients* (to be submitted on Preceptor Statement). "Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be used, administration of the dose to the patient, and follow-up and study of patient case histories.

(5) For each physician named in Item 4 of Form RHS 8-5 complete Supplement A of Form RHS 8-5A and Items 8 and 9 of Form RHS 8-5 (Preceptor statement and the statement of training and experience in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained, the dates, total number of hours and type of training (e.g., lectures, laboratory sessions).

SCHEDULE RHS 8–3

EXEMPT QUANTITIES

Radioactive Material	Micro–curies
Antimony–122 (Sb 122)	100
Antimony–124 (Sb 124)	10
Antimony–125 (Sb 125)	10
Arsenic–73 (As 73)	100
Arsenic–74 (As 74)	10
Arsenic–76 (As 76)	10
Arsenic–77 (As 77)	100
Barium–13l (Ba 131)	10
Barium–133 (Ba 133)	10
Barium–140 (Ba 140)	10
Bismuth–210 (Bi 210)	1
Bromine–82 (Br 82)	10
Cadmium–l09 (Cd 109)	10
Cadmium–115m (Cd 115m)	10
Cadmium–115 (Cd 115)	100
Calcium–45 (Ca 45)	10
Calcium–47 (Ca 47)	10
Carbon–14 (C 14)	100
Cerium–141 (Ce 141)	100
Cerium–143 (Ce 143)	100
Cerium–144 (Ce 144)	1
Cesium–129 (Cs 129)	100
Cesium–131 (Cs 131)	1,000
Cesium–134m (Cs 134m)	100
Cesium–134 (Cs 134)	1
Cesium–135 (Cs 135)	10

Radioactive Material	Micro–curies
Cesium–136 (Cs 136)	10
Cesium–137 (Cs 137)	10
Chlorine–36 (Cl 36)	10
Chlorine–38 (Cl 38)	10
Chromium–51 (Cr 51)	1,000
Cobalt–57 (Co 57)	100
Cobalt–58m (Co 58m)	10
Cobalt–58 (Co 58)	10
Cobalt–60 (Co 60)	1
Copper–64 (Cu 64)	100
Dysprosium–165 (Dy 165)	10
Dysprosium–166 (Dy 166)	100
Erbium–169 (Er 169)	100
Erbium–171 (Er 171)	100
Europium–152 (Eu 152)9.2 h	100
Europium–152 (Eu 152)13 yr	1
Europium–154 (Eu 154)	1
Europium–155 (Eu 155)	10
Fluorine–18 (F 18)	1,000
Gadolinium–153 (Gd 153)	10
Gadolinium–159 (Gd 159)	100
Gallium–67 (Ga 67)	100
Gallium–72 (Ga 72)	10
Germanium–68 (Ge 68)	10
Germanium–71 (Ge 71)	100
Gold–195 (Au 195)	10

(Rule 1200-02-10-.33, continued)

Radioactive Material	Micro–curies
Gold–198 (Au 198)	100
Gold–l99 (Au 199)	100
Hafnium–181 (Hf 181)	10
Holmium–166 (Ho 166)	100
Hydrogen–3 (H 3)	1,000
Indium–111 (In 111)	100
Indium–113m (In 113m)	100
Indium–114m (In 114m)	10
Indium–115m (In 115m)	100
Indium–115 (In 115)	10
Iodine–123 (I 123)	100
Iodine–125 (I 125)	1
Iodine–126 (I 126)	1
Iodine–129 (I 129)	0.1
Iodine–131 (I 131)	1
Iodine–132 (I 132)	10
Iodine–133 (I 133)	1
Iodine–134 (I 134)	10
Iodine–135 (I 135)	10
Iridium–192 (Ir 192)	10
Iridium–194 (Ir 194)	100
Iron–52 (Fe 52)	10
Iron–55 (Fe 55)	100
Iron–59 (Fe 59)	10
Krypton–85 (Kr 85)	100
Krypton–87 (Kr 87)	10
Lanthanum–140 (La 140)	10
Lutetium–177 (Lu 177)	100
Manganese–52 (Mn 52)	10
Manganese–54 (Mn 54)	10
Manganese–56 (Mn 56)	10
Mercury–197m (Hg 197m)	100
Mercury–197 (Hg 197)	100
Mercury–203 (Hg 203)	10
Molybdenum–99 (Mo 99)	100
Neodymium–147(Nd 147)	100
Neodymium–149 (Nd 149)	100
Nickel–59 (Ni 59)	100
Nickel–63 (Ni 63)	10
Nickel–65 (Ni 65)	100
Niobium–93m (Nb 93m)	10
Niobium–95 (Nb 95)	10
Niobium–97 (Nb 97)	10
Osmium–185 (Os 185)	10
Osmium–191m (Os 191m)	100
Osmium–191 (Os 191)	100
Osmium–193 (Os 193)	100
Palladium–103 (Pd 103)	100
Palladium–109 (Pd 109)	100
Phosphorus–32 (P 32)	10
Platinum–191 (Pt 191)	100
Platinum–193m (Pt 193m)	100
Platinum–193 (Pt 193)	100
Platinum–197m (Pt 197m)	100
Platinum–197 (Pt 197)	100
Polonium–210 (Po 210)	0.1
Potassium–42 (K 42)	10
Potassium–43 (K 43)	10
Praseodymium–142 (Pr 142)	100
Praseodymium–l43 (Pr 143)	100
~~Praseodymium–l47 (Pr 147)~~	~~100~~
Promethium–147 (Pm 147)	10
Promethium–149 (Pm 149)	10
Rhenium–186 (Re 186)	100
Rhenium–188 (Re 188)	100
Rhodium–103m (Rh 103m)	100
Rhodium–105 (Rh 105)	100
Rubidium–81 (Rb 81)	10
Rubidium–86 (Rb 86)	10
Rubidium–87 (Rb 87)	10
Ruthenium–97 (Ru 97)	100
Ruthenium–103 (Ru 103)	10
Ruthenium–105 (Ru 105)	10
Ruthenium–106 (Ru 106)	1
Samarium–151 (Sm 151)	10
Samarium–153 (Sm 153)	100
Scandium–46 (Sc 46)	10
Scandium–47 (Sc 47)	100
Scandium–48 (Sc 48)	10
Selenium–75 (Se 75)	10
Silicon–31 (Si 31)	100
Silver–105 (Ag 105)	10
Silver–110m (Ag 110m)	1
Silver–111 (Ag 111)	100
Sodium–22 (Na 22)	10
Sodium–24 (Na 24)	10
Strontium–85 (Sr 85)	10
Strontium–89 (Sr 89)	1
Strontium–90 (Sr 90)	0.1
Strontium–91 (Sr 91)	10
Strontium–92 (Sr 92)	10
Sulfur–35 (S 35)	100
Tantalum–182 (Ta 182)	10
Technetium–96 (Tc 96)	10
Technetium–97m (Tc 97m)	100
Technetium–97 (Tc 97)	100
Technetium–99m (Tc 99m)	100
Technetium–99 (Tc 99)	10
Tellurium–125m (Te 125m)	10
Tellurium–127m (Te 127m)	10
Tellurium–127 (Te 127)	100
Tellurium–129m (Te 129m)	10
Tellurium–129 (Te 129)	100
Tellurium–131m (Te 131m)	10
Tellurium–132 (Te 132)	10
Terbium–160 (Tb 160)	10
Thallium–200 (Tl 200)	100
Thallium–201 (Tl 201)	100

(Rule 1200-02-10-.33, continued)

Radioactive Material	Micro–curies
Thallium–202 (Tl 202)	100
Thallium–204 (Tl 204)	10
Thulium–170 (Tm 170)	10
Thulium–171 (Tm 171)	10
Tin–113 (Sn 113)	10
Tin–125 (Sn 125)	10
Tungsten–181 (W 181)	10
Tungsten–185 (W 185)	10
Tungsten–187 (W 187)	100
Vanadium–48 (V 48)	10
Xenon–131m (Xe 131m)	1,000
Xenon–133 (Xe 133)	100
Xenon–135 (Xe 135)	100
Ytterbium–175 (Yb 175)	100
Yttrium–87 (Y 87)	10
Yttrium–88 (Y 88)	10
Yttrium–90 (Y 90)	10
Yttrium–91 (Y 91)	10
Yttrium–92 (Y 92)	100
Yttrium–93 (Y 93)	100
Zinc–65 (Zn 65)	10
Zinc–69m (Zn 69m)	100
Zinc–69 (Zn 69)	1,000
Zirconium–93 (Zr 93)	10
Zirconium–95 (Zr 95)	10
Zirconium–97 (Zr 97)	10
Any radioactive material not listed above other than alpha–emitting radioactive material	0.1
Any alpha emitting radioactive material not listed above other than transuranic radioactive material	0.01

(Rule 1200-02-10-.33, continued)

SCHEDULE RHS 8-4

EXEMPT CONCENTRATIONS

Element (atomic number	Isotope	Column I Gas Concentration µCi/ml[1]	Column II and Solid Concentration µCi/ml[2]
Antimony (51)	Sb-122		3x10-4
	Sb-124		2x10-4
	Sb-125		1x10-3
Argon (18)	Ar-37	1x10-3	
	Ar-41	$4x10^{-7}$	
Arsenic (33)	As-73		5x10-3
	As-74		5x10-4
	As-76		2x10-4
	As-77		8x10-4
Barium (56)	Ba-131		2x10-3
	Ba-140		3x10-4
Beryllium (4)	Be-7		2x10-2
Bismuth (83)	Bi-206		4x10-4
Bromine (35)	Br -82	$4x10^{-7}$	3x10-3
Cadmium (48)	Cd-109		2x10-3
	Cd-115m		3x10-4
	Cd-115		3x10-4
Calcium (20)	Ca-45		$9x10^{-5}$
	Ca-47		5x10-4
Carbon (6)	C-14	$1x10^{-6}$	8x10-3
Cerium (58)	Ce-141		9x10-4
	Ce-143		4x10-4
	Ce-144		1x10-4
Cesium (55)	Cs-131		2x10-2
	Cs-134m		6x10-2
	Cs-134		$9x10^{-5}$
Chlorine (17)	Cl-38	$9x10^{-7}$	4x10-3
Chromium (24)	Cr-51		2x10-2
Cobalt (27)	Co-57		5x10-3
	Co-58		1x10-3
	Co-60		5x10-4
Copper (29)	Cu-64		3x10-3
Dysprosium (66)	Dy-165		4x10-3
	Dy-166		4x10-4
Erbium (68)	Er-169		9x10-4
	Er-171		1x10-3
Europium (63)	Eu-152 (T_r = 9.2h)		6x10-4
	Eu-155		2x10-3
Fluorine(9)	F-18	$2x10^{-6}$	8x10-3
Gadolinium (64)	Gd-153		2x10-3
	Gd-159		8x10-4
Gallium (31)	Ga-72		4x10-4
Germanium (32)	Ge-71		2x10-2

(Rule 1200-02-10-.33, continued)

Gold (79)	Au-196		2x10-3
	Au-198		5x10-4
	Au-199		2x10-3
Hafnium (72)	Hf-181		7x10-4
Hydrogen (1)	H-3	$5x10^{-6}$	3x10-2
Indium (49)	In-113m		1x10-2
	In-114m		2x10-4
Iodine (53)	I-126	$3x10^{-9}$	$2x10^{-5}$
	I-131	$3x10^{-9}$	$2x10^{-5}$
	I-132	$8x10^{-8}$	6x10-4
	I-133	$1x10^{-8}$	$7x10^{-5}$
	I-134	$2x10^{-7}$	1x10-3
Iridium (77)	Ir-190		2x10-3
	Ir-192		4x10-4
	Ir-194		3x10-4
Iron (26)	Fe-55		8x10-3
	Fe-59		6x10-4
Krypton (36)	Kr-85m	$1x10^{-6}$	
	Kr-85	$3x10^{-6}$	
Lanthanum (57)	La-140		2x10-4
Lead (82)	Pb-203		4x10-3
Lutetium (71)	Lu-177		1x10-3
Manganese (25)	Mn-52		3x10-4
	Mn-54		1x10-3
	Mn-56		1x10-3
Mercury (80)	Hg-197m		2x10-3
	Hg-197		3x10-3
	Hg-203		2x10-4
Molybdenum (42)	Mo-99		2x10-3
Neodymium (60)	Nd-147		6x10-4
	Nd-149		3x10-3
Nickel (28)	Ni-65		1x10-3
Niobium (41)	Nb-95		1x10-3
	Nb-97		9x10-3
Osmium (76)	Os-185		7x10-4
	Os-191m		3x10-2
	Os-191		2x10-3
	Os-193		6x10-4
Palladium (46)	Pd-103		3x10-3
	Pd-109		9x10-4
Phosphorus (15)	P-32		2x10-4
Platinum (78)	Pt-191		1x10-3
	Pt-193m		1x10-2
	Pt-197m		1x10-2
	Pt-197		1x10-3
Polonium (84)	Po-210		$7x10^{-6}$
Potassium (19)	K-42		3x10-3
Praseodymium (59)	Pr-142		3x10-4
	Pr-143		5x10-4
Promethium (61)	Pm-147		2x10-3
	Pm-149		4x10-4
Radium (88)	Ra-226		$1x10^{-7}$
	Ra-228		$3x10^{-7}$
Rhenium (75)	Re-183		6x10-3

(Rule 1200-02-10-.33, continued)

	Re-186		9x10-4
	Re-188		6x10-4
Rhodium (45)	Rh-103m		1x10-1
	Rh-105		1x10-3
Rubidium (37)	Rb-86		7x10-4
Ruthenium (44)	Ru-97		4x10-3
	Ru-103		8x10-4
	Ru-105		1x10-3
	Ru-106		1x10-4
Samarium (62)	Sm-153		8x10-4
Scandium (21)	Sc-46		4x10-4
	Sc-47		9x10-4
	Sc-48		3x10-4
Selenium (34)	Se-75		3x10-3
Silicon (14)	Si-31		9x10-3
Silver (47)	Ag-105		1x10-3
	Ag-110m		3x10-4
	Ag-111		4x10-4
Sodium (11)	Na-24		2x10-3
Strontium (38)	Sr-85		1x10-3
	Sr-89		1x10-4
	Sr-91		7x10-4
	Sr-92		7x10-4
Sulfur (16)	S-35	$9x10^{-8}$	6x10-4
Tantalum (73)	Ta-182		4x10-4
Technetium (43)	Tc-96m		1x10-1
	Tc-96		1x10-3
Tellurium (52)	Te-125m		2x10-3
	Te-127m		6x10-4
	Te-127		3x10-3
	Te-129m		3x10-4
	Te-131m		6x10-4
	Te-132		3x10-4
Terbium (65)	Tb-160		4x10-4
Thallium (81)	Tl-200		4x10-3
	Tl-201		3x10-3
	Tl-202		1x10-3
	Tl-204		1x10-3
Thulium (69)	Tm-170		5x10-4
	Tm-171		5x10-3
Tin (50)	Sn-113		9x10-4
	Sn-125		2x10-4
Tungsten (74)	W-181		4x10-3
	W-187		7x10-4
Vanadium (23)	V-48		3x10-4
Xenon (54)	Xe-131m	$4x10^{-6}$	
	Xe-133	$3x10^{-6}$	
	Xe-135	$1x10^{-6}$	
Ytterbium (70)	Yb-175		1x10-3
Yttrium (39)	Y-90		2x10-4
	Y-91m		3x10-2
	Y-91		3x10-4
	Y-92		6x10-4
	Y-93		3x10-4
Zinc (30)	Zn-65		1x10-3
	Zn-69m		7x10-4

(Rule 1200-02-10-.33, continued)

	Zn-69		2x10-2
Zirconium (40)	Zr-95		6x10-4
	Zr-97		2x10-4
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years.		$1x10\text{-}1^{0}$	$1x10^{-6}$

[1] Values are given in Column I only for those materials normally used as gases
[2] µCi/gm for solids

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule RHS 8-4 the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 1200-2-10-.04 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule RHS 8-4 for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

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

SCHEDULE RHS 8-5

GENERAL LICENSING OF CERTAIN NAMED DEVICES

The following devices and equipment incorporating radioactive material, when manufactured, tested, and labeled by the manufacturer in accordance with the specification contained in a specific license or equivalent licensing document issued by the Division, the U.S. Nuclear Regulatory Commission or any Agreement State are placed under a general license pursuant to 1200-2-10-.10(1):

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

(b) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 50 millicuries of hydrogen 3 (tritium) per device.

Authority: *T.C.A. §§68-23-101 et seq., 68-23-206, 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 15, 1978; effective October 2, 1978. Amendment filed April 3, 1986; effective May 31, 1986. Amendment filed June 5, 1991; effective September 28, 1991. Amendment filed December 21, 2009; effective March 21, 2010. Repeal of rule filed December 21, 2009; effective March 21, 2010; withdrawal of repeal filed February 24, 2010.*

1200-02-10-.34 SUPPLEMENTAL FEES FOR CALENDAR YEAR 2001.

(1) Purpose. Adequate funds are required to facilitate the proper administration of The Radiological Health Service Act and The Medical Radiation Inspection Safety Act. Failure to properly administer these acts threatens the health and safety of the citizens of the state.

(Rule 1200-02-10-.35, continued)

Operating revenue for the administration of these acts is collected on a calendar year basis. Projected revenue needs of the Division in 2001 cannot be met by current registration and licensing fees. Rulemaking to increase 2001 fees cannot be completed prior to the first assessment date, January 1, 2001. Therefore, one time supplemental fees are hereby established to provide the Division with additional revenue during Calendar Year 2001. Division invoices will establish due dates for payment these supplemental fees, except that after the effective date of this Rule the operator of a disposal/processing facility shall begin to collect and submit the base fee ($0.01/lb) required by 1200-02-10-.31(8)(d) and the supplemental fee ($0.005/lb) together.

(2) Supplemental Fees Schedules.

(a) In addition to the fees established in paragraph (3) of Rule 1200-02-10-.24 Registration, persons subject to registration anytime during Calendar Year 2001 shall pay a supplemental fee to be determined according to Schedule I of this paragraph:

SCHEDULE I	
Class I Equipment----------	$ 10.00 per tube
Class II Equipment----------	$ 40.00 per tube
Class III Equipment----------	$ 20.00 per tube
Class IV Equipment----------	$ 50.00 per tube
Class V Equipment----------	$ 200.00 per tube
Class VI Equipment----------	$ 300.00 per tube
Class VII Equipment----------	$ 500.00 per tube
plus, for each accelerator initial review, a supplemental fee of	$ 125.00 per maximum nominal rated MeV (total supplemental initial review fee not to exceed $ 50,000.00)
A person providing inspection services under paragraph 1200-02-10-.27(4), except as provided by paragraph 1200-02-10-.24(3)(c)	$ 200.00

(b) In addition to the fees established in paragraphs (6) through (19) of Rule 1200-02-10-.31 Fees for Licenses, persons subject to licensure anytime during Calendar Year 2001 shall pay a supplemental fee to be determined according to Schedule II of this paragraph:

(Rule 1200-02-10-.35, continued)

Schedule II		
Category GL	----------	$ 50.00
Category 1	----------	$ 100.00
Category 2	----------	$ 200.00
Category 2d	In addition to the supplemental fee for Category 2, the operator of a disposal/processing facility shall collect and remit a supplemental fee, on items contaminated or potentially contaminated with radioactive material or on low-level radioactive waste received, of----------	$0.005/lb
	Not withstanding the requirements of paragraph 1200-02-10-.31(8) and Rule 1200-02-10-.32, licensees with multiple sites within the state will be levied the supplemental fee only once on items moved directly from one site to another.	
Category 3	----------	$ 300.00
Category 4	----------	$ 500.00
Category 5	----------	$ 700.00
Category 6	----------	$ 2,000.00
Category 7	----------	$ 1,000.00
Category 8	----------	$ 3,750.00
Category 9	----------	$ 5,000.00
Category 10	----------	$ 7,500.00
Category 11	----------	$ 10,000.00
Category 12	----------	$ 125,000.00
Category 13	----------	At least $ 50.00 not greater than $ 125,000.00
	The Category 13 supplemental fee shall be determined on a case-by-case basis. The determination shall be based on an analysis of the hazard, the scope of the difficulty encountered in the review process and the specifics of the activity, following the categories established in paragraphs (6) through (19) of Rule 1200-02-10-.31.	

Authority: *T.C.A. §§4-5-201 et seq., 68-202-201 et seq., and 68-203-101 et seq.* ***Administrative History:*** *Original rule filed Apri1 11, 2001; effective June 25, 2001.*

1200-02-10-.35 REPEALED ~~TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST~~.

~~(1) Training for an authorized nuclear pharmacist.~~

~~(a) Except as provided below in subparagraph (b), a licensee shall require the authorized nuclear pharmacist to be a pharmacist who:~~

~~1. Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or~~

~~2. Has completed 700 hours in a structured educational program consisting of both:~~

~~(i) Didactic training in the following areas:~~

~~(I) Radiation physics and instrumentation;~~

~~(II) Radiation protection;~~

~~(III) Mathematics pertaining to the use and measurement of radioactivity;~~

(Rule 1200-02-10-.35, continued)

~~(IV) Chemistry of radioactive material for medical use; and~~

~~(V) Radiation biology; and~~

~~(ii) Supervised experience in a nuclear pharmacy involving the following:~~

~~(I) Shipping, receiving and performing related radiation surveys;~~

~~(II) Using and performing checks for proper operation of dose calibrators, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;~~

~~(III) Calculating, assaying and safely preparing dosages for individuals;~~

~~(IV) Using administrative controls to avoid mistakes in the administration of radioactive material;~~

~~(V) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and~~

~~3. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to operate independently a nuclear pharmacy.~~

~~(b) Training for experienced nuclear pharmacists. A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in part 1200-2-10-.35(1)(a)2. before April 18, 2002, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (see part 1200-2-10-.35(1)(a)3. to qualify as an authorized nuclear pharmacist.~~

Authority: *T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206.* ***Administrative History:*** *Original rule filed July 18, 2002; effective October 1, 2002. Repeal filed December 21, 2009; effective March 21, 2010.*

1200-02-10-.36 RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION.

(1) General provisions and scope.

(a) The criteria in this rule apply to the decommissioning of facilities licensed under Chapter 1200-02-10 and Chapters 1200-02-07, 1200-02-08, 1200-02-09, 1200-02-11 and 1200-02-12. For low-level waste disposal facilities (Chapter 1200-02-11), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(b) Reserved.

(c) After a site has been decommissioned and the license terminated in accordance with the criteria in this rule, the Division will require additional cleanup 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.

(Rule 1200-02-10-.36, continued)

(d) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1,000 years after decommissioning.

(2) Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if:

(a) 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 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and

(b) The residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels that are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, potentially expected to result from decontamination and waste disposal.

(3) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

(a) A licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of paragraph 1200-02-10-.36(2):

1. Would result in net public or environmental harm or

2. Were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels that 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 mrem (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 specified in paragraph 1200-02-10-.12(4); and

(d) 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 ALARA and would not exceed either:

1. 100 mrem (1 mSv) per year; or

2. 500 mrem (5 mSv) per year provided the licensee:

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of part 1 above:

(I) Are not technically achievable,

(II) Would be prohibitively expensive or

(III) 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 and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Periodic rechecks shall be carried out no less frequently than every five (5) years to assure that the institutional controls remain in place as necessary to meet the criteria of subparagraph 1200-02-10-.36(3)(b). Acceptable financial assurance mechanisms are those in subparagraph 1200-02-10-.12(4)(d).

(4) Alternate criteria for license termination.

(a) The Division may terminate a license using alternate criteria greater than the dose criterion of paragraph 1200-02-10-.36(2) and subparagraph 1200-02-10-.36(3)(b), 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 the 1 mSv/y (100 mrem/y) limit of Rules 1200-02-05-.60 and 1200-02-05-.61, by submitting an analysis of possible sources of exposure;

2. Has employed to the extent practicable restrictions on site use according to the provisions of paragraph 1200-02-10-.36(3) in minimizing exposures at the site; and

(i) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

(ii) Reserved.

(b) The use of alternate criteria to terminate a license requires the approval of the Division. The Division will consider staff recommendations to address any comments provided by the Environmental Protection Agency and any public comments submitted under paragraph (5) below.

(5) Public notification and public participation. Whenever the Division deems such notice to be in the public interest, the Division may:

(a) Notify and solicit comments from:

1. Local governments and other State government agencies in the vicinity of the site that could be affected by the decommissioning; and

2. The Environmental Protection Agency for cases where the licensee proposes to release a site under paragraph 1200-02-10-.36(4).

(b) Publish a notice in the Tennessee Administrative Register, and in another appropriate forum that is readily accessible to individuals near the site, and solicit comments from affected parties. Another appropriate forum may include local newspapers and letters to State or local organizations.

(Rule 1200-02-10-.36, continued)

Authority: *T.C.A. §§4-5-201 et seq. and 68-202-101 et seq.* ***Administrative History:*** *Original rule filed July 18, 2002; effective October 1, 2002.*

1200-02-10-.37 SCHEDULE 10-6: DETERMINATION OF A_1 AND A_2.

(1) Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table A-1. The curie (Ci) values specified are obtained by converting from the terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent (0.1 %) or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

(2) For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of A_1 and A_2 requires Division approval, except that the values of A_1 and A_2 in Table A-2 may be used without obtaining Division approval.

(3) In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than ten (10) days or longer than that of the parent nuclide, shall be considered as a single radionuclide. The activity to be taken into account, and the A_1 or A_2 value to be applied, shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten (10) days or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

(4) For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_{I} \frac{B(i)}{A_1(i)} \text{ less than or equal to } 1$$

(b) For normal form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_{I} \frac{B(i)}{A_2(i)} \text{ less than or equal to } 1$$

Where B(i) is the activity of radionuclide I and $A_1(i)$ and $A_2(i)$ are the A_1 and A_2 values for radionuclide I, respectively.

Alternatively, an A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_{I} \frac{f(i)}{A_1(i)}}$$

Where f(i) is the fraction of activity of nuclide I in the mixture and $A_1(i)$ is the appropriate A_1 value for nuclide I.

An A_1 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_{I} \frac{f(i)}{A_2(i)}}$$

Where f(i) is the fraction of activity of nuclide I in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I.

(5) When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped. The lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph (4). Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

Table A-1: A_1 and A_2 Values for Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Ac-225	Actinium(89)	0.6	16.2	1×10^{-2}	0.270	2.1×10^{3}	5.8×10^{4}
Ac-227		40	1080	2×10^{-5}	5.41×10^{-4}	2.7	7.2×10^{1}
Ac-228		0.6	16.2	0.4	10.8	8.4×10^{4}	2.2×10^{6}
Ag-105	Silver(47)	2	54.1	2	54.1	1.1×10^{3}	3.0×10^{4}
Ag-108m		0.6	16.2	0.6	16.2	9.7×10^{-1}	2.6×10^{1}
Ag-110m		0.4	10.8	0.4	10.8	1.8×10^{2}	4.7×10^{3}
Ag-111		0.6	16.2	0.5	13.5	5.8×10^{3}	1.6×10^{5}
Al-26	Aluminum(13)	0.4	10.8	0.4	10.8	7.0×10^{-4}	1.9×10^{-2}
Am-241	Americium(95)	2	54.1	2×10^{-4}	5.41×10^{-3}	1.3×10^{-1}	3.4
Am-242m		2	54.1	2×10^{-4}	5.41×10^{-3}	3.6×10^{-1}	1.0×10^{1}
Am-243		2	54.1	2×10^{-4}	5.41×10^{-3}	7.4×10^{-3}	2.0×10^{-1}
Ar-37	Argon(18)	40	1080	40	1080	3.7×10^{3}	9.9×10^{4}
Ar-39		20	541	20	541	1.3	3.4×10^{1}
Ar-41		0.6	16.2	0.6	16.2	1.5×10^{6}	4.2×10^{7}
Ar-42		0.2	5.41	0.2	5.41	9.6	2.6×10^{2}
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	6.2×10^{4}	1.7×10^{6}
As-73		40	1080	40	1080	8.2×10^{2}	2.2×10^{4}
As-74		1	27.0	0.5	13.5	3.7×10^{3}	9.9×10^{4}
As-76		0.2	5.41	0.2	5.41	5.8×10^{4}	1.6×10^{6}
As-77		20	541	0.5	13.5	3.9×10^{4}	1.0×10^{6}
At-211	Astatine(85)	30	811	2	54.1	7.6×10^{4}	2.1×10^{6}
Au-193	Gold(79)	6	162	6	162	3.4×10^{4}	9.2×10^{5}
Au-194		1	27.0	1	27.0	1.5×10^{4}	4.1×10^{5}
Au-195		10	270	10	270	1.4×10^{2}	3.7×10^{3}
Au-196		2	54.1	2	54.1	4.0×10^{3}	1.1×10^{5}
Au-198		3	81.1	0.5	13.5	9.0×10^{3}	2.4×10^{5}
Au-199		10	270	0.9	24.3	7.7×10^{3}	2.1×10^{5}
Ba-131	Barium(56)	2	54.1	2	54.1	3.1×10^{3}	8.4×10^{4}
Ba-133m		10	270	0.9	24.3	2.2×10^{4}	6.1×10^{5}
Ba-133		3	81.1	3	81.1	9.4	2.6×10^{2}
Ba-140		0.4	10.8	0.4	10.8	2.7×10^{3}	7.3×10^{4}
Be-7	Beryllium(4)	20	541	20	541	1.3×10^{4}	3.5×10^{5}
Be-10		20	541	0.5	13.5	8.3×10^{-4}	2.2×10^{-2}
Bi-205	Bismuth(83)	0.6	16.2	0.6	16.2	1.5×10^{-3}	4.2×10^{4}
Bi-206		0.3	8.11	0.3	8.11	3.8×10^{3}	1.0×10^{5}
Bi-207		0.7	18.9	0.7	18.9	1.9	5.2×10^{1}
Bi-210m		0.3	8.11	3×10^{-2}	0.811	2.1×10^{-5}	5.7×10^{-4}
Bi-210		0.6	16.2	0.5	13.5	4.6×10^{3}	1.2×10^{5}
Bi-212		0.3	8.11	0.3	8.11	5.4×10^{5}	1.5×10^{7}

(Rule 1200-02-10-.37, continued)

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Bk-247	Berkelium(97)	2	54.1	2×10^{-4}	5.41×10^{-3}	3.8×10^{-2}	1.0
Bk-249		40	1080	8×10^{-2}	2.16	6.1×10^{1}	1.6×10^{3}
Br-76	Bromine(35)	0.3	8.11	0.3	8.11	9.4×10^{4}	2.5×10^{6}
Br-77		3	81.1	3	81.1	2.6×10^{4}	7.1×10^{5}
Br-82		0.4	10.8	0.4	10.8	4.0×10^{4}	1.1×10^{6}
C-11	Carbon(6)	1	27	0.5	13.5	3.1×10^{7}	8.4×10^{8}
C-14		40	1080	2	54.1	1.6×10^{-1}	4.5
Ca-41	Calcium(20)	40	1080	40	1080	3.1×10^{-3}	8.5×10^{-2}
Ca-45		40	1080	0.9	24.3	6.6×10^{2}	1.8×10^{4}
Ca-47		0.9	24.3	0.5	13.5	2.3×10^{4}	6.1×10^{5}
Cd-109	Cadmium(48)	40	1080	1	27.0	9.6×10^{1}	2.6×10^{3}
Cd-113m		20	541	9×10^{-2}	2.43	8.3	2.2×10^{2}
Cd-115m		0.3	8.11	0.3	8.11	9.4×10^{2}	2.5×10^{4}
Cd-115		4	108	0.5	13.5	1.9×10^{4}	5.1×10^{5}
Ce-139	Cerium(58)	6	162	6	162	2.5×10^{2}	6.8×10^{3}
Ce-141		10	270	0.5	13.5	1.1×10^{3}	2.8×10^{4}
Ce-143		0.6	16.2	0.5	13.5	2.5×10^{4}	6.6×10^{5}
Ce-144		0.2	5.41	0.2	5.41	1.2×10^{2}	3.2×10^{3}
Cf-248	Californium(98)	30	811	3×10^{-3}	8.11×10^{-2}	5.8×10^{1}	1.6×10^{3}
Cf-249		2	54.1	2×10^{-4}	5.41×10^{-3}	1.5×10^{-1}	4.1
Cf-250		5	135	5×10^{-4}	1.35×10^{-2}	4.0	1.1×10^{2}
Cf-251		2	54.1	2×10^{-4}	5.41×10^{-3}	5.9×10^{-2}	1.6
Cf-252		0.1	2.70	1×10^{-3}	2.70×10^{-2}	2.0×10^{1}	5.4×10^{2}
Cf-253		40	1080	6×10^{-2}	1.62	1.1×10^{3}	2.9×10^{4}
Cf-254		3×10^{-3}	8.11×10^{-2}	6×10^{-4}	1.62×10^{-2}	3.1×10^{2}	8.5×10^{3}
Cl-36	Chlorine(17)	20	541	0.5	13.5	1.2×10^{-3}	3.3×10^{-2}
Cl-38		0.2	5.41	0.2	5.41	4.9×10^{6}	1.3×10^{8}
Cm-240	Curium(96)	40	1080	2×10^{-2}	0.541	7.5×10^{2}	2.0×10^{4}
Cm-241		2	54.1	0.9	24.3	6.1×10^{2}	1.7×10^{4}
Cm-242		40	1080	1×10^{-2}	0.270	1.2×10^{2}	3.3×10^{3}
Cm-243		3	81.1	3×10^{-4}	8.11×10^{-3}	1.9	5.2×10^{1}
Cm-244		4	108	4×10^{-4}	1.08×10^{-2}	3.0	8.1×10^{1}
Cm-245		2	54.1	2×10^{-4}	5.41×10^{-3}	6.4×10^{-3}	1.7×10^{-1}
Cm-246		2	54.1	2×10^{-4}	5.41×10^{-3}	1.1×10^{-2}	3.1×10^{-1}
Cm-247		2	54.1	2×10^{-4}	5.41×10^{-3}	3.4×10^{-6}	9.3×10^{-5}
Cm-248		4×10^{-2}	1.08	5×10^{-5}	1.35×10^{-3}	1.6×10^{-4}	4.2×10^{-3}
Co-55	Cobalt(27)	0.5	13.5	0.5	13.5	1.1×10^{5}	3.1×10^{6}
Co-56		0.3	8.11	0.3	8.11	1.1×10^{3}	3.0×10^{4}
Co-57		8	216	8	216	3.1×10^{2}	8.4×10^{3}
Co-58m		40	1080	40	1080	2.2×10^{5}	5.9×10^{6}
Co-58		1	27.0	1	27.0	1.2×10^{3}	3.2×10^{4}
Co-60		0.4	10.8	0.4	10.8	4.2×10^{1}	1.1×10^{3}
Cr-51	Chromium(24)	30	811	30	811	3.4×10^{3}	9.2×10^{4}
Cs-129	Cesium(55)	4	108	4	108	2.8×10^{4}	7.6×10^{5}
Cs-131		40	1080	40	1080	3.8×10^{3}	1.0×10^{5}
Cs-132		1	27.0	1	27.0	5.7×10^{3}	1.5×10^{5}
Cs-134m		40	1080	9	243	3.0×10^{5}	8.0×10^{6}
Cs-134		0.6	16.2	0.5	13.5	4.8×10^{1}	1.3×10^{3}
Cs-135		40	1080	0.9	24.3	4.3×10^{-5}	1.2×10^{-3}
Cs-136		0.5	13.5	0.5	13.5	2.7×10^{3}	7.3×10^{4}
Cs-137		2	54.1	0.5	13.5	3.2	8.7×10^{1}
Cu-64	Copper(29)	5	135	0.9	24.3	1.4×10^{5}	3.9×10^{6}
Cu-67		9	243	0.9	24.3	2.8×10^{4}	7.6×10^{5}
Dy-159	Dysprosium(66)	20	541	20	541	2.1×10^{2}	5.7×10^{3}
Dy-165		0.6	16.2	0.5	13.5	3.0×10^{5}	8.2×10^{6}
Dy-166		0.3	8.11	0.3	8.11	8.6×10^{3}	2.3×10^{5}
Er-169	Erbium(68)	40	1080	0.9	24.3	3.1×10^{3}	8.3×10^{4}
Er-171		0.6	16.2	0.5	13.5	9.0×10^{4}	2.4×10^{6}

(Rule 1200-02-10-.37, continued)

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Es-253	Einsteinium(99) [a]	200	5400	2×10^{-2}	5.41×10^{-1}	.....	.....
Es-254		30	811	3×10^{-3}	8.11×10^{-2}	.....	.....
Es-254m		0.6	16.2	0.4	10.8	.....	.....
Es-255							
Eu-147	Europium(63)	2	54.1	2	54.1	1.4×10^{3}	3.7×10^{4}
Eu-148		0.5	13.5	0.5	13.5	6.0×10^{2}	1.6×10^{4}
Eu-149		20	541	20	541	3.5×10^{2}	9.4×10^{3}
Eu-150		0.7	18.9	0.7	18.9	6.1×10^{4}	1.6×10^{6}
Eu-152m		0.6	16.2	0.5	13.5	8.2×10^{4}	2.2×10^{6}
Eu-152		0.9	24.3	0.9	24.3	6.5	1.8×10^{2}
Eu-154		0.8	21.6	0.5	13.5	9.8	2.6×10^{2}
Eu-155		20	541	2	54.1	1.8×10^{1}	4.9×10^{2}
Eu-156		0.6	16.2	0.5	13.5	2.0×10^{3}	5.5×10^{4}
F-18	Fluorine(9)	1	27.0	0.5	13.5	3.5×10^{6}	9.5×10^{7}
Fe-52	Iron(26)	0.2	5.41	0.2	5.41	2.7×10^{5}	7.3×10^{6}
Fe-55		40	1080	40	1080	8.8×10^{1}	2.4×10^{3}
Fe-59		0.8	21.6	0.8	21.6	1.8×10^{3}	5.0×10^{4}
Fe-60		40	1080	0.2	5.41	7.4×10^{-4}	2.0×10^{-2}
Fm-255	Fermium(100) [b]	40	1080	0.8	21.6		
Fm-257		10	270	8×10^{-3}	2.16×10^{-1}		
Ga-67	Gallium(31)	6	162	6	162	2.2×10^{4}	6.0×10^{5}
Ga-68		0.3	8.11	0.3	8.11	1.5×10^{6}	4.1×10^{7}
Ga-72		0.4	10.8	0.4	10.8	1.1×10^{5}	3.1×10^{6}
Gd-146	Gadolinium(64)	0.4	10.8	0.4	10.8	6.9×10^{2}	1.9×10^{4}
Gd-148		3	81.1	3×10^{-4}	8.11×10^{-3}	1.2	3.2×10^{1}
Gd-153		10	270	5	135	1.3×10^{2}	3.5×10^{3}
Gd-159		4	108	0.5	13.5	3.9×10^{4}	1.1×10^{6}
Ge-68	Germanium(32)	0.3	8.11	0.3	8.11	2.6×10^{2}	7.1×10^{3}
Ge-71		40	1080	40	1080	5.8×10^{3}	1.6×10^{5}
Ge-77		0.3	8.11	0.3	8.11	1.3×10^{5}	3.6×10^{6}
H-3	Hydrogen(1)		See T-Tritium				
Hf-172	Hafnium(72)	0.5	13.5	0.3	8.11	4.1×10^{1}	1.1×10^{3}
Hf-175		3	81.1	3	81.1	3.9×10^{2}	1.1×10^{4}
Hf-181		2	54.1	0.9	24.3	6.3×10^{2}	1.7×10^{4}
Hf-182		4	108	3×10^{-2}	0.811	8.1×10^{-6}	2.2×10^{-4}
Hg-194	Mercury(80)	1	27.0	1	27.0	1.3×10^{-1}	3.5
Hg-195m		5	135	5	135	1.5×10^{4}	4.0×10^{5}
Hg-197m		10	270	0.9	24.3	2.5×10^{4}	6.7×10^{5}
Hg-197		10	270	10	270	9.2×10^{3}	2.5×10^{5}
Hg-203		4	108	0.9	24.3	5.1×10^{2}	1.4×10^{4}
Ho-163	Holmium(67)	40	1080	40	1080	2.7	7.6×10^{1}
Ho-166m		0.6	16.2	0.3	8.11	6.6×10^{-2}	1.8
Ho-166		0.3	8.11	0.3	8.11	2.6×10^{4}	7.0×10^{5}
I-123	Iodine(53)	6	162	6	162	7.1×10^{4}	1.9×10^{6}
I-124		0.9	24.3	0.9	24.3	9.3×10^{3}	2.5×10^{5}
I-125		20	541	2	54.1	6.4×10^{2}	1.7×10^{4}
I-126		2	54.1	0.9	24.3	2.9×10^{3}	8.0×10^{4}
I-129		Unlimited	Unlimited	Unlimited	Unlimited	6.5×10^{-6}	1.8×10^{-4}
I-131		3	81.1	0.5	13.5	4.6×10^{3}	1.2×10^{5}
I-132		0.4	10.8	0.4	10.8	3.8×10^{5}	1.0×10^{7}
I-133		0.6	16.2	0.5	13.5	4.2×10^{4}	1.1×10^{6}
I-134		0.3	8.11	0.3	8.11	9.9×10^{5}	2.7×10^{7}
I-135		0.6	16.2	0.5	13.5	1.3×10^{5}	3.5×10^{6}
In-111	Indium(49)	2	54.1	2	54.1	1.5×10^{4}	4.2×10^{5}
In-113m		4	108	4	108	6.2×10^{5}	1.7×10^{7}
In-114m		0.3	8.11	0.3	8.11	8.6×10^{2}	2.3×10^{4}
In-115m		6	162	0.9	24.3	2.2×10^{5}	6.1×10^{6}
Ir-189	Iridium(77)	10	270	10	270	1.9×10^{3}	5.2×10^{4}
Ir-190		0.7	18.9	0.7	18.9	2.3×10^{3}	6.2×10^{4}

(Rule 1200-02-10-.37, continued)

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Ir-192		1	27.0	0.5	13.5	3.4×10^{2}	9.2×10^{3}
Ir-193m		10	270	10	270	2.4×10^{3}	6.4×10^{4}
Ir-194		0.2	5.41	0.2	5.41	3.1×10^{4}	8.4×10^{5}
K-40	Potassium(19)	0.6	16.2	0.6	16.2	2.4×10^{-7}	6.4×10^{-6}
K-42		0.2	5.41	0.2	5.41	2.2×10^{5}	6.0×10^{6}
K-43		1.0	27.0	0.5	13.5	1.2×10^{5}	3.3×10^{6}
Kr-81	Krypton(36)	40	1080	40	1080	7.8×10^{-4}	2.1×10^{-2}
Kr-85m		6	162	6	162	3.0×10^{5}	8.2×10^{6}
Kr-85		20	541	10	270	1.5×10^{1}	3.9×10^{2}
Kr-87		0.2	5.41	0.2	5.41	1.0×10^{6}	2.8×10^{7}
La-137	Lanthanum(57)	40	1080	2	54.1	1.6×10^{-3}	4.4×10^{-2}
La-140		0.4	10.8	0.4	10.8	2.1×10^{4}	5.6×10^{5}
Lu-172	Lutetium(71)	0.5	13.5	0.5	13.5	4.2×10^{3}	1.1×10^{5}
Lu-173		8	216	8	216	5.6×10^{1}	1.5×10^{3}
Lu-174m		20	541	8	216	2.0×10^{2}	5.3×10^{3}
Lu-174		8	216	4	108	2.3×10^{1}	6.2×10^{2}
Lu-177		30	811	0.9	24.3	4.1×10^{3}	1.1×10^{5}
MFP	For mixed fission products, use formula for mixtures or Table A-2						
Mg-28	Magnesium(12)	0.2	5.41	0.2	5.41	2.0×10^{5}	5.4×10^{6}
Mn-52	Manganese(25)	0.3	8.11	0.3	8.11	1.6×10^{4}	4.4×10^{5}
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8×10^{-5}	1.8×10^{-3}
Mn-54		1	27.0	1	27.0	2.9×10^{2}	7.7×10^{3}
Mn-56		0.2	5.41	0.2	5.41	8.0×10^{5}	2.2×10^{7}
Mo-93	Molybdenum(42)	40	1080	7	189	4.1×10^{-2}	1.1
Mo-99		0.6	16.2	0.5	13.5 [c]	1.8×10^{4}	4.8×10^{5}
N-13	Nitrogen(7)	0.6	16.2	0.5	13.5	5.4×10^{7}	1.5×10^{9}
Na-22	Sodium(11)	0.5	13.5	0.5	13.5	2.3×10^{2}	6.3×10^{3}
Na-24		0.2	5.41	0.2	5.41	3.2×10^{5}	8.7×10^{6}
Nb-92m	Niobium(41)	0.7	18.9	0.7	18.9	5.2×10^{3}	1.4×10^{5}
Nb-93m		40	1080	6	162	8.8	2.4×10^{2}
Nb-94		0.6	16.2	0.6	16.2	6.9×10^{-3}	1.9×10^{-1}
Nb-95		1	27.0	1	27.0	1.5×10^{3}	3.9×10^{4}
Nb-97		0.6	16.2	0.5	13.5	9.9×10^{5}	2.7×10^{7}
Nd-147	Neodymium(60)	4	108	0.5	13.5	3.0×10^{3}	8.1×10^{4}
Nd-149		0.6	16.2	0.5	13.5	4.5×10^{5}	1.2×10^{7}
Ni-59	Nickel(28)	40	1080	40	1080	3.0×10^{-3}	8.0×10^{-2}
Ni-63		40	1080	30	811	2.1	5.7×10^{1}
Ni-65		0.3	8.11	0.3	8.11	7.1×10^{5}	1.9×10^{7}
Np-235	Neptunium(93)	40	1080	40	1080	5.2×10^{1}	1.4×10^{3}
Np-236		7	189	1×10^{-3}	2.70×10^{-2}	4.710-4	1.3×10^{-2}
Np-237		2	54.1	2×10^{-4}	5.41×10^{-3}	2.6×10^{-5}	7.1×10^{-4}
Np-239		6	162	0.5	13.5	8.6×10^{3}	2.3×10^{5}
Os-185	Osmium(76)	1	27.0	1	27.0	2.8×10^{2}	7.5×10^{3}
Os-191m		40	1080	40	1080	4.6×10^{4}	1.3×10^{6}
Os-191		10	270	0.9	24.3	1.6×10^{3}	4.4×10^{4}
Os-193		0.6	16.2	0.5	13.5	2.0×10^{4}	5.3×10^{5}
Os-194		0.2	5.41	0.2	5.41	1.1×10^{1}	3.1×10^{2}
P-32	Phosphorus(15)	0.3	8.11	0.3	8.11	1.1×10^{4}	2.9×10^{5}
P-33		40	1080	0.9	24.3	5.8×10^{3}	1.6×10^{5}
Pa-230	Protactinium(91)	2	54.1	0.1	2.70	1.2×10^{3}	3.3×10^{4}
Pa-231		0.6	16.2	6×10^{-5}	1.62×10^{-3}	1.7×10^{-3}	4.7×10^{-2}
Pa-233		5	135	0.9	24.3	7.7×10^{2}	2.1×10^{4}
Pb-201	Lead(82)	1	27.0	1	27.0	6.2×10^{4}	1.7×10^{6}
Pb-202		40	1080	2	54.1	1.2×10^{-4}	3.4×10^{-3}
Pb-203		3	81.1	3	81.1	1.1×10^{4}	3.0×10^{5}
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	4.5×10^{-6}	1.2×10^{-4}
Pb-210		0.6	16.2	9×10^{-3}	0.243	2.8	7.6×10^{1}
Pb-212		0.3	8.11	0.3	8.11	5.1×10^{4}	1.4×10^{6}

(Rule 1200-02-10-.37, continued)

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Pd-103	Palladium(46)	40	1080	40	1080	2.8×10^{3}	7.5×10^{4}
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	1.9×10^{-5}	5.1×10^{-4}
Pd-109		0.6	16.2	0.5	13.5	7.9×10^{4}	2.1×10^{6}
Pm-143	Promethium(61)	3	81.1	3	81.1	1.3×10^{2}	3.4×10^{3}
Pm-144		0.6	16.2	0.6	16.2	9.2×10^{1}	2.5×10^{3}
Pm-145		30	811	7	189	5.2	1.4×10^{2}
Pm-147		40	1080	0.9	24.3	3.4×10^{1}	9.3×10^{2}
Pm-148m		0.5	13.5	0.5	13.5	7.9×10^{2}	2.1×10^{4}
Pm-149		0.6	16.2	0.5	13.5	1.5×10^{4}	4.0×10^{5}
Pm-151		3	81.1	0.5	13.5	2.7×10^{4}	7.3×10^{5}
Po-208	Polonium(84)	40	1080	2×10^{-2}	0.541	2.2×10^{1}	5.9×10^{2}
Po-209		40	1080	2×10^{-2}	0.541	6.2×10^{-1}	1.7×10^{1}
Po-210		40	1080	2×10^{-2}	0.541	1.7×10^{2}	4.5×10^{3}
Pr-142	Praseodymium(59)	0.2	5.41	0.2	5.41	4.3×10^{4}	1.2×10^{6}
Pr-143		4	108	0.5	13.5	2.5×10^{3}	6.7×10^{4}
Pt-188	Platinum(78)	0.6	16.2	0.6	16.2	2.5×10^{3}	6.8×10^{4}
Pt-191		3	81.1	3	81.1	8.7×10^{3}	2.4×10^{5}
Pt-193m		40	1080	9	243	5.8×10^{3}	1.6×10^{5}
Pt-193		40	1080	40	1080	1.4	3.7×10^{1}
Pt-195m		10	270	2	54.1	6.2×10^{3}	1.7×10^{5}
Pt-197m		10	270	0.9	24.3	3.7×10^{5}	1.0×10^{7}
Pt-197		20	541	0.5	13.5	3.2×10^{4}	8.7×10^{5}
Pu-236	Plutonium(94)	7	189	7×10^{-4}	1.89×10^{-2}	2.0×10^{1}	5.3×10^{2}
Pu-237		20	541	20	541	4.5×10^{2}	1.2×10^{4}
Pu-238		2	54.1	2×10^{-4}	5.41×10^{-3}	6.3×10^{-1}	1.7×10^{1}
Pu-239		2	54.1	2×10^{-4}	5.41×10^{-3}	2.3×10^{-3}	6.2×10^{-2}
Pu-240		2	54.1	2×10^{-4}	5.41×10^{-3}	8.4×10^{-3}	2.3×10^{-1}
Pu-241		40	1080	1×10^{-2}	0.270	3.8	1.0×10^{2}
Pu-242		2	54.1	2×10^{-4}	5.41×10^{-3}	1.5×10^{-4}	3.9×10^{-3}
Pu-244		0.3	8.11	2×10^{-4}	5.41×10^{-3}	6.7×10^{-7}	1.8×10^{-5}
Ra-223	Radium(88)	0.6	16.2	3×10^{-2}	0.811	1.9×10^{3}	5.1×10^{4}
Ra-224		0.3	8.11	6×10^{-2}	1.62	5.9×10^{3}	1.6×10^{5}
Ra-225		0.6	16.2	2×10^{-2}	0.541	1.5×10^{3}	3.9×10^{4}
Ra-226		0.3	8.11	2×10^{-2}	0.541	3.7×10^{-2}	1.0
Ra-228		0.6	16.2	4×10^{-2}	1.08	1.0×10^{1}	2.7×10^{2}
Rb-81	Rubidium(37)	2	54.1	0.9	24.3	3.1×10^{5}	8.4×10^{6}
Rb-83		2	54.1	2	54.1	6.8×10^{2}	1.8×10^{4}
Rb-84		1	27.0	0.9	24.3	1.8×10^{3}	4.7×10^{4}
Rb-86		0.3	8.11	0.3	8.11	3.0×10^{3}	8.1×10^{4}
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	3.2×10^{-9}	8.6×10^{-8}
Rb (natural)		Unlimited	Unlimited	Unlimited	Unlimited	6.7×10^{6}	1.8×10^{8}
Re-183	Rhenium(75)	5	135	5	135	3.8×10^{2}	1.0×10^{4}
Re-184m		3	81.1	3	81.1	1.6×10^{2}	4.3×10^{3}
Re-184		1	27.0	1	27.0	6.9×10^{2}	1.9×10^{4}
Re-186		4	108	0.5	13.5	6.9×10^{3}	1.9×10^{5}
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4×10^{-9}	3.8×10^{-8}
Re-188		0.2	5.41	0.2	5.41	3.6×10^{4}	9.8×10^{5}
Re-189		4	108	0.5	13.5	2.5×10^{4}	6.8×10^{5}
Re (natural)		Unlimited	Unlimited	Unlimited	Unlimited		2.4×10^{-8}
Rh-99	Rhodium(45)	2	54.1	2	54.1	3.0×10^{3}	8.2×10^{4}
Rh-101		4	108	4	108	4.1×10^{1}	1.1×10^{3}
Rh-102m		2	54.1	0.9	24.3	2.3×10^{2}	6.2×10^{3}
Rh-102		0.5	13.5	0.5	13.5	4.5×10^{1}	1.2×10^{3}
Rh-103m		40	1080	40	1080	1.2×10^{6}	3.3×10^{7}
Rh-105		10	270	0.9	24.3	3.1×10^{4}	8.4×10^{5}
Rn-222	Radon(86)	0.2	5.41	4×10^{-3}	0.108	5.7×10^{3}	1.5×10^{5}
Ru-97	Ruthenium(44)	4	108	4	108	1.7×10^{4}	4.6×10^{5}

(Rule 1200-02-10-.37, continued)

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Ru-103		2	54.1	0.9	24.3	1.2×10^{3}	3.2×10^{4}
Ru-105		0.6	16.2	0.5	13.5	2.5×10^{5}	6.7×10^{6}
Ru-106		0.2	5.41	0.2	5.41	1.2×10^{2}	3.3×10^{3}
S-35	Sulfur(16)	40	1080	2	54.1	1.6×10^{3}	4.3×10^{4}
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	1.5×10^{4}	4.0×10^{5}
Sb-124		0.6	16.2	0.5	13.5	6.5×10^{2}	1.7×10^{4}
Sb-125		2	54.1	0.9	24.3	3.9×10^{1}	1.0×10^{3}
Sb-126		0.4	10.8	0.4	10.8	3.1×10^{3}	8.4×10^{4}
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	6.7×10^{5}	1.8×10^{7}
Sc-46		0.5	13.5	0.5	13.5	1.3×10^{3}	3.4×10^{4}
Sc-47		9	243	0.9	24.3	3.1×10^{4}	8.3×10^{5}
Sc-48		0.3	8.11	0.3	8.11	5.5×10^{4}	1.5×10^{6}
Se-75	Selenium(34)	3	81.1	3	81.1	5.4×10^{2}	1.5×10^{4}
Se-79		40	1080	2	54.1	2.6×10^{-3}	7.0×10^{-2}
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	1.4×10^{6}	3.9×10^{7}
Si-32		40	1080	0.2	5.41	3.9	1.1×10^{2}
Sm-145	Samarium(62)	20	541	20	541	9.8×10^{1}	2.6×10^{3}
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	8.5×10^{-1}	2.3×10^{-8}
Sm-151		40	1080	4	108	9.7×10^{-1}	2.6×10^{1}
Sm-153		4	108	0.5	13.5	1.6×10^{4}	4.4×10^{5}
Sn-113	Tin(50)	4	108	4	108	3.7×10^{2}	1.0×10^{4}
Sn-117m		6	162	2	54.1	3.0×10^{3}	8.2×10^{4}
Sn-119m		40	1080	40	1080	1.4×10^{2}	3.7×10^{3}
Sn-121m		40	1080	0.9	24.3	2.0	5.4×10^{1}
Sn-123		0.6	16.2	0.5	13.5	3.0×10^{2}	8.2×10^{3}
Sn-125		0.2	5.41	0.2	5.41	4.0×10^{3}	1.1×10^{5}
Sn-126		0.3	8.11	0.3	8.11	1.0×10^{-3}	2.8×10^{-2}
Sr-82	Strontium(38)	0.2	5.41	0.2	5.41	2.3×10^{3}	6.2×10^{4}
Sr-85m		5	135	5	135	1.2×10^{6}	3.3×10^{7}
Sr-85		2	54.1	2	54.1	8.8×10^{2}	2.4×10^{4}
Sr-87m		3	81.1	3	81.1	4.8×10^{5}	1.3×10^{7}
Sr-89		0.6	16.2	0.5	13.5	1.1×10^{3}	2.9×10^{4}
Sr-90		0.2	5.41	0.1	2.70	5.1	1.4×10^{2}
Sr-91		0.3	8.11	0.3	8.11	1.3×10^{5}	3.6×10^{6}
Sr-92		0.8	21.6	0.5	13.5	4.7×10^{5}	1.3×10^{7}
T	Tritium(1)	40	1080	40	1080	3.6×10^{2}	9.7×10^{3}
Ta-178	Tantalum(73)	1	27.0	1	27.0	4.2×10^{6}	1.1×10^{8}
Ta-179		30	811	30	811	4.1×10^{1}	1.1×10^{3}
Ta-182		0.8	21.6	0.5	13.5	2.3×10^{2}	6.2×10^{3}
Tb-157	Terbium(65)	40	1080	10	270	5.6×10^{-1}	1.5×10^{1}
Tb-158		1	27.0	0.7	18.9	5.6×10^{-1}	1.5×10^{1}
Tb-160		0.9	24.3	0.5	13.5	4.2×10^{2}	1.1×10^{4}
Tc-95m	Technetium(43)	2	54.1	2	54.1	8.3×10^{2}	2.2×10^{4}
Tc-96m		0.4	10.8	0.4	10.8	1.4×10^{6}	3.8×10^{7}
Tc-96	.	0.4	10.8	0.4	10.8	1.2×10^{4}	3.2×10^{5}
Tc-97m		40	1080	40	1080	5.6×10^{2}	1.5×10^{4}
Tc-97	.	Unlimited	Unlimited	Unlimited	Unlimited	5.2×10^{-5}	1.4×10^{-3}
Tc-98	.	0.7	18.9	0.7	18.9	3.2×10^{-5}	8.7×10^{-4}
Tc-99m		8	216	8	216	1.9×10^{5}	5.3×10^{6}
Tc-99		40	1080	0.9	24.3	6.3×10^{-4}	1.7×10^{-2}
Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	6.8×10^{3}	1.8×10^{5}
Te-121m		5	135	5	135	2.6×10^{2}	7.0×10^{3}
Te-121		2	54.1	2	54.1	2.4×10^{3}	6.4×10^{4}
Te-123m		7	189	7	189	3.3×10^{2}	8.9×10^{3}
Te-125m		30	811	9	243	6.7×10^{2}	1.8×10^{4}
Te-127m		20	541	0.5	13.5	3.5×10^{2}	9.4×10^{3}
Te-127		20	541	0.5	13.5	9.8×10^{4}	2.6×10^{6}
Te-129m		0.6	16.2	0.5	13.5	1.1×10^{3}	3.0×10^{4}

(Rule 1200-02-10-.37, continued)

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Te-129		0.6	16.2	0.5	13.5	7.7×10^{5}	2.1×10^{7}
Te-131m		0.7	18.9	0.5	13.5	3.0×10^{4}	8.0×10^{5}
Te-132		0.4	10.8	0.4	10.8	1.1×10^{4}	3.0×10^{5}
Th-227	Thorium(90)	9	243	1×10^{-2}	0.270	1.1×10^{3}	3.1×10^{4}
Th-228		0.3	8.11	4×10^{-4}	1.08×10^{-2}	3.0×10^{1}	8.2×10^{2}
Th-229		0.3	8.11	3×10^{-5}	8.11×10^{-4}	7.9×10^{-3}	2.1×10^{-1}
Th-230		2	54.1	2×10^{-4}	5.41×10^{-3}	7.6×10^{-4}	2.1×10^{-2}
Th-231		40	1080	0.9	24.3	2.0×10^{4}	5.3×10^{5}
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0×10^{-9}	1.1×10^{-7}
Th-234		0.2	5.41	0.2	5.41	8.6×10^{2}	2.3×10^{4}
Th (natural)		Unlimited	Unlimited	Unlimited	Unlimited	8.1×10^{-9}	2.2×10^{-7}
Ti-44	Titanium(22)	0.5	13.5	0.2	5.41	6.4	1.7×10^{2}
Tl-200	Thallium(81.1)	0.8	21.6	0.8	21.6	2.2×10^{4}	6.0×10^{5}
Tl-201		10	270	10	270	7.9×10^{3}	2.1×10^{5}
Tl-202		2	54.1	2	54.1	2.0×10^{3}	5.3×10^{4}
Tl-204		4	108	0.5	13.5	1.7×10^{1}	4.6×10^{2}
Tm-167	Thulium(69)	7	189	7	189	3.1×10^{3}	8.5×10^{4}
Tm-168		0.8	21.6	0.8	21.6	3.1×10^{2}	8.3×10^{3}
Tm-170		4	108	0.5	13.5	2.2×10^{2}	6.0×10^{3}
Tm-171		40	1080	10	270	4.0×10^{1}	1.1×10^{3}
U-230	Uranium(92)	40	1080	1×10^{-2}	0.270	1.0×10^{3}	2.7×10^{4}
U-232	.	3	81.1	3×10^{-4}	8.11×10^{-3}	8.3×10^{-1}	2.2×10^{1}
U-233	.	10	270	1×10^{-3}	2.70×10^{-2}	3.6×10^{-4}	9.7×10^{-3}
U-234	.	10	270	1×10^{-3}	2.70×10^{-2}	2.3×10^{-4}	6.2×10^{-3}
U-235	.	Unlimited	Unlimited	Unlimited	Unlimited	8.0×10^{-8}	2.2×10^{-6}
U-236	.	10	270	1×10^{-3}	2.70×10^{-2}	2.4×10^{-6}	6.5×10^{-5}
U-238	.	Unlimited	Unlimited	Unlimited	Unlimited	1.2×10^{-8}	3.4×10^{-7}
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	2.6×10^{-8}	7.1×10^{-7}
U (enriched 5% or less)		Unlimited	Unlimited	Unlimited	Unlimited		(See Table A-3)
U (enriched more than 5%)		10	270	1×10^{-3}	2.70×10^{-2}		(See Table A-3)
U (depleted)		Unlimited	Unlimited	Unlimited	Unlimited		(See Table A-3)
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	6.3×10^{3}	1.7×10^{5}
V-49		40	1080	40	1080	3.0×10^{2}	8.1×10^{3}
W-178	Tungsten(74)	1	27.0	1	27.0	1.3×10^{3}	3.4×10^{4}
W-181	.	30	811	30	811	2.2×10^{2}	6.0×10^{3}
W-185	.	40	1080	0.9	24.3	3.5×10^{2}	9.4×10^{3}
W-187	.	2	54.1	0.5	13.5	2.6×10^{4}	7.0×10^{5}
W-188	.	0.2	5.41	0.2	5.41	3.7×10^{2}	1.0×10^{4}
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	4.8×10^{4}	1.3×10^{6}
Xe-123		0.2	5.41	0.2	5.41	4.4×10^{5}	1.2×10^{7}
Xe-127		4	108	4	108	1.0×10^{3}	2.8×10^{4}
Xe-131m		40	1080	40	1080	3.1×10^{3}	8.4×10^{4}
Xe-133		20	541	20	541	6.9×10^{3}	1.9×10^{5}
Xe-135		4	108	4	108	9.5×10^{4}	2.6×10^{6}
Y-87	Yttrium(39)	2	54.1	2	54.1	1.7×10^{4}	4.5×10^{5}
Y-88		0.4	10.8	0.4	10.8	5.2×10^{2}	1.4×10^{4}
Y-90		0.2	5.41	0.2	5.41	2.0×10^{4}	5.4×10^{5}
Y-91m	.	2	54.1	2	54.1	1.5×10^{6}	4.2×10^{7}
Y-91		0.3	8.11	0.3	8.11	9.1×10^{2}	2.5×10^{4}
Y-92		0.2	5.41	0.2	5.41	3.6×10^{5}	9.6×10^{6}
Y-93		0.2	5.41	0.2	5.41	1.2×10^{5}	3.3×10^{6}
Yb-169	Ytterbium(70)	3	81.1	3	81.1	8.9×10^{2}	2.4×10^{4}
Yb-175		30	811	0.9	24.3	6.6×10^{3}	1.8×10^{5}
Zn-65	Zinc(30)	2	54.1	2	54.1	3.0×10^{2}	8.2×10^{3}

(Rule 1200-02-10-.37, continued)

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Zn-69m		2	54.1	0.5	13.5	1.2×10^{5}	3.3×10^{6}
Zn-69		4	108	0.5	13.5	1.8×10^{6}	4.9×10^{7}
Zr-88	Zirconium(40)	3	81.1	3	81.1	6.6×10^{2}	1.8×10^{4}
Zr-93		40	1080	0.2	5.41	9.3×10^{-5}	2.5×10^{-3}
Zr-95		1	27.0	0.9	24.3	7.9×10^{2}	2.1×10^{4}
Zr-97		0.3	8.11	0.3	8.11	7.1×10^{4}	1.9×10^{6}

a International shipments of einsteinium require multilateral approval of A_1 and A_2 values.
b International shipments of fermium require multilateral approval of A_1 and A_2 values.
c 20 Ci for Mo-99 for domestic use.

Table A-2: General Values for A_1 and A_2

Contents	A_1 (TBq)		A_2 (TBq)	
Only beta- or gamma-emitting nuclides are known to be present.	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available	0.10	2.70	2×10^{-5}	5.41×10^{-4}

Table A-3: Activity-mass Relationships for Uranium

Uranium Enrichment[1] wt % U-235 present	Specific Activity TBq/g	Specific Activity Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1.0	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5.0	1.0×10^{-7}	2.7×10^{-6}
10.0	1.8×10^{-7}	4.8×10^{-6}
20.0	3.7×10^{-7}	1.0×10^{-5}
35.0	7.4×10^{-7}	2.0×10^{-5}
50.0	9.3×10^{-7}	2.5×10^{-5}
90.0	2.2×10^{-6}	5.8×10^{-5}
93.0	2.6×10^{-6}	7.0×10^{-5}
95.0	3.4×10^{-6}	9.1×10^{-5}

1. The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

Authority: *T.C.A. §§4-5-201 et seq. and 68-202-101 et seq.* ***Administrative History:*** *Original rule filed July 18, 2002; effective October 1, 2002.*