

**RULES
OF
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH**

CHAPTER 1200-2-7

USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

TABLE OF CONTENTS

1200-2-7-.01	Purpose		Applications
1200-2-7-.02	Scope	1200-2-7-.04	Teletherapy
1200-2-7-.03	Interstitial, Intracavitary, and Superficial		

1200-2-7-.01 PURPOSE

This Chapter establishes requirements for the use of sealed sources of radioactive material in the healing arts. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

Authority: T.C.A. §68-28-101 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.

1200-2-7-.02 SCOPE

Except as otherwise specifically provided, this Chapter applies to all persons who use sealed sources in the healing arts.

Authority: T.C.A. §68-28-101 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.

1200-2-7-.03 INTERSTITIAL, INTRACAVITARY, AND SUPERFICIAL APPLICATIONS

- (1) Accountability, storage, and transit.
 - (a) Except as otherwise specifically authorized by the Division, every hospital, clinic or physician possessing sealed sources shall 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 material in each sealed source and signature of individual(s) involved in each removal from and each return to storage.
 - (b) Every hospital, clinic or physician possessing sealed sources shall conduct a physical inventory at least quarterly to account for all sealed sources possessed by him. Records of the inventories shall be maintained for inspection by the Division and shall include the identity of the sealed sources, the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.
 - (c) When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be

necessary to insure that provisions of 1200-2-5-.03, -21200-2-5-.06(1), and 1200-2-5-.07 are met.

- (d) Each licensee shall 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, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.
 - (e) Each licensee shall assure that needles or standard medical applicator cells containing cobalt 60 as wire, radium 226, or cesium 137 are not opened while in the licensee's possession unless specifically authorized by a license issued by the Division.
- (2) Testing sealed sources for leakage and contamination.
- (a) All sealed sources with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage prior to initial use and at intervals not to exceed six (6) months.
 - (b) If there is reason to suspect that a sealed source or device containing a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.
 - (c) The test required by (a) and (b) of this paragraph (2) 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.¹
 - (d) Any test conducted pursuant to 1200-2-7-.03(2)(a) and (b) which 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 shall be considered evidence that the sealed source is leaking. The source shall be immediately withdrawn from use and decontaminated and repaired or disposed of in accordance with Division regulations. A report shall be filed within five (5) days of the test with the Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, describing the equipment involved, the test results, and the corrective action taken.
 - (e) Leak tests results shall be recorded in units of microcuries and maintained for inspection by the Division.
- (3) Radiation surveys.
- (a) For patients to whom brachytherapy sealed sources have been applied, the maximum radiation level at a distance of 1 meter from the patient, or optionally at the bedside shall be determined by measurement or calculation and preferably by both. This radiation level shall be entered on the caution sign posted as required by 1200-2-7-.03(4).
 - (b) The radiation levels in the patient's room and the surrounding area shall be determined (by measurement or calculation), recorded, and maintained for inspection by the Division.

¹ Assay methods for testing radium sources outlined in the appendix to ANSI Standard 44.2 are acceptable for this purpose.

- (c) The licensee shall assure that patients treated with cobalt 60, cesium 137, iridium 192, or radium 226 implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been removed.
- (4) Posting.
 - (a) In addition to the requirements of 1200-2-5-.12, the bed, cubicle, or room of the brachytherapy patient shall be posted with a sign indicating the presence of brachytherapy sealed sources. This sign shall incorporate the radiation symbol, and specify the radionuclide, the date, the activity, and the individual to contact for radiation safety instructions. The sign is not required provided the exception in 1200-2-5-.13(2) is met.
 - (b) The following information shall be included in the patient's chart:
 - 1. The radionuclide administered, number of sources, activity in millicuries, and time and date of administration;
 - 2. The radiation symbol, the exposure rate at 1 meter, and name of the individual who made the determination;
 - 3. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 1200-2-5-.03.

Authority: T.C.A. §68-28-101 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.

1200-2-7-.04 TELETHERAPY

- (1) Equipment.
 - (a) The housing shall be so constructed that at 1 meter from the sealed source, the maximum *exposure* rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. An acceptable method for determining compliance with this requirement is outlined in Section 4.22(a), in Report No. 33 of the National Council on Radiation Protection and Measurements (NCRP) issued February 1, 1968.
 - (b) For teletherapy equipment installed after the effective date of these regulations, the leakage radiation measured at 1 meter from the sealed source when the beam control mechanism is in the "on" position shall not exceed the larger of 1 roentgen per hour or 0.1 percent of the useful beam.
 - (c) Adjustable or removable beam-defining diaphragms shall allow transmission of not more than five (5) percent of the useful beam *exposure* rate.
 - (d) The beam control mechanism shall be of a positive design capable of acting in any position of the housing. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum of risk of exposure.
 - (e) The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.

- (f) When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.
 - (g) The equipment shall be provided with a locking device to prevent unauthorized use.
 - (h) There shall be at the housing and at the control panel a warning device that plainly indicated whether the beam is "on" or "off".
 - (i) The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.
 - (j) Teletherapy sealed sources shall be tested for leakage and contamination in accordance with the procedures described in 1200-2-7-.03(2) of this Chapter, except that tests of leakage may be made by wiping surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.
 - (k) The treatment room shall be so constructed that persons within the room may at all times be able to escape.
 - (l) Windows, mirror systems, or closed-circuit television shall be provided and shall be so located that both the patient and the control panel will be under observation at all times by the operator at his position at the control pane.
- (2) Shielding.
- (a) Primary barriers shall be provided for any area that the useful beam may strike when using the largest possible diaphragm opening. Such barriers shall extend at least 1 foot (30.5 centimeters) beyond the useful beam for any possible orientation.
 - (b) Secondary barriers shall be provided for all occupied areas exposed to leakage and scattered radiation.
- (3) Operation. No individual who is occupationally exposed to radiation shall be in the treatment room during irradiation unless he is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.
- (4) Calibration and spot-check measurements.
- (a) Any licensee authorized to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:
 1. Prior to the first use of the unit for treating humans;
 2. Prior to treating:
 - (i) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;
 - (ii) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;

- (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- 3. At intervals not exceeding one year.
- (b) Full calibration measurement required by (a) of this paragraph shall include determination of:
 - 1. The *exposure* rate or dose rate to an accuracy within) 3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
 - 2. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - 3. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
 - 4. Timer accuracy; and
 - 5. The accuracy of all distance measuring devices used for treating humans.
- (c) Full calibration measurements shall be made in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396).
- (d) The *exposure* rate or dose rate values determined in (b)1 of this paragraph shall be corrected mathematically for physical decay for intervals not exceeding one month.
- (e) Full calibration measurements required by (a) of this paragraph and physical decay corrections required by (d) of this paragraph shall be performed by a qualified expert as defined in 1200-2-4-.04(1)(pp). Deleted: xx
- (f) Any licensee authorized to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.
- (g) Spot-check measurements required by (f) of this paragraph shall include determination of:
 - 1. Timer accuracy;
 - 2. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - 3. The accuracy of all distance measuring devices used for treating humans;
 - 4. The exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions;
 - 5. The difference between the measurement made in (g)4 of this subparagraph and the anticipated output, expressed as a percentage of the anticipated output (i.e.,

the value obtained at last full calibration corrected mathematically for physical decay).

- (h) Spot-check measurements required by (f) of this paragraph shall be performed in accordance with procedures established by a qualified expert. (A qualified expert need not actually perform the spot-check measurements). If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.
- (i) The licensee shall determine if a person is a qualified expert in accordance with the requirements of 1200-2-4-.04(1)(pp).

Deleted: xx

- (5) Requirement to calibrate instruments used for calibration and spot-check measurements.
 - (a) Full calibration measurements required by paragraph (4) shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two (2) years and after any servicing that may have affected system calibration.
 - (b) Spot-check measurements required by paragraph (4) shall be performed using a dosimetry system that has been calibrated in accordance with (a) of this paragraph. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with (a) of this paragraph. This alternative calibration method shall have been performed within the previous one (1) year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.
- (6) Inspection and servicing of the source exposure mechanism.
 - (a) The licensee shall cause each teletherapy unit used to treat humans to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.
 - (b) Inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State.
- (7) The licensee shall determine in accordance with 1200-2-4-.04(1)(pp) if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot-check measurements.
- (8) Monitor and survey instruments.
 - (a) Each licensee authorized to use teletherapy units for treating humans shall install a permanent radiation monitor in each teletherapy room for continuous monitoring of beam status.
 - (b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that may result in an exposed or partially exposed source. The visible indicator of high radiation levels must be located so as to be observable by a person entering the treatment room

- (c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.
 - (d) Each radiation monitor must be tested for proper operation each day before the teletherapy unit is used for treatment of patients.
 - (e) If a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may have resulted in an exposed or partially exposed source. Survey instruments or dosimeters must be tested daily before use.
- (9) *Records.* The licensee shall maintain, for inspection by the Division, records of the measurements, tests, corrective actions, inspection and servicing of the teletherapy unit, instrument calibrations and records of licensee's evaluation of the qualified expert's training and experience made under 1200-2-7-.04(4),(5),(7) or (8), as applicable.

Authority: T.C.A. §68-28-101 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.

**RULES
OF
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH**

**CHAPTER 1200-2-8
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS**

TABLE OF CONTENTS

1200-2-8-.01	Purpose	1200-2-8-.09	Fluoroscopic Radiography
1200-2-8-.02	Scope	1200-2-8-.10	Required Administrative Procedures for Industrial Radiography Program
1200-2-8-.03	Definitions	1200-2-8-.11	Shielded Room X-Ray Radiography
1200-2-8-.04	Equipment Control	1200-2-8-.12	Reporting Requirements
1200-2-8-.05	Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants	<u>1200-2-8-.13</u>	<u>Reserved</u>
1200-2-8-.06	Precautionary Procedures in Radiographic Operations	<u>1200-2-8-.14</u>	<u>Reserved</u>
1200-2-8-.07	Minimum Subjects To Be Covered in Training Radiographers	<u>1200-2-8-.15</u>	<u>Recordkeeping Requirements</u>
1200-2-8-.08	Cabinet Radiography	<u>1200-2-8-.16</u>	<u>Schedule RHS 8-35: Radiographer Certification</u>

1200-2-8-.01 PURPOSE

This Chapter establishes requirements for the use of sources of radiation for industrial radiography operations. Except for the requirements of this Chapter clearly applicable only to devices employing sealed radioactive sources, e.g., 1200-2-8-.04(1) and (5), both radiation machines and sealed radioactive sources are covered by this Chapter. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.02 SCOPE

The regulations in this Chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. Nothing in this Chapter shall apply to the use of sources of radiation in the healing arts.

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.03 DEFINITIONS

- (1) Annual refresher safety training means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions and receive answers to their safety questions.

- (2) Associated equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides or comes in contact with the source (e.g., guide tube, control tube, control (drive) cable, removable source stop, 'J' tube and collimator) when it is used as an exposure head.
- (3) Cabinet radiography means industrial radiography using radiation machines in an enclosed interlocked cabinet in which:
- (a) The radiation machine will not operate unless all openings are closed with interlocks activated;
 - (b) The cabinet is so shielded that every location on the exterior meets the conditions for an unrestricted area as defined in Chapter 1200-2-5; and
 - (c) The cabinet is so constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.
 - (d) Baggage entrance and exit openings of airport baggage systems need not be interlocked. All other openings in these systems shall be interlocked. The operator shall be present during operation to ensure no individual enters the device through the baggage entrance or exit opening(s).
- (4) Certifying entity means an independent certifying organization meeting the requirements in Appendix A to 10 CFR 34 or an Agreement State meeting the requirements in Appendix A to 10 CFR 34 (see Schedule RHS 8-35, Rule 1200-2-8-.15).
- (5) Collimator means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.
- (6) Control (drive) cable means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.
- (7) Control drive mechanism means a device that enables the source assembly to be moved to and from the exposure device.
- (8) Control tube means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.
- (9) Exposure head means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a 'source stop.')
- (10) Field station means a facility where licensed material may be stored or used and from which equipment is dispatched.
- (11) Guide tube (or projection sheath) means a flexible or rigid tube (i.e., 'J' tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.
- (12) Hands-on experience means experience in all of those areas considered to be directly involved in the radiography process.

Deleted: 1

(13) Independent certifying organization means an independent organization that meets all of the criteria of appendix A to 10 CFR 34 (see Rule 1200-2-8-.18).

(14) Permanent radiographic installation means an enclosed shielded room, cell or vault, not located at a temporary job-site, in which radiography is performed.

- Deleted: 3
- Deleted: a
- Deleted: installation or structure designed or intended for radiography and
- Deleted: regularly
- Deleted: 4

(15) Personal supervision means supervision with the radiographer:

- (a) Physically present at the site where sources of radiation and associated equipment are being used;
- (b) Observing the radiographer's assistant's performance; and
- (c) In such proximity that immediate assistance can be given if required.

(16) Practical examination means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

(17) Radiographer means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Division's regulations and all license or registration conditions.

- Deleted: 5
- Deleted: these

(18) Radiographer certification means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing and experience criteria.

(19) Radiographer's assistant means any individual who, under the direct supervision of a radiographer, uses [sources of radiation,]** related handling tools or radiation survey instruments in industrial radiography.

- Deleted: 6
- Deleted: ,
- Deleted: personal
- Deleted: 7

(20) Radiographic exposure device (also called a camera or a projector) means:

- (a) Any instrument having a sealed source in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure; or
- (b) Any apparatus that may produce, when the associated controls are operated, one or more forms of radiation used for making a radiographic exposure.]**

(21) Radiographic operations means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

(22) S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

(23) Shielded position means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

- (24) Shielded room x-ray radiography means industrial radiography utilizing radiation machines that is conducted in an enclosed room:
 - (a) Which is not occupied during radiographic operations;
 - (b) Which is shielded so that every location on the exterior meets the conditions for an unrestricted area as defined in Chapter 1200-2-5; and
 - (c) The only access to which is through openings that are interlocked so that the radiation machine will not operate unless all openings are closed with interlocks activated. [**]
- (25) Source assembly means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.
- (26) Source changer means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transportation and storage of sealed sources.
- (27) Storage area means any location, facility or vehicle that is used to store, to transport or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and that is locked or has a physical barrier to prevent accidental exposure, tampering with or unauthorized removal of the device, container or source.
- (28) Storage container means a device in which sealed sources are secured and stored.
- (29) Temporary job site means a location where industrial radiography is performed and where licensed material may be stored other than the location(s) listed in the specific license or registration.

Authority: T.C.A. §§4-5-201 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 19, 1989; effective September 27, 1989. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.04 EQUIPMENT CONTROL

- (1) Limits on levels of radiation from storage containers and source changers. The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 mSvs) per hour at any exterior surface and 10 millirem (0.1 mSvs) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.
- (2) Locking of radiographic exposure devices, storage containers and source changers:
 - (a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container shall be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in paragraph 1200-2-8-.06(1). In addition, during radiographic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

Deleted: 8

Deleted: 9

Deleted: 10

Deleted: 11

Deleted: transported or

Deleted: 12

Deleted: ny

Deleted: for radiographic exposure devices and

Deleted: :

Deleted: ¶

(a) Radiographic exposure devices measuring less than 4 inches (10 centimeters) from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at 6 inches (15 centimeters) from any exterior surface of the device. Radiographic exposure devices measuring a minimum of 4 inches (10 centimeters) from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and 10 milliroentgens per hour at 1 meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

Deleted: (b) Subparagraph (1)(a) of this Rule applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers shall meet the requirements of 1200-2-8-.04(10), and paragraph (1) of this Rule applies only to storage containers and source changers. ¶

Deleted: sources of radiation

Deleted: and storage containers

Deleted: source of radiation

Deleted: production of radiation, or removal or exposure of a sealed source

Deleted: Each source of radiation

Deleted: except

Deleted: who is under the personal supervision of a radiographer, or as may be otherwise authorized pursuant to Chapter 1200-5

Deleted: Each source changer and storage container shall have a lock and be kept locked when containing sealed sources except when the container ... [1]

(b) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(3) Storage precautions:

(a) Locked radiographic exposure devices, source changers and storage containers shall be physically secured to prevent tampering with or removal by unauthorized persons.

(b) The licensee shall store licensed material in a manner that will minimize danger from explosion or fire.

(4) Radiation survey instruments:

(a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present to make physical radiation surveys as required by this chapter and Chapter 1200-2-5 of these regulations. Instrumentation required by this paragraph shall have a range such that 2 millirems (0.02 mSvs) per hour through 1 rem (0.01 Sv) per hour can be measured.

(b) Each radiation survey instrument shall be calibrated:

1. At energies appropriate for use and at intervals not to exceed six (6) months and after each instrument servicing, except for battery changes;
2. Such that accuracy within plus or minus 20 percent ($\pm 20\%$) can be demonstrated; and
3. For linear scale instruments, at 2 points located approximately one-third and two-thirds of full scale on each scale; for logarithmic scale instruments, at mid-range of each decade and at 2 points of at least one decade; and for digital instruments, at 3 points between 2 and 1,000 millirems (0.02 and 10 mSvs) per hour.

(c) In accordance with Rule 1200-2-8-.15, the licensee shall maintain records of calibrations, dates and results thereof for inspection by the Division for three (3) years after the date of calibration.

(5) Leak testing, repairing, tagging, opening, modifying and replacing of sealed sources:

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Division, the U.S. Nuclear Regulatory Commission, or any Agreement State.

(b) Each sealed source shall be tested for leakage at intervals not to exceed six (6) months. In the absence of a certificate from a transferor that a test has been made within the six (6) months prior to the transfer, the sealed source shall not be put into use until tested.

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed

Deleted: Radiographic exposure devices, source changers, and storage containers, shall be locked and surveyed to assure that the sealed source is in the shielded position:

Deleted: 1. Before being moved from one location to another; and
2. Before being secured at a given location.

Deleted: Chapter

Deleted: -

Deleted: -

Deleted: 2

Deleted: milliroentgens

Deleted: 1

Deleted: roentgen

Deleted: three

Deleted: 3

Deleted: At

Deleted: two or more widely separated

Deleted: , other than zero,

Deleted: .

sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to 1200-2-10-.13(6)(e). Records of leak test results shall identify each sealed source and its container by serial number and shall be kept in units of microcuries or disintegrations per minute (dpm) and maintained for inspection by the Division for three (3) years after the test is made.

- (d) Any test conducted pursuant to (b) and (c) of this paragraph that reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Division regulations. Two copies of a report shall be filed within five (5) days after obtaining results of the test with the Division at its office located at L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, describing the equipment involved, the test results and the corrective action taken.
- (e) A sealed source that is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one (1) inch (2.54 centimeters) square bearing the conventional radiation caution symbol, as described in Chapter 1200-2-5, and at least the instructions:

“DANGER – RADIOACTIVE MATERIAL – DO NOT HANDLE –

NOTIFY CIVIL AUTHORITIES IF FOUND”

- (f) Each exposure device using depleted uranium (DU) shielding and an S-tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. The analysis shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and shall be performed by a person specifically authorized by the Division, the U.S. NRC or an Agreement State to perform the analysis.
1. Should such testing reveal the presence of 0.005 microcuries (185 Bq) or more of removable DU contamination, the exposure device shall be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again.
 2. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device shall be tested for DU contamination if the interval of storage exceeded 12 months.
 3. Licensees will have until July 1, 2002, to comply with the DU leak-testing requirements of this subparagraph.
- (6) Quarterly inventory. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation received and possessed by him. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Division. The records shall include the quantities and kinds of radioactive material, location of all sources of radiation, and the date of inventory. Each sealed source and its radiographic exposure device shall be identified by serial number.
- (7) Utilization logs.

- (a) Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:
 - 1. A description (make, model and serial number) of each radiographic exposure device or transport or storage container in which the sealed source is located;
 - 2. The identity and signature of the radiographer to whom assigned; and
 - 3. The plant or site, where used and dates of use, including the dates removed and returned to storage.
- (b) The licensee shall retain the logs required by subparagraph (a) for three (3) years after the log is made.
- (8) Inspection and maintenance of radiographic exposure devices, source changers, transport and storage containers, associated equipment and survey instruments.
 - (a) The licensee shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers prior to use each day the equipment is used to ensure that the equipment is in good working condition, that the sources are adequately shielded and that required labeling is present. Survey instrument operability shall be performed using check sources or other appropriate means. If equipment problems are found, the equipment shall be removed from service until repaired.
 - (b) The licensee shall have written procedures for:
 - 1. Inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers at intervals not to exceed three (3) months, or before the first use thereafter, to assure proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired. Records of these inspections and maintenance shall be retained for three (3) years for inspection by the Division.
 - 2. Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program shall include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.
- (9) Permanent radiographic installations.
 - (a) Permanent radiographic installations having high radiation area entrance controls of the types described in Chapter 1200-2-5 shall also meet the special requirements in (b) and (c) of this paragraph.
 - (b) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed or a radiation area is generated. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed or a radiation area is generated.

Deleted:

Deleted: current

Deleted: at the address specified in the license or registration. These logs shall be kept available for three (3) years from the date of the recorded event for inspection by the Division. The logs shall

Deleted:

Deleted: (a)

Deleted: and, if appropriate,

Deleted: (

Deleted:)

Deleted: contained therein

Deleted: (b)

Deleted: (c)

Deleted: Locations (

Deleted:)

Deleted: check for obvious defects in

Deleted: conduct a program of i

Deleted: prior to

(c) The alarm system shall be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test shall include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry shall be tested monthly. If an entrance control device or an alarm is operating improperly, it shall be immediately labeled as defective and repaired within seven (7) calendar days. The facility may continue to be used during this seven-day period, provided the licensee implements the continuous surveillance requirements of paragraph 1200-2-8-.06(1) and uses an alarming ratemeter. The licensee or registrant shall retain records of these tests for three (3) years for inspection by the Division.

Deleted: at intervals not to exceed three (3) months, or prior to the first use thereafter of the source of radiation in the installation

(10) Performance requirements for radiography equipment. Equipment utilizing radioactive material used in industrial radiographic operations shall meet the following minimum criteria:

(a) Each radiographic exposure device and all associated equipment shall meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981) American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018 (ANSI N432). An applicant or licensee may submit engineering analyses to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Division may find this an acceptable alternative to actual testing of the component under the above referenced standard.

(b) In addition to the requirements specified above in subparagraph (a), the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

Deleted: of this paragraph

Deleted: and associated equipment

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

Deleted: Each

Deleted: shall have

Deleted: by the user

- (i) Chemical symbol and mass number of the radionuclide in the device;
- (ii) Radioactivity and the date on which this radioactivity was last measured;
- (iii) Model (or product code) and serial number of the sealed source;
- (iv) Manufacturer of the sealed source; and
- (v) Licensee's name, address and telephone number.

Deleted: number

2. Any radiographic exposure device intended for use as a Type B transport container shall meet the applicable requirements of 10 CFR Part 71.

Deleted: be currently approved by the U.S. Nuclear Regulatory Commission as a Type B package according to

3. Modification of [radiographic exposure devices]**, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

Deleted: any

(c) In addition to the requirements specified in above subparagraphs (a) and (b), the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers:

Deleted: of this paragraph

Deleted: routine operation

1. The coupling between the source assembly and the source control cable shall be designed in such a manner that the source assembly shall not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
 2. The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system shall only be released by means of a deliberate operation on the exposure device.
 3. The outlet fittings, lock box and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers that shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
 4. Each sealed source or source assembly shall have attached to it or engraved in it, a durable, legible, visible label with the words: ~~“CAUTION (or “DANGER”) – RADIOACTIVE.”~~ The label shall not interfere with the safe operation of the exposure device or associated equipment.
 5. The guide tube shall ~~be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.~~
 6. Guide tubes shall be used when moving the source out of the device.
 7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.
 8. The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432-1980.
 9. Source changers shall provide a system for assuring that the source shall not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.
- (d) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, shall comply with the requirements of this paragraph.
- (e) All radiographic exposure devices and associated equipment in use after January 10, 1996, shall comply with the requirements of this paragraph (10).
- (f) Notwithstanding subparagraph (1)(a) above, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

Deleted:

Deleted: have passed the
Deleted: s for the control tube as specified in ANSI N432

Deleted: (10)

(11) Labeling, storage and transportation.

- (a) The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION (or "DANGER")
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")

- (b) The licensee shall not transport licensed material unless the material is packaged and the package is labeled, marked and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR part 71.
- (c) Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner that will minimize danger from explosion or fire.
- (d) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering or unauthorized removal of the licensed material from the vehicle.

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.05 PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHER'S ASSISTANTS

- (1) Training.
- (a) The licensee or registrant shall not permit any individual to act as a radiographer as defined in this Chapter until such individual:
1. Has been instructed in the subjects outlined in 1200-2-8-.07 and has demonstrated understanding thereof by successful completion of a written test and a field examination on the subjects covered that has been approved by the Division;
 2. Has received copies of and instruction in:
 - (i) The regulations contained in this Chapter;
 - (ii) The applicable rules of Chapters 1200-2-5 and 1200-2-9;
 - (iii) License or registration conditions; and
 - (iv) The licensee's or registrant's operating and emergency procedures and shall have been tested in a manner approved by the Division to demonstrate understanding thereof; and
 3. Has physically demonstrated competence to use the sources of radiation, related handling tools, and survey instruments that will be employed in his assignment.

- (b) The licensee or registrant shall not permit any individual to act as a radiographer's assistant as defined in this Chapter until such individual:
 - 1. Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures and shall have been tested in a manner approved by the Division to demonstrate understanding thereof; and
 - 2. Has physically demonstrated competence to use, under the personal supervision of the radiographer, the sources of radiation, related handling tools, and survey instruments that will be employed in his assignment.

(c) Each licensee shall maintain the following records of training and certification for three (3) years after the record is made for inspection by the Division.

- 1. Records of training of each radiographer and each radiographer's assistant. The record shall include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and
- 2. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records shall list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records shall also include a list showing the items checked and any non-compliance(s) observed by the radiological safety officer.

Deleted: Records
Deleted: the above
Deleted: testing
Deleted: , including copies of the written tests and dates of oral tests and field examinations, shall be maintained

(d) Whenever a radiographer's assistant uses sources of radiation or related handling tools or conducts radiation surveys required by 1200-2-8-.06(3)(b) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer.

(2) Operating and emergency procedures. The licensee or registrant shall submit to the Division a copy of current operating and emergency procedures prior to the issuance or renewal of a license or registration. The licensee or registrant shall retain a copy of the operating and emergency procedures until the Division terminates the license or registration that authorizes the activity for which the procedures were developed. If the operating and emergency procedures are superseded, the superseded procedures shall be retained by the licensee or registrant for three (3) years after each change. These procedures shall include specific instructions in at least the following:

- (a) The handling and use of sources of radiation to be employed such that no individual shall be exposed to radiation doses in excess of the limits established in Chapter 1200-2-5 of these regulations;
- (b) Methods and occasions for conducting radiation surveys;
- (c) Methods for controlling access to radiographic areas;
- (d) Methods and occasions for locking and securing sources of radiation;
- (e) Personnel monitoring and the use of personnel monitoring equipment;

- (f) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles and control of sources of radiation during transportation;
- (g) Minimizing exposure of individuals in the event of an accident;
- (h) The procedure for notifying proper persons in the event of an accident;
- (i) Maintenance of records;
- (j) The inspection and maintenance of radiographic exposure devices and storage containers; and
- (k) Steps that shall be taken immediately by radiographic personnel in the event a pocket dosimeter is found to be off-scale.

(3) Personnel monitoring control.

(a) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct-reading pocket dosimeter, an operating alarm ratemeter, and personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

1. Pocket dosimeters shall have a range from zero to 200 millirems (2mSvs) and shall be recharged at the start of each shift. Electronic personal dosimeters shall only be used in place of ion-chamber pocket dosimeters.
2. Each personnel dosimeter shall be assigned to and worn by only one individual.
3. Film badges shall be replaced at periods not to exceed one (1) month and other personnel dosimeters processed and evaluated by an accredited NCLAP processor shall be replaced at periods not to exceed three (3) months.
4. After replacement, each personnel dosimeter shall be processed as soon as possible.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be read and the exposures recorded at the beginning and end of each shift. In accordance with Rule 1200-2-8-15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for three (3) years after the record is made.

(c) Pocket dosimeters, or electronic personal dosimeters, shall be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent ($\pm 20\%$) of the true radiation exposure. In accordance with Rule 1200-2-8-15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for three (3) years after the record is made.

(d) If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 200 millirems (2 mSvs), and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations

Deleted: as

Deleted: such

Deleted: either a film badge or a thermoluminescent

Deleted: (TLD)

Deleted: An

Deleted: to be worn in permanent radiography facilities where other appropriate alarming or warning devices are in routine use

Deleted:

Deleted: at least

Deleted: milliroentgens

Deleted: but not greater than 1 roentgen

Deleted: film badge and TLD

Deleted: Pocket

Deleted: daily

Deleted: T

Deleted: retain

Deleted: one (1) year

Deleted: 30

Deleted: discharged beyond its range

Deleted: ,

by that individual shall cease. The individual's personnel dosimeter shall be sent for processing within 24 hours. In addition, the individual shall not return to work with sources of radiation until a determination of the individual's radiation exposure has been made. This determination of exposure shall be made by the RSO or the RSO's designee. The results of this determination shall be included in the records maintained in accordance with Rule 1200-2-8-.15.

Deleted: film badge or TLD

Deleted: immediately

Deleted: T

(e) If the personnel dosimeter that is required by subparagraph (a) is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in subparagraph (a) is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the period for which the personnel dosimeter was lost or damaged shall be included in the records maintained in accordance with Rule 1200-2-8-.15.

Deleted: (e) Reports received from the film badge or TLD processor shall be kept for inspection by the Division until the Division authorizes disposition.

Deleted: f

Deleted: a film badge or TLD

Deleted: film badge or TLD

Deleted: film badge or TLD

(f) Dosimetry reports received from the accredited NVLAP personnel dosimeter processor shall be retained for inspection by the Division in accordance with Rule 1200-2-8-.15.

(g) Each alarm ratemeter shall:

1. Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;
2. Be set to give an alarm signal at a preset dose rate of 500 millirem/hr (5mSv/hr) with an accuracy of plus or minus 20 percent ($\pm 20\%$) of the true radiation dose rate;
3. Require special means to change the preset alarm function; and
4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with Rule 1200-2-8-.15.

Deleted: mR

(4) Conducting industrial radiographic operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, at least one other qualified radiographer or an individual who has at a minimum met the requirements of paragraph 1200-2-8-.07(3) shall accompany the radiographer. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography shall not be performed if only one qualified individual is present.

(b) Reserved.

(c) Licensees will have until July 1, 2002, to meet the requirements for having two qualified individuals present at locations other than a permanent radiographic installation.

(5) Radiation safety officer (RSO) for industrial radiography. The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(6) Supervision of radiographers' assistants. Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation

surveys required by subparagraph 1200-2-8-.06(3)(b) to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision shall include:

- (a) ~~The radiographer's physical presence at the site where the sealed sources are being used;~~
- (b) ~~The availability of the radiographer to give immediate assistance if required; and~~
- (c) ~~The radiographer's direct observation of the assistant's performance of the operations referred to in this section.~~

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.06 PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

- (1) Security. During each radiographic operation the radiographer or the other individual present as required by subparagraph 1200-2-8-.05(4)(a), shall maintain continuous, direct, visual surveillance of the operation to protect against unauthorized entry into a high radiation area as defined in Chapter 1200-2-5 except at permanent radiographic installations where all entryways are locked and the requirements of paragraph 1200-2-8-.04(9) are met.
- (2) Posting. Areas in which radiography is being performed shall be conspicuously posted according to the standards set out in Chapter 1200-2-5, without exceptions.
- (3) Radiation surveys and survey records.
 - (a) The licensee or registrant shall ensure that at least one calibrated and operable radiation survey instrument is available:
 - 1. At the location of its radiographic operations; and
 - 2. At the storage area, as defined in 1200-2-8-.03, whenever a radiographic exposure device, a storage container or source is being placed in storage.
 - (b) After each exposure, the licensee or registrant shall ensure that a survey with a calibrated and operable radiation survey instrument is made to determine that the sealed source has been returned to its shielded position or that the radiation from the radiation machine has been terminated. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube. ~~The survey shall determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head or dismantling equipment.~~
 - (c) Any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area, the licensee shall ensure that a survey with a calibrated and operable radiation survey instrument is made to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. ~~In accordance with Rule 1200-2-8-.15, the licensee shall record and maintain results of the last storage survey of the workday, required by this subparagraph, for three (3) years for inspection by the Division.~~

Deleted: radiographer's assistant

Deleted: a

Deleted: ¶
(a) Where the high radiation area is equipped with a control device or alarm system as required in Chapter 1200-2-5 of these regulations; or

Deleted: (b) Where the high radiation area is locked to protect against unauthorized or accidental entry. ¶

Deleted: T

Deleted: (c)

Deleted: shall be recorded and retained

Deleted:

- (d) Records shall be kept of the duration of each radiographic exposure and the number of exposures made. In addition, for each radiographic exposure employing a radiation machine the voltage and current used shall be noted. These records shall be maintained for three (3) years for inspection by the Division and for field work may be kept on the area survey form.
- (e) Each licensee or registrant conducting industrial radiography at a temporary job-site shall have the following documents available at that site for inspection by the Division:
 1. Appropriate license or registration;
 2. Operating and emergency procedures;
 3. Applicable regulations;
 4. Survey records required pursuant to 1200-2-8-.06 and Chapter 1200-2-5 for the period of operation at the site;
 5. Daily pocket dosimeter records for the period of operation at the site; and
 6. The latest instrument calibration and leak test records for specific devices in use at the site. Acceptable records include tags or labels that are affixed to the device or survey meter.

(4) Radiation surveys.

Formatted

- (a) Conduct surveys with a calibrated and operable radiation survey instrument that meets the requirements of Rule 1200-2-8-.04(4).
- (b) Using a survey instrument meeting the requirements of subparagraph (a), conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey shall determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.
- (c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in paragraph 1200-2-8-.03(27)), to ensure that the sealed source is in its shielded position.
- (d) Maintain records in accordance with Rule 1200-2-8-.15.

Authority: T.C.A. §§4-5-201 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 19, 1989; effective September 27, 1989. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.07 MINIMUM SUBJECTS TO BE COVERED IN TRAINING RADIOGRAPHERS

- (1) A licensee shall not permit any individual to act as a radiographer until the individual:
 - (a) Has received training in the subjects below in paragraph (7), in addition to a minimum of two (2) months of on-the-job training, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A to 10 CFR 34 (see Schedule RHS 8-35, Rule 1200-2-8-.16). (An

independent organization that would like to be recognized as a certifying entity shall submit its request to the Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC. 20555-0001.) or

- (b) The licensee may, until July 1, 2002, allow an individual who has not met the requirements above in subparagraph (1)(a) to act as a radiographer after the individual has received training in the subjects outlined below in paragraph (7) and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Division.
- (2) In addition, the licensee shall not permit any individual to act as a radiographer until the individual:
- (a) Has received copies of and instruction in the requirements in this chapter; in applicable rules of Chapters 1200-2-5 and 1200-2-10, in applicable U.S. DOT regulations as referenced in 10 CFR part 71, license or registration conditions and the licensee's or registrant's operating and emergency procedures;
 - (b) Has demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material.
 - (c) Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment and in the use of radiation survey instruments.
 - (d) Has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described above in subparagraphs (2)(a) and (2)(c) by successful completion of a practical examination covering this material.
- (3) The licensee shall not permit any individual to act as a radiographer's assistant until the individual:
- (a) Has received copies of and instruction in the requirements in this chapter; in applicable rules of Chapters 1200-2-5 and 1200-2-10, in applicable U.S. DOT regulations as referenced in 10 CFR part 71, license or registration conditions and the licensee's or registrant's operating and emergency procedures;
 - (b) Has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment and radiation survey instruments that the assistant will use; and
 - (c) Has demonstrated understanding of the instructions provided above in subparagraph (3)(a) by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described above in subparagraph (3)(b) by successful completion of a practical examination on the use of such hardware.
- (4) The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.
- (5) Except as provided below in subparagraph (5)(d), the radiological safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Division's regulations, license requirements and the applicant's operating and emergency procedures are followed. The inspection program shall:

- (a) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six (6) months; and
- (b) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six (6) months since the last inspection, the radiographer shall demonstrate knowledge of the training requirements of subparagraph 1200-2-8-.07(2)(c) and the radiographer's assistant shall re-demonstrate knowledge of the training requirements of subparagraph 1200-2-8-.07(3)(b) by a practical examination before these individuals can next participate in a radiographic operation.
- (c) The Division may consider alternatives in those situations where the individual serves as both radiographer and radiological safety officer.
- (d) In those operations where a single individual serves as both radiographer and radiological safety officer and performs all radiography operations, an inspection program is not required.
- (6) The licensee shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with subparagraph 1200-2-8-.05(1)(c).
- (7) The licensee shall include the following subjects required above in paragraph (1):

(a) Fundamentals of radiation safety, including:

- 1. Characteristics of [x¹]**and gamma radiation.
- 2. Units of radiation dose and quantity of radioactivity.
- 3. Hazards of exposure to radiation.
- 4. Levels of radiation from [sources of radiation]** to be used.
- 5. Methods of controlling radiation dose and exposure;
 - (i) Working time.
 - (ii) Working distance.
 - (iii) Shielding.

(b) Radiation detection instrumentation to be used, including:

- 1. Use of radiation survey instruments.
 - (i) Operation.
 - (ii) Calibration.
 - (ii) Limitations.

- Deleted: 1
- Deleted: .
- Deleted: (a)
- Deleted: (b)
- Deleted: (c)
- Deleted: (d)
- Deleted: (e)
- Deleted: .
- Deleted: 1.
- Deleted: 2.
- Deleted: 3.
- Deleted: 2
- Deleted: .
- Deleted: (a)
- Deleted: 1.
- Deleted: 2.
- Deleted: 3.

¹ Ⓢ

- 2. Survey techniques. Deleted: (b)
 - 3. Use of personnel monitoring equipment. Deleted: (c)
 - (i) Film badges and other personnel dosimeters. Deleted: 1.
 - (ii) Pocket dosimeters. Deleted: 2.
 - (iii) Alarm ratemeters.]** Deleted: 3.
 - (c) Radiographic equipment to be used, including:
 - 1. Operation and control of radiographic exposure equipment, remote handling equipment and storage containers, including pictures or models of source assemblies (pigtailed). Deleted: 3
Deleted: .
Deleted: (a)
Deleted: Remote
Deleted: (b)
 - 2. Storage, control and disposal of licensed material; and Deleted: Radiographic exposure devices and sealed sources.
Deleted: (c) Storage containers.
 - 3. Inspection and maintenance of equipment.
 - (d) The requirements of pertinent state regulations; Deleted: 4
Deleted: .
 - (e) The licensee's or registrant's written operating and emergency procedures.]** Deleted: 5
Deleted:
 - (f) Case histories of radiography accidents.
- (8) Licensees will have until July 1, 2002, to comply with the additional training requirements specified above in paragraphs (2) and (3).
- (9) Licensees will have until July 1, 2002 to comply with the certification requirements specified above in paragraph (1). Records of radiographer certification maintained in accordance with part 1200-2-8-.05(1)(c)1 provide appropriate affirmation of certification requirements specified above in paragraph (1).

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.08 CABINET RADIOGRAPHY

- (1) The only requirement of this Chapter which applies to cabinet radiography as defined in this Chapter is that no registrant shall permit any individual to operate a cabinet radiography unit until such individual has:
 - (a) Received a copy of the operating procedures for the unit;
 - (b) Received instruction in the operating procedures;
 - (c) Demonstrated an understanding of the operating procedures; and
 - (d) Demonstrated competence in the use of the unit.

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.09 FLUOROSCOPIC RADIOGRAPHY

Radiography utilizing fluoroscopy should be done only by remote observation; however, if direct viewing of the screen by personnel is used, the registrant shall demonstrate that radiation exposure limits are not exceeded.

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.10 REQUIRED ADMINISTRATIVE PROCEDURES FOR INDUSTRIAL RADIOGRAPHY PROGRAM

(1) Licensees and registrants and applicants for a license or registration, shall have a program for training radiographers and radiographer's assistants and submit to the Division for approval a schedule or description of such program;

(a) The program shall include;

1. Initial training;

- 1. This initial training shall consist of a complete training program as outlined in 1200-2-8-.07 or
2. Resumes of prior training and experience of individuals that show fulfillment of the requirements of 1200-2-8-.07(1) and (2) and the initial training of such individuals in the licensee's or registrant's specific radiography program as outlined in 1200-2-8-.07(3), (4) and (5);

2. Periodic training (shall be at least annual);

3. On-the-job training;

4. Means to be used by the licensee or registrant to determine the radiographer's knowledge and understanding of and ability to comply with:

(i) Division regulations and licensing or registration requirements; and

(ii) The licensee's or registrant's operating and emergency procedures; and

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

(b) After [May 28, 1999], a license applicant need not describe its initial training and examination program for radiographers in the subjects outlined in [Sec. 34.43(g)].

Deleted: that
Deleted: s the
Deleted: (a)

Deleted: (b)

Deleted: (c)

Deleted: (d)

Deleted: 1.

Deleted: 2.

Deleted: (e)

(c) From [June 27, 1997 to May 28, 1999], a license applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in [Sec. 43.34(g)].

(2) Licensees and registrants and applicants for a license or registration, shall

- (2) The licensee or registrant shall establish and submit to the Division for approval written operating and emergency procedures as described in 1200-2-8-.05(2);
- (3) The licensee or registrant shall establish and submit to the Division a description of its inspection program adequate to ensure that its radiographers and radiographer's assistants follow the Division's regulatory requirements and the licensee's or registrant's operating and emergency procedures. The inspection program shall:
 - (a) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three (3) months;
 - (b) Provide that if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than three (3) months since the last inspection, that individual's performance shall be observed and recorded the next time the individual participates in a radiographic operation; and
 - (c) Include the retention of inspection records on the performance of radiographers or radiographer's assistants for three (3) years;
- (4) The licensee or registrant shall submit 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
- (5) The licensee who desires to conduct his own leak tests shall establish procedures to be followed in testing sealed sources for possible leakage and/or contamination and shall submit to the Division for approval a description of such procedures including:
 - (a) Instrumentation to be used;
 - (b) Method of performing tests, e.g., points on equipment to be smeared and method of taking the smear; and
 - (c) Pertinent experience of the person who will perform the test.

(6) The licensee or registrant, or applicant for a license or registration, shall identify the locations where all records required by this chapter and Chapters 1200-2-5 and 1200-2-10 will be maintained.

Authority: T.C.A. §§4-5-201 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 19, 1989; effective September 27, 1989. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.11 SHIELDED ROOM X-RAY RADIOGRAPHY

- (1) The only requirements of this Chapter applying to shielded room x-ray radiography are as follows:
 - (a) All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.
 - (b) Emergency shut-off switches shall be located within the high radiation areas so as to be accessible to individuals therein within the warning period in paragraph (5). These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. The emergency shut-off switches shall include a manual reset that must be reset at the switch before x-rays can again be produced from the control panel. After an emergency shut-off switch has been activated, it shall be possible to produce x-rays again only from the control panel.
 - (c) The interlock system and the emergency shut-off system shall be separate electrical and/or mechanical systems.
 - (d) The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be so positioned that they can be observed from any position or orientation within the room.
 - (e) An audible warning signal within the room shall be actuated for at least ten (10) seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel.
 - (f) The x-ray equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of x-ray radiation by the equipment.
 - (g) All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced.
 - (h) Surveys shall be made as required in 1200-2-8-.06(3)(b). Personnel devices providing an audible signal when activated by radiation will be acceptable for this survey. Proper operation of this device shall be checked daily and a record maintained of this check. All personnel working with the x-ray equipment shall be provided with such a device. This device shall be designed so as to clearly indicate entry into a 2 milliroentgen per hour x-ray radiation field.
 - (i) All personnel associated with the x-ray equipment shall be provided with personnel monitoring devices that shall be calibrated for the x-ray energies being utilized. Records of personnel exposure shall be maintained as required in Chapter 1200-2-5.
 - (j) No registrant shall permit any individual to operate a radiation machine for shielded room x-ray radiography until such individual has received a copy of, instruction in, and demonstrated an understanding of operating and emergency procedures for the unit, and competence in its use. (See 1200-2-8-.05(2)(a), (c), (d), (e), (g), (h), (i), (j) and (k)).

These operating and emergency procedures shall be submitted to the Division for approval prior to their adoption.

- (k) All safety and warning devices, including interlocks and emergency shut-off switches, shall be tested at intervals not to exceed three (3) months to determine that they are functioning properly. Records shall be maintained of all tests.
- (l) If a safety or warning device malfunctions, the x-ray control panel shall be locked in the "off" position. It shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

Authority: T.C.A. §§4-5-201 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. Repeal and new rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.12 REPORTING REQUIREMENTS

- (1) In addition to the reporting requirements specified in other chapters of these regulations, each licensee or registrant shall provide a written report to the Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:
 - (a) Unintentional disconnection of the source assembly from the control cable.
 - (b) Inability to retract the source assembly to its fully shielded position and secure it in this position.
 - (c) Failure of any component (critical to safe operation of the device) to properly perform its intended function.
- (2) The licensee or registrant shall include the following information in each report submitted under (1) of this Rule:
 - (a) A description of the equipment problem.
 - (b) Cause of each incident, if known.
 - (c) Manufacturer and model number of equipment involved in the incident.
 - (d) Place, time and date of the incident.
 - (e) Actions taken to establish normal operations.
 - (f) Corrective actions taken or planned to prevent recurrence.
 - (g) Qualifications of personnel involved in the incident.
- (3) Reports of overexposure submitted under Chapter 1200-2-5 that involve failure of safety components of radiography equipment shall also include the information specified in (2) of this Rule.

Authority: T.C.A. §§4-5-201 et seq., 68-202-203 and 68-202-206. *Administrative History:* Original rule filed October 27, 1993; effective January 10, 1994.

1200-2-8-.13 RESERVED

1200-2-8-.14 RESERVED

1200-2-8-.15 RECORDKEEPING REQUIREMENTS.

- (1) Location of documents and records.
 - (a) Each licensee shall maintain copies of records required by this part and other applicable parts of this chapter at the location specified in the license.
 - (b) Each licensee shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:
 1. The license authorizing the use of licensed material;
 2. A copy of "State Regulations for Protection Against Radiation;
 3. Utilization records for each radiographic exposure device dispatched from that location as required by paragraph 1200-2-8-.04(7).
 4. Records of equipment problems identified in daily checks of equipment as required by paragraph 1200-2-8-.04(8). The licensee shall maintain each record for three (3) years after it is made. The record shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.
 5. Records of alarm system and entrance control checks required by paragraph 1200-2-8-.04(9), if applicable. The licensee shall maintain each record for three (3) years after it is made.
 6. Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by paragraph 1200-2-8-.05(3). The licensee shall maintain each record for three (3) years after it is made.
 7. Records of dosimetry reports received from the accredited NVLAP personnel dosimeter processor as required by paragraph 1200-2-8-.05(3). The licensee shall maintain each record for three (3) years after it is made.
 8. Operating and emergency procedures required by paragraph 1200-2-8-.05(2). The licensee shall maintain a copy of current operating and emergency procedures until the Division terminates the license. Superseded material shall be retained for three (3) years after the change is made.
 9. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by paragraph 1200-2-8-.04(4). The licensee shall maintain each record for three (3) years after it is made.

10. Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by paragraph 1200-2-8-.05(3). The licensee shall maintain each record for three (3) years after it is made.
11. Latest survey records required by paragraph 1200-2-8-.06(4). The licensee shall maintain the record of each exposure device survey conducted before the device is placed in storage, if that survey is the last one performed in the workday, for three (3) years after it is made.
12. The shipping papers for the transportation of radioactive materials required by Chapter 1200-2-10; and
13. When operating under reciprocity pursuant to Rule 1200-2-10-.29, a copy of the Agreement State license authorizing the use of licensed materials.

1200-2-8-.16 SCHEDULE RHS 8-35: RADIOGRAPHER CERTIFICATION.

- (1) Requirements for an independent certifying organization. An independent certifying organization shall:
 - (a) Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;
 - (b) Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;
 - (c) Have a certification program open to nonmembers, as well as members;
 - (d) Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;
 - (e) Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board;
 - (f) Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
 - (g) Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
 - (h) Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;
 - (i) Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;
 - (j) Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

- (k) Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the same company or corporation (or a wholly owned subsidiary of such company or corporation) does not employ the individuals proctoring each examination as any of the examinees;
 - (l) Exchange information about certified individuals with the Division and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and
 - (m) Provide a description to the Division of its procedures for choosing examination sites and for providing an appropriate examination environment.
- (2) Requirements for certification programs. All certification programs shall:
- (a) Require applicants for certification to:
 - 1. Receive training in the topics set forth in Rule 1200-2-8-.07; and
 - 2. Satisfactorily complete a written examination covering these topics;
 - (b) Require applicants for certification to provide documentation that demonstrates that the applicant has:
 - 1. Received training in the topics set forth in Rule 1200-2-8-.07;
 - 2. Satisfactorily completed a minimum period of on-the-job training; and
 - 3. Received verification by an Agreement State or a U.S. NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;
 - (c) Include procedures to ensure that all examination questions are protected from disclosure;
 - (d) Include procedures for denying an application, revoking, suspending and reinstating a certificate;
 - (e) Provide a certification period of not less than three (3) years or more than five (5) years;
 - (f) Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training in industrial radiography.
 - (h) Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.
- (3) Requirements for written examinations. All examinations shall be:
- (a) Designed to test an individual's knowledge and understanding of the topics listed in Rule 1200-2-8-.07;
 - (b) Written in a multiple-choice format;
 - (c) Have test items drawn from a question bank containing psychometrically valid questions

based on the material in Rule 1200-2-8-.07.

Authority: T.C.A. §§4-5-201 et seq. and 68-202-203 and 206.

Each source changer and storage container shall have a lock and be kept locked when containing sealed sources except when the container or source changer is under the direct surveillance of a radiographer or a radiographer's assistant under the personal supervision of a radiographer.

**RULES
OF
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH**

**CHAPTER 1200-2-10
LICENSING AND REGISTRATION**

TABLE OF CONTENTS

1200-2-10-.01	Purpose		Licensee
1200-2-10-.02	Scope	1200-2-10-.20	Division Action on Application to Renew or Amend
1200-2-10-.03	Exemptions: Source Material		Inalienability of Licenses
1200-2-10-.04	Exemptions: Radioactive Materials Other Than Source Material	1200-2-10-.21	Transfer of Material
1200-2-10-.05	Reserved	1200-2-10-.22	Modification, Revocation, and Termination of Licenses
1200-2-10-.06	Exemptions: U.S. Department of Energy and U.S. Nuclear Regulatory Commission Contractors	1200-2-10-.23	Registration
		1200-2-10-.24	Reports
1200-2-10-.07	Other Exemptions	1200-2-10-.25	Records
1200-2-10-.08	Types of Licenses	1200-2-10-.26	Inspections
1200-2-10-.09	General Licenses - Source Material	1200-2-10-.27	Tests
1200-2-10-.10	General Licenses - Radioactive Material Other Than Source Material	1200-2-10-.28	Reciprocal Recognition of Licenses
1200-2-10-.11	Filing of Application for Specific Licenses	1200-2-10-.29	Transportation of Radioactive Material
1200-2-10-.12	General Requirements for the Issuance of Specific Licenses	1200-2-10-.30	Fees for Licenses
1200-2-10-.13	Special Requirements for Issuance of Specific Licenses	1200-2-10-.31	Licensing of Shippers of Radioactive Material into or Within Tennessee
1200-2-10-.14	Specific Licenses for Certain Groups of Medical Uses of Radioactive Material	1200-2-10-.32	Acceptable Training and Experience for Medical Uses of Radioactive Material
1200-2-10-.15	Issuance of Specific Licenses	1200-2-10-.33	Supplemental Fees for Calendar Year 2001
1200-2-10-.16	Specific Terms and Conditions of Licenses	<u>1200-2-10-.34</u>	<u>Training for an Authorized Nuclear Pharmacist</u>
1200-2-10-.17	Expiration of Licenses	<u>1200-2-10-.35</u>	<u>Radiological Criteria for License Termination</u>
1200-2-10-.18	Renewal of License	<u>1200-2-10-.36</u>	<u>Schedule 10-6: Determination of A₁ and A₂</u>
1200-2-10-.19	Amendment of Licenses at Request of		

1200-2-10-.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.

1200-2-10-.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 1200-2-10-.03, 1200-2-10-.04, 1200-2-10-.06, 1200-2-10-.07 or 1200-2-10-.30 shall be registered with the Division in accordance with the requirements of 1200-2-10-.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.

1200-2-10-.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.
- (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

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.

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
 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 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. *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.

1200-2-10-.04 EXEMPTIONS: RADIOACTIVE MATERIALS OTHER THAN SOURCE MATERIAL

- (1) Exempt concentrations.
- (a) Except as provided in 1200-2-10-.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 1200-2-10-.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 1200-2-10-.13(8) or the general license provided in 1200-2-10-.29.
- (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 products²:
- (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.

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.

- (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.
- (f) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.
- (g) Electron tubes³ 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

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.

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 transferred² 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) which 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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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).
- (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 1200-2-10-.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

Authority: T.C.A. §68-23-101 et seq. and 68-23-206. **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.

1200-2-10-.05 RESERVED

1200-2-10-.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.

1200-2-10-.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.

1200-2-10-.08 TYPES OF LICENSES. Licenses for radioactive materials are of two types:

- (1) General licenses provided in this Chapter are effective without the filing of applications with the Division or the issuance of licensing documents to particular persons.
- (2) Specific licenses are issued to named persons upon applications filed pursuant 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.

1200-2-10-.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 1200-2-5 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.

1200-2-10-.10 GENERAL LICENSES⁴ – 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 Agreement State and authorizing distribution under the general license of this paragraph or its equivalent.
- (2) Certain measuring, gauging or controlling devices⁵.

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

- (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 and local governmental agencies to 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, when such devices are manufactured and labeled in accordance with the specifications contained in a specific license issued by the Division pursuant to 1200-2-10-.13(4) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.
- (b) Persons who own, receive, acquire, possess, use or transfer radioactive material in a device pursuant to the general license contained in (a) of this paragraph (2):
 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 2. of this subparagraph and other testing, installation, servicing, and removal from installation, involving the radioactive material, its shielding or containment, are performed,
 - (i) In accordance with the instructions provided by the labels, or
 - (ii) By a person holding an applicable specific license issued by the Division, the U.S. Nuclear Regulatory Commission, and Agreement State or a Licensing State to perform such activities.
 4. Shall maintain records showing compliance with the requirements of 2. and 3. of this subparagraph. 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 concerning the radioactive material, its shielding or containment;

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.

5. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device 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, or disposed of by transfer to a person holding an applicable specific license to receive the radioactive material contained in the device and, within 30 days furnish to the Division a report containing a brief description of the event and the remedial action taken;
 6. Shall not abandon the device containing radioactive material;
 7. Except as provided in 8. of this subparagraph, shall transfer or dispose of the devices containing radioactive material only by transfer to a licensee of the Division, the U.S. Nuclear Regulatory Commission, and Agreement State or a Licensing State, whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Division a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;
 8. Shall transfer the devices to another general licensee only:
 - (i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this paragraph (2) and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Division the manufacturer's name and model number of the device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Division and the transferee; or
 - (ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;
 9. Shall comply with the provisions of 1200-2-5-.23 and 1200-2-5-.24 for reporting radiation incidents, theft or loss of radioactive material.
- (c) The general license provided in this paragraph is subject to the provisions of 1200-2-10-.16(1), (2) and (3), 1200-2-10-.23(1), (2) and (3), 1200-2-10-.26 through 1200-2-10-.28, and 1200-2-10-.30.
- (d) The general license in 1200-2-10-.10(2)(a) does not authorize the manufacture 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 1200-2-5, except that they shall comply with the provisions of 1200-2-5-.23 and 1200-2-5-.24.
 - (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 1200-2-10-.16 through 1200-2-10-.30, as applicable.
- (4) Calibration and reference sources.
 - (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 in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR, Part 32 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 1200-2-10-.16, 1200-2-10-.22, 1200-2-10-.23, 1200-2-10-.26, 1200-2-10-.27, 1200-2-10-.28, 1200-2-10-.30, and Chapters 1200-2-4 and 1200-2-5 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.

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

⁶ Showing only the name of the appropriate material.

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 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):
 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 1200-2-5 of these regulations except that such persons shall comply with the provisions of 1200-2-5-.17(1) and 1200-2-5-.23 and 1200-2-5-.24.
 - (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 1200-2-10-.16, 1200-2-10-.22, 1200-2-10-.23, 1200-2-10-.26, 1200-2-10-.27, 1200-2-10-.28, 1200-2-10-.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 8-51 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-

- 2-10, 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 1200-2-5-.17.
- (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 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) The licensee possessing or using radioactive materials under this general license shall report in writing to the Director, Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, any changes in the information furnished by him in the application submitted pursuant to subparagraph (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 1200-2-5 with respect to radioactive materials covered by this general license, except that such person using the Mock Iodine-125 described in part (a) shall comply with the provisions of 1200-2-5-.17, 1200-2-5-.23, and 1200-2-5-.24.

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

- (a) Except as provided in subparagraphs (8)(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 1200-2-10.
- (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. §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.

1200-2-10-.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.
- (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.

1200-2-10-.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;
 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 instrument(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.

- (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 provide 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.

- (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 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:
 - 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, 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.
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;

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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.12(4)(j)3 as such regulation was constituted on the date shown immediately below.

(Authorized signature for Insurer)

(Name of person signing)

(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 1200-2-10-.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 1200-2-10-.12(4). The current reclaiming cost estimate covered by the test is: \$ _____.
2. This firm guarantees, through the corporate guarantee specified in 1200-2-10-.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 1200-2-10-.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 not 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 1200-2-10-.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).

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

- | | <u>YES</u> | <u>NO</u> |
|---|------------|-----------|
| 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) \$ _____
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 1200-2-10-.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 1200-2-10-.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 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 1200-2-10-.12(4) monies in an amount equal to the current reclaiming cost estimates as specified in 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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.
- (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 or 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.

1200-2-10-.13 SPECIAL REQUIREMENTS FOR ISSUANCE OF SPECIFIC LICENSES

- (1) 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 the use of a variety of radioactive materials for a variety of human uses.
- (2) 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.
 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) 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 1200-2-10-.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 and distribution of devices to persons generally licensed under 1200-2-10-.10(2). In addition to the requirements set forth in 1200-2-10-.12, a specific license to distribute certain devices of the types enumerated in 1200-2-10-.10(2) to persons generally licensed under 1200-2-10-.10(2) will be issued only if:
- (a) The applicant submits 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 any period of one calendar quarter a dose in excess of 10 percent of the limits specified in 1200-2-5-.03(1); 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;

TABLE RHS 7-1

TABLE OF ORGAN DOSES

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

- (b) Each device bears a durable, legible clearly visible label or labels approved by the Division which contain 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 manual 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 _____, Serial No. _____,⁷ 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 _____, Serial No. _____,⁷ are subject to a general license or the equivalent and the regulations of a Licensing State. This label shall be

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

maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)

- (c) 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 which 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 on particulars which include, but are not necessarily 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;
- (d) In the event the applicant desires that the general licensee under 1200-2-10-.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 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 a calendar quarter dose in excess of 10 percent of the limits specified in 1200-2-5-.03(1);
- (e) Each person licensed under 1200-2-10-.13(5) shall:

1. Furnish a copy of the general license contained in 1200-2-10-.10(2) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 1200-2-10-.10(2).
 2. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to 1200-2-10-.10(2), or alternatively, furnish a copy of the general license contained in 1200-2-10-.10(2), to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in 1200-2-10-.10(2) is furnished to such person, it shall be accompanied by a note explaining that 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 1200-2-10-.10(2); and
- (f) Each person licensed under 1200-2-10-.13(5) to distribute devices to generally licensed persons shall:
1. Report to the Division at its offices located at L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, all transfers of such devices to persons for use under the general license in 1200-2-10-.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 1200-2-10-.13(5) for use under a general license in that state's regulations equivalent to 12010-.10(2).
 4. Reports required by 1, 2, and 3 of this subparagraph (f) 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. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons generally licensed under 1200-2-10-.10(2) during the reporting period the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.
 5. Keep records showing the name, address, and a point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 1200-2-10-.10(2) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The record shall show the date of each transfer, the isotope and quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this subparagraph. The records required by this part 5 shall be maintained for a period of five (5) 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 1200-2-10-.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 1200-2-8-.07; or
 - (ii) Resumes of prior training and experience of individuals which show fulfillment of the requirements of 1200-2-8-.07(1) and (2) and the program for the initial training of such individuals in the licensee's or registrant's specific industrial radiography program as outlined in 1200-2-8-.07(3), (4) and (5);
 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 1200-2-8-.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 1200-2-10-.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 if⁸:
- (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 1200-2-10-.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 1200-2-10-.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
 - (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 time 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 1200-2-10-.12, a specific license to manufacture, assemble, repair, or distribute to persons generally licensed under 1200-2-10-.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.

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.

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

Deleted: and

(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:

1. The requested site for manufacture and/or distribution of radiopharmaceuticals is located within Tennessee;

Deleted: (a)

Deleted: this State

Deleted: (b)

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;

(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 licensees; and

Deleted: 1. The radiopharmaceutical containing radioactive material will be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the 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

4. The applicant satisfies the following labeling requirements:

Deleted: 2. The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(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.

Deleted: (c)

Deleted: ,

Deleted: ,

Deleted: package

Deleted: (d)

Deleted: The

Deleted: package of the radiopharmaceutical contains information on the

(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.

Deleted: radionuclide,

Deleted: , and

(iii) and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Division for distribution to persons licensed pursuant to 1200-2-10-.14, Group I, Group II, Group IV and Group V, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a

Deleted: of assay

Deleted: ,

Licensing State. The labels, leaflets or brochures required by this subparagraph 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.]**

Formatted

- (b) A licensee described above by subpart (a)2(iii):
1. May prepare radioactive drugs for medical use, as defined in subparagraph 1200-2-4-.04(o), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified below in parts (b)2 and (b)3 this paragraph, or an individual under the supervision of an authorized nuclear pharmacist.
 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)(III).
 - (ii) This individual meets the requirements specified in part 1200-2-10-.35(1)(a)2 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 above in parts 1 and 2 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)(III)) as an authorized nuclear pharmacist if the individual is identified as of (effective date of amendment), 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 certification by the Board of Pharmaceutical Specialties, the Division, U.S. Nuclear Regulatory Commission or other Agreement State license and a copy of the state pharmacy license or registration, no later than 30 days after the date that the licensee allows, pursuant to subparts 2(i) and 2(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 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 1200-2-10-.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 for uses listed in Group III of 1200-2-10-.14(6) will be issued only if⁹:
- (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;
 - (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, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; and

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 may submit the pertinent information specified in this paragraph (10).*

- (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 1200-2-10-.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:
- (a) The requested site for manufacture and/or distribution of sources and devices is located within this State;
 - (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 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 which do not require long term storage (*e.g.*, gold-198 seeds) may be on a leaflet or brochure which accompanies the source; and
 - (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 1200-2-10-.12, a specific license to manufacture or distribute radioactive material for use under the general license of 1200-2-10-.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.
 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)

- (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-129 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 1200-2-5-.17.
- (14) Distribution of radioactive material in exempt quantities¹⁰.
- (a) An application for a specific license to distribute NARM to persons exempt from these regulations pursuant to 1200-2-10-.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;

¹⁰ See footnote 2 of this Chapter.

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 1200-2-10-.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 than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 1200-2-10-.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 1200-2-10-.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 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 1200-2-10-.13(14) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.10(4).* In addition to the requirements set forth in 1200-2-10-.12, a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 1200-2-10-.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 1200-2-10-.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, by July 1, 1993, 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;
 - (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	Molybdenum-99	0.01	30,000
Americium-241	0.001	2	Neptunium-237	0.001	2
Americium-242	0.001	2	Nickel-63	0.01	20,000
Americium-243	0.001	2	Niobium-94	0.01	300
Antimony-124	0.01	4,000	Phosphorus-32	0.5	100
Antimony-126	0.01	6,000	Phosphorus-33	0.5	1,000
Barium-133	0.01	10,000	Polonium-210	0.01	10
Barium-140	0.01	30,000	Potassium-42	0.01	9,000
Bismuth-207	0.01	5,000	Promethium-145	0.01	4,000
Bismuth-210	0.01	600	Promethium-147	0.01	4,000
Cadmium-109	0.01	1,000	Ruthenium-106	0.01	200
Cadmium-113	0.01	80	Samarium-151	0.01	4,000
Calcium-45	0.01	20,000	Scandium-46	0.01	3,000
Californium-252	0.001	9 (20 mg)	Selenium-75	0.01	10,000
Carbon-14	0.01	50,000	Silver-110m	0.01	1,000
	Non CO		Sodium-22	0.01	9,000
Cerium-141	0.01	10,000	Sodium-24	0.01	10,000
Cerium-144	0.01	300	Strontium-89	0.01	3,000
Cesium-134	0.01	2,000	Strontium-90	0.01	90
Cesium-137	0.01	3,000	Sulfur-35	0.5	900
Chlorine-36	0.5	100	Technetium-99	0.01	10,000
Chromium-51	0.01	300,000	Technetium-99m	0.01	400,000
Cobalt-60	0.001	5,000	Tellurium-127m	0.01	5,000
Copper-64	0.01	200,000	Tellurium-129m	0.01	5,000
Curium-242	0.001	60	Terbium-160	0.01	4,000
Curium-243	0.001	3	Thulium-170	0.01	4,000
Curium-244	0.001	4	Tin-113	0.01	10,000
Curium-245	0.001	2	Tin-123	0.01	3,000
Europium-152	0.01	500	Tin-126	0.01	1,000
Europium-154	0.01	400	Titanium-44	0.01	100
Europium-155	0.01	3,000	Vanadium-48	0.01	7,000
Germanium-68	0.01	2,000	Xenon-133	1.0	900,000
Gadolinium-153	0.01	5,000	Yttrium-91	0.01	2,000
Gold-198	0.01	30,000	Zinc-65	0.01	5,000
Hafnium-172	0.01	400	Zirconium-93	0.01	400
Hafnium-181	0.01	7,000	Zirconium-95	0.01	5,000
Holmium-166m	0.01	100	Any other beta-gamma emitter	0.01	10,000
Hydrogen-3	0.5	20,000	Mixed fission products	0.01	1,000
Iodine-125	0.5	10	Mixed corrosion products	0.01	10,000
Iodine-131	0.5	10	Contaminated equipment beta-gamma	0.001	10,000
Indium-114m	0.01	1,000	Irradiated material, any form other than solid noncombustible	0.01	1,000
Iridium-192	0.001	40,000	Irradiated material, solid noncombustible	0.001	10,000
Iron-55	0.01	40,000	Mixed radioactive waste, beta-gamma	0.01	1,000
Iron-59	0.01	7,000	Packaged mixed waste, beta-gamma ²	0.001	10,000
Krypton-85	1.0	6,000,000	Any other alpha emitter	0.001	2
Lead-210	0.01	8	Contaminated equipment, alpha	0.0001	20
Manganese-56	0.01	60,000	Packaged waste, alpha ²	0.0001	20
Mercury-203	0.01	10,000	Combinations of radioactive materials listed above ¹		

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 1200-2-10-.12, all specific licenses to possess uranium hexafluoride in excess of 50 kilograms in a single container or 1000 kilograms total must, by July 1, 1993, 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 1200-2-2-.12, all specific licenses to possess plutonium in excess of 2 curies in unsealed form or on foils or plated sources must, by July 1, 1993, 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;
 - (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 than one hour after the licensee declares an emergency.¹¹
 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.

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 99-540 or other state or federal reporting requirements.

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. §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 March 31, 1992; effective May 15, 1992.

1200-2-10-.14 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 which 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, possess 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;
 - (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 which 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 within five (5) days of the test with the Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37203 describing 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.

- (J) 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.

- (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).

Deleted: Assure that patients treated with cobalt-

Deleted: 60, cesium-

Deleted: 137, iridium-

Deleted: 192, and/or radium-

Deleted: 226 implants remain hospitalized until a source count and a radiation survey of the patient confirm that all implants have been removed; and

Formatted

- (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;
 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:
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. §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.

1200-2-10-.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.

1200-2-10-.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 his use and possession of the material licensed to the locations and purposes authorized in the license.
- (4) Each licensee authorized under 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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.
- (7) Each licensee shall:
 - (a) Notify the Division of Radiological Health, Department of Environment and Conservation, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code (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.

Authority: T.C.A. §68-23-101 et seq, 68-23-206 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.

1200-2-10-.17 EXPIRATION OF LICENSES. Except as provided in 1200-2-10-.18(2) each specific license shall expire at the end of the day, in the month and year stated therein.

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.

1200-2-10-.18 RENEWAL OF LICENSE

- (1) Applications for renewal of specific licenses shall be filed in accordance with 1200-2-10-.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 Division department.

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.

1200-2-10-.19 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE. Applications for amendment of a license shall be filed in accordance with 1200-2-10-.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.

1200-2-10-.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 1200-2-10-.12 and 1200-2-10-.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.

1200-2-10-.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.

1200-2-10-.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 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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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.

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.

1200-2-10-.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 Division.
- (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 which would warrant the Division to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule or regulation of the Division. 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. **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.

1200-2-10-.24 REGISTRATION

- (1) The owner or person having possession of any radiation machine or accelerator, except those specifically exempted in 1200-2-10-.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 1200-2-9. The application for Certified Registration must be received by the Division within ten (10) days after acquisition of the accelerator; however an accelerator may not be energized until registered pursuant to Chapter 1200-2-9. In addition, every person who provides inspections as provided for in 1200-2-10-.27(4) shall register with the Division of Radiological Health, Tennessee Department of Environment and Conservation. Registration under this Rule shall be on Division Form RHS 8-4 or Form RHS 8-4b, as appropriate, as furnished by the Division 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 1200-2-10-.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." The fees for the classes of radiation machines in 1200-2-10-.24(3)(a) will be prorated on a quarterly basis. Positive proof of the date of acquisition of the machine must be supplied in order to qualify for proration of fee.

- (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 1200-2-10-.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 1200-2-10-.27 by personnel of the Division of Radiological Health, Tennessee Department of Environment and Conservation.
- (3) 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: All diagnostic equipment used exclusively for dental diagnostic procedures.	\$55.00 per tube
---	------------------

- CLASS II

Priority Two Medical Radiation Machines: All medical diagnostic x-ray equipment, not in Class III, used exclusively for medical or veterinary diagnostic procedures.	\$110.00 per tube
--	-------------------

- CLASS III

Priority One Medical Radiation Machines: All diagnostic x-ray equipment used in radiologists' offices, orthopedic surgeons' offices, or hospitals exclusively for medical diagnostic procedures.	\$180.00 per tube
--	-------------------

- CLASS IV

Therapy Medical Radiation Machines: All x-ray equipment with energies less than 0.9 MeV used for the purpose of medical or veterinary radiation therapy.	\$250.00 per tube
---	-------------------

- CLASS V

Priority Two Industrial and Educational Radiation Machines: Closed-beam analytical radiation machines, gauges, or industrial radiation machines used in shielded room or cabinet radiography. \$400.00 per tube

CLASS VI

Priority One Industrial and Educational Radiation Machines: All x-ray machines used for industrial radiography and all open-beam analytical x-ray machines not specifically included in Class I, II, III, IV, V, or VII. \$600.00 per tube

CLASS VII

Accelerator: All devices defined as accelerators as per "State Regulations for Protection Against Radiation." \$1000.00 annual fee, plus an initial fee of \$250.00 per maximum nominal rated MeV for initial Certified Registration review (initial review fee not to exceed \$100,000.00).

- (b) Every person providing inspection services as permitted by 1200-2-10-.27(4), except as provided by 1200-2-10-.24(3)(c), shall pay an annual registration fee of Four Hundred Dollars (\$400.00) to the Division of Radiological Health. The payment shall be made payable to the "Treasurer, State of Tennessee."
 - (c) An individual providing inspection services as permitted by 1200-2-10-.27(4) and 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 inspections only for that registrant shall be exempt from the annual fee required in (b) above.
 - (d) A registrant submitting proof of an inspection in accordance with 1200-2-10-.27(4) shall only be required to pay a fee equal to eighteen percent (18%) of that listed for the appropriate Class in 1200-2-10-.24(3)(a), provided that all tubes of the radiation machines possessed by that registrant are inspected in accordance with 1200-2-10-.27(3) and a copy of the inspection results are submitted and are accompanied with any corrective actions taken pursuant to the results found. Any inadequacy found in the inspection or the corrective action may result in full fee payment with possible additional penalties being levied.
 - (e) Reserved.
- (4) Any failure to pay an invoiced amount by the date specified on the invoice, unless qualified by 1200-2-10-.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. §68-23-101 et seq., 68-202-101 et seq. and 4-5-201 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 January 26, 1993; effective March 12, 1993.

1200-2-10-.25 REPORTS

- (1) Any person who sells, leases, transfers, assembles, reassembles, or lends radiation machines, except those exempted from registration by 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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.

1200-2-10-.26 RECORDS. Each licensee and registrant shall keep records showing the receipt, transfer and disposal of all 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.

1200-2-10-.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.
 - 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 1200-2-10-.27(1)(a)1. shall not be interpreted as authorization to disregard instructions pursuant to 1200-2-5-.14(2).
 - (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 workers' representative shall be an employee of the licensee or registrant and should be a worker as defined in 1200-2-4-.04(~~rrr~~) and shall have received instructions as specified in 1200-2-4-~~12~~.

Deleted: ww

Deleted: 5

Deleted: 14(2)
 - 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.
- (b) If, upon receipt of such complaint, the Division determines that the complaint meets the requirements set forth in 1200-2-10-.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 1200-2-10-.27(4), and
- (d) According to the same criteria and to the satisfaction of the Division and provided the appropriate Division inspection results forms are completed and submitted with the applicable fee, and

- (e) By the Division of Radiological Health on a selected number of those facilities providing an inspection report as permitted by 1200-2-10-.27(4).
- (4) Except as provided in 1200-2-10-.27(5), inspections by individuals, other than employees of the Division, who meet one set of the following criteria, have paid an annual registration fee to the Division of Radiological Health and whose inspections are satisfactory to the Division, shall be accepted as inspections for radiation machine registrants to pay a reduced registration fee as provided by 1200-2-10-.24(3)(d).

Formal Education or Certification plus Experience

- | | |
|--|---|
| (a) 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 |
| (b) 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 |
| (c) 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 |
| (d) 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 |
| (e) 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 |
| (f) 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 found by the Division to be unacceptable under 1200-2-10-.27(4) shall not qualify for the 82 percent (82%) fee reduction otherwise permitted in 1200-2-10-.24(3)(d).

Authority: T.C.A. §68-202-101 et seq., 68-203-101 et seq. and 4-5-201 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 January 26, 1993; effective March 12, 1993.

1200-2-10-.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.

1200-2-10-.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;
 - (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 1200-2-10-.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 1200-2-10-.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.

1200-2-10-.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~~
 - (b) ~~Transport licensed material.~~
- (2) An application by physicians as defined in 1200-2-4-.04(1)(m) for an amendment to a specific license may be submitted to the Division 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;~~

Deleted: Each person who transports radioactive material outside of the confines of his plant or place of use, or who delivers radioactive material to a carrier for transport shall:

Deleted: Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U.S. Department of Transportation (USDOT) in effect October 1, 1989, and the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference at 39 CFR 111.1 (1974).

Deleted: If the regulations of the USDOT are not applicable to a shipment of radioactive material by rail, highway or water because the shipment or the transportation of the shipment is not in interstate commerce, or to a shipment of radioactive material by air because the shipment is not transported in civil aircraft, the shipper and carrier shall conform to the standards and requirements of USDOT regulations to the same extent as if the shipment were subject to those regulations. Any notification referred to in those regulations must be filed with or made to the Division of Radiological Health, L&C Annex, 401 Church Street, Nashville, Tennessee 37243-

Deleted: 1532.

Deleted: x

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 1200-2-4-.07.
- (5) Exemption for low-level materials.
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 $\mu\text{Ci/g}$ (70 Bq/g).
 2. A licensee is exempt from all requirements of this rule other than paragraphs 1200-2-10-30(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 1200-2-10-30(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 1200-2-4-.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).

(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.

(d) 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/in²) 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) This general license applies only to a licensee who 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.
- (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 mCi/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 1200-2-10-.30(3) and (4); or
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 1200-2-5-.115(5)(a).

(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 1200-2-10-.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 1200-2-10-.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.

(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 1200-2-10-.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 1200-2-10-.27(1) and Rule 1200-2-10-.28, the licensee shall notify the Director, Division of Radiological Health, at the

address given in Rule 1200-2-4-.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/in²) 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 A₁ value of the radionuclides as specified in appendix A, Table A-1 for special form radioactive material;
 - (ii) 3000 times the A₂ value of the radionuclides as specified in appendix A, Table A-1 for normal form radioactive material; or
 - (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 (7) 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 (7) 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 (7) day period during which departure of the shipment is estimated to occur;
 4. The seven (7) 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 (7) day period during which arrival of the shipment is estimated to occur; and
 6. A point of contact, with a telephone number, for current shipment information.
- (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 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. §68-23-206 and 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 January 8, 1990; effective May 1, 1990.

1200-2-10-.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 1200-2-10-.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 Division that all of the requirements concerning disposal of radioactive material and the 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. 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 1200-2-10-.02.
- (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.
- Notwithstanding the requirements of this paragraph 1200-2-10-.31(8) and Rule 1200-2-10-.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.
- (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
- (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.
 - (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.
 - (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

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. §4-5-201 et seq., 68-202-201 et seq. and 68-203-101 et seq. **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.

1200-2-10-.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, which 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:
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;
 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. *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: Division of Radiological Health, Tennessee Department of Environment and Conservation, L&C Annex, 3rd Floor, 401 Church Street, Nashville, TN 37243-1532. 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 1200-2-5-.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.
 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 material 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 1200-2-10-.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. §68-23-206, 4-5-201 et seq., and Acts of 1991, Public Chapter 417. *Administrative History:* Original rule filed September 3, 1991; effective October 18, 1991.

1200-2-10-.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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.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.
- (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 1200-2-10-.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 1200-2-10-.33(1)(a), above.)
 - (b) Clinical training in specific therapy procedures;
 - 1. For Group IV
 - (i) Iodine-131 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 1200-2-10-.14 or other sealed sources in therapy procedures, a physician should have:
 - (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 1200-2-10-.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)
 - (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.
- (6) 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	Radioactive Material	Micro-curies
Antimony-122 (Sb 122)	100	Barium-131 (Ba 131)	10
Antimony-124 (Sb 124)	10	Barium-133 (Ba 133)	10
Antimony-125 (Sb 125)	10	Barium-140 (Ba 140)	10
Arsenic-73 (As 73)	100	Bismuth-210 (Bi 210)	1
Arsenic-74 (As 74)	10	Bromine-82 (Br 82)	10
Arsenic-76 (As 76)	10	Cadmium-109 (Cd 109)	10
Arsenic-77 (As 77)	100	Cadmium-115m (Cd 115m)	10
		Cadmium-115 (Cd 115)	100

Calcium-45 (Ca 45)	10	Iodine-135 (I 135)	10
Calcium-47 (Ca 47)	10	Iridium-192 (Ir 192)	10
Carbon-14 (C 14)	100	Iridium-194 (Ir 194)	100
Cerium-141 (Ce 141)	100	Iron-52 (Fe 52)	10
Cerium-143 (Ce 143)	100	Iron-55 (Fe 55)	100
Cerium-144 (Ce 144)	1	Iron-59 (Fe 59)	10
Cesium-129 (Cs 129)	100	Krypton-85 (Kr 85)	100
Cesium-131 (Cs 131)	1,000	Krypton-87 (Kr 87)	10
Cesium-134m (Cs 134m)	100	Lanthanum-140 (La 140)	10
Cesium-134 (Cs 134)	1	Lutetium-177 (Lu 177)	100
Cesium-135 (Cs 135)	10	Manganese-52 (Mn 52)	10
Cesium-136 (Cs 136)	10	Manganese-54 (Mn 54)	10
Cesium-137 (Cs 137)	10	Manganese-56 (Mn 56)	10
Chlorine-36 (Cl 36)	10	Mercury-197m (Hg 197m)	100
Chlorine-38 (Cl 38)	10	Mercury-197 (Hg 197)	100
Chromium-51 (Cr 51)	1,000	Mercury-203 (Hg 203)	10
Cobalt-57 (Co 57)	100	Molybdenum-99 (Mo 99)	100
Cobalt-58m (Co 58m)	10	Neodymium-147(Nd 147)	100
Cobalt-58 (Co 58)	10	Neodymium-149 (Nd 149)	100
Cobalt-60 (Co 60)	1	Nickel-59 (Ni 59)	100
Copper-64 (Cu 64)	100	Nickel-63 (Ni 63)	10
Dysprosium-165 (Dy 165)	10	Nickel-65 (Ni 65)	100
Dysprosium-166 (Dy 166)	100	Niobium-93m (Nb 93m)	10
Erbium-169 (Er 169)	100	Niobium-95 (Nb 95)	10
Erbium-171 (Er 171)	100	Niobium-97 (Nb 97)	10
Europium-152 (Eu 152)9.2 h	100	Osmium-185 (Os 185)	10
Europium-152 (Eu 152)13 yr	1	Osmium-191m (Os 191m)	100
Europium-154 (Eu 154)	1	Osmium-191 (Os 191)	100
Europium-155 (Eu 155)	10	Osmium-193 (Os 193)	100
Fluorine-18 (F 18)	1,000	Palladium-103 (Pd 103)	100
Gadolinium-153 (Gd 153)	10	Palladium-109 (Pd 109)	100
Gadolinium-159 (Gd 159)	100	Phosphorus-32 (P 32)	10
Gallium-67 (Ga 67)	100	Platinum-191 (Pt 191)	100
Gallium-72 (Ga 72)	10	Platinum-193m (Pt 193m)	100
Germanium-68 (Ge 68)	10	Platinum-193 (Pt 193)	100
Germanium-71 (Ge 71)	100	Platinum-197m (Pt 197m)	100
Gold-195 (Au 195)	10	Platinum-197 (Pt 197)	100
Gold-198 (Au 198)	100	Polonium-210 (Po 210)	0.1
Gold-199 (Au 199)	100	Potassium-42 (K 42)	10
Hafnium-181 (Hf 181)	10	Potassium-43 (K 43)	10
Holmium-166 (Ho 166)	100	Praseodymium-142 (Pr 142)	100
Hydrogen-3 (H 3)	1,000	Praseodymium-143 (Pr 143)	100
Indium-111 (In 111)	100	Praseodymium-147 (Pr 147)	100
Indium-113m (In 113m)	100	Promethium-147 (Pm 147)	10
Indium-114m (In 114m)	10	Promethium-149 (Pm 149)	10
Indium-115m (In 115m)	100	Rhenium-186 (Re 186)	100
Indium-115 (In 115)	10	Rhenium-188 (Re 188)	100
Iodine-123 (I 123)	100	Rhodium-103m (Rh 103m)	100
Iodine-125 (I 125)	1	Rhodium-105 (Rh 105)	100
Iodine-126 (I 126)	1	Rubidium-81 (Rb 81)	10
Iodine-129 (I 129)	0.1	Rubidium-86 (Rb 86)	10
Iodine-131 (I 131)	1	Rubidium-87 (Rb 87)	10
Iodine-132 (I 132)	10	Ruthenium-97 (Ru 97)	100
Iodine-133 (I 133)	1	Ruthenium-103 (Ru 103)	10
Iodine-134 (I 134)	10	Ruthenium-105 (Ru 105)	10

Ruthenium-106 (Ru 106)	1	Thallium-202 (Tl 202)	100
Samarium-151 (Sm 151)	10	Thallium-204 (Tl 204)	10
Samarium-153 (Sm 153)	100	Thulium-170 (Tm 170)	10
Scandium-46 (Sc 46)	10	Thulium-171 (Tm 171)	10
Scandium-47 (Sc 47)	100	Tin-113 (Sn 113)	10
Scandium-48 (Sc 48)	10	Tin-125 (Sn 125)	10
Selenium-75 (Se 75)	10	Tungsten-181 (W 181)	10
Silicon-31 (Si 31)	100	Tungsten-185 (W 185)	10
Silver-105 (Ag 105)	10	Tungsten-187 (W 187)	100
Silver-110m (Ag 110m)	1	Vanadium-48 (V 48)	10
Silver-111 (Ag 111)	100	Xenon-131m (Xe 131m)	1,000
Sodium-22 (Na 22)	10	Xenon-133 (Xe 133)	100
Sodium-24 (Na 24)	10	Xenon-135 (Xe 135)	100
Strontium-85 (Sr 85)	10	Ytterbium-175 (Yb 175)	100
Strontium-89 (Sr 89)	1	Yttrium-87 (Y 87)	10
Strontium-90 (Sr 90)	0.1	Yttrium-88 (Y 88)	10
Strontium-91 (Sr 91)	10	Yttrium-90 (Y 90)	10
Strontium-92 (Sr 92)	10	Yttrium-91 (Y 91)	10
Sulphur-35 (S 35)	100	Yttrium-92 (Y 92)	100
Tantalum-182 (Ta 182)	10	Yttrium-93 (Y 93)	100
Technetium-96 (Tc 96)	10	Zinc-65 (Zn 65)	10
Technetium-97m (Tc 97m)	100	Zinc-69m (Zn 69m)	100
Technetium-97 (Tc 97)	100	Zinc-69 (Zn 69)	1,000
Technetium-99m (Tc 99m)	100	Zirconium-93 (Zr 93)	10
Technetium-99 (Tc 99)	10	Zirconium-95 (Zr 95)	10
Tellurium-125m (Te 125m)	10	Zirconium-97 (Zr 97)	10
Tellurium-127m (Te 127m)	10		
Tellurium-127 (Te 127)	100	Any radioactive material not listed above other than alpha-emitting radioactive material	0.1
Tellurium-129m (Te 129m)	10		
Tellurium-129 (Te 129)	100	Any alpha emitting radioactive material not listed above other than transuranic radioactive material	0.01
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		

SCHEDULE RHS 8-4

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}^1$	Column II and Solid Concentration $\mu\text{Ci/ml}^2$
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
	Chlorine (17)	Cl-38	9×10^{-7}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152		6×10^{-4}
	Eu-155 ($T_r = 9.2\text{h}$)		2×10^{-3}
Fluorine(9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}

Gold (79)	Au-196		2x10 ⁻³
	Au-198		5x10 ⁻⁴
	Au-199		2x10 ⁻³
Hafnium (72)	Hf-181		7x10 ⁻⁴
Hydrogen (1)	H-3	5x10 ⁻⁶	3x10 ⁻²
Indium (49)	In-113m		1x10 ⁻²
	In-114m		2x10 ⁻⁴
Iodine (53)	I-126	3x10 ⁻⁹	2x10 ⁻⁵
	I-131	3x10 ⁻⁹	2x10 ⁻⁵
	I-132	8x10 ⁻⁸	6x10 ⁻⁴
	I-133	1x10 ⁻⁸	7x10 ⁻⁵
	I-134	2x10 ⁻⁷	1x10 ⁻³
Iridium (77)	Ir-190		2x10 ⁻³
	Ir-192		4x10 ⁻⁴
	Ir-194		3x10 ⁻⁴
	Fe-55		8x10 ⁻³
Iron (26)	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
	Mo-99		2x10 ⁻³
Molybdenum (42)	Nd-147		6x10 ⁻⁴
	Neodymium (60)	Nd-149	3x10 ⁻³
Nickel (28)	Ni-65		1x10 ⁻³
	Niobium (41)	Nb-95	1x10 ⁻³
Osmium (76)	Nb-97		9x10 ⁻³
	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	
Radium (88)	Pm-149		4x10 ⁻⁴
	Ra-226		1x10 ⁻⁷

	Ra-228		3×10^{-7}	
Rhenium (75)	Re-183		6×10^{-3}	
	Re-186		9×10^{-4}	
	Re-188		6×10^{-4}	
	Rh-103m		1×10^{-1}	
Rhodium (45)	Rh-105		1×10^{-3}	
	Rb-86		7×10^{-4}	
Rubidium (37)	Ru-97		4×10^{-3}	
Ruthenium (44)	Ru-103		8×10^{-4}	
	Ru-105		1×10^{-3}	
	Ru-106		1×10^{-4}	
	Sm-153		8×10^{-4}	
Samarium (62)	Sc-46		4×10^{-4}	
	Sc-47		9×10^{-4}	
Scandium (21)	Sc-48		3×10^{-4}	
	Se-75		3×10^{-3}	
Selenium (34)	Si-31		9×10^{-3}	
Silicon (14)	Ag-105		1×10^{-3}	
Silver (47)	Ag-110m		3×10^{-4}	
	Ag-111		4×10^{-4}	
	Na-24		2×10^{-3}	
Sodium (11)	Sr-85		1×10^{-3}	
Strontium (38)	Sr-89		1×10^{-4}	
	Sr-91		7×10^{-4}	
	Sr-92		7×10^{-4}	
	S-35	9×10^{-8}	6×10^{-4}	
Sulfur (16)	Ta-182		4×10^{-4}	
Tantalum (73)	Tc-96m		1×10^{-1}	
	Tc-96		1×10^{-3}	
Technetium (43)	Te-125m		2×10^{-3}	
	Te-127m		6×10^{-4}	
Tellurium (52)	Te-127		3×10^{-3}	
	Te-129m		3×10^{-4}	
	Te-131m		6×10^{-4}	
	Te-132		3×10^{-4}	
	Tb-160		4×10^{-4}	
	Terbium (65)	Tl-200		4×10^{-3}
		Tl-201		3×10^{-3}
Tl-202			1×10^{-3}	
Tl-204			1×10^{-3}	
Thallium (81)	Tm-170		5×10^{-4}	
	Tm-171		5×10^{-3}	
Thulium (69)	Sn-113		9×10^{-4}	
	Sn-125		2×10^{-4}	
Tin (50)	W-181		4×10^{-3}	
	W-187		7×10^{-4}	
Tungsten (74)	V-48		3×10^{-4}	
	Xe-131m	4×10^{-6}		
Vanadium (23)	Xe-133	3×10^{-6}		
	Xe-135	1×10^{-6}		
	Yb-175		1×10^{-3}	
Xenon (54)	Y-90		2×10^{-4}	
	Y-91m		3×10^{-2}	
Ytterbium (70)	Y-91		3×10^{-4}	
	Y-91		3×10^{-4}	

	Y-92	6x10 ⁻⁴
	Y-93	3x10 ⁻⁴
Zinc (30)	Zn-65	1x10 ⁻³
	Zn-69m	7x10 ⁻⁴
	Zn-69	2x10 ⁻²
Zirconium (40)	Zr-95	6x10 ⁻⁴
	Zr-97	2x10 ⁻⁴
Beta and/or gamma emitting radioactive material not listed above with half- life less than 3 years.		
	1x10 ⁻¹⁰	1x10 ⁻⁶

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

² μ Ci/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:

Concentration of Isotope A in Product		Concentration of Isotope B in Product	
_____	+	_____	≤ 1
Exempt concentration of Isotope A		Exempt concentration of Isotope B	

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. and 68-23-206. *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.

1200-2-10-.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. 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 of 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 1200-2-10-.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 1200-2-10-.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 1200-2-10-.27(4), except as provided by paragraph 1200-2-10-.24(3)(c)-----	\$ 200.00

(b) In addition to the fees established in paragraphs (6) through (19) of Rule 1200-2-10-.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:

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

Schedule II		
	remit a supplemental fee, on items contaminated or potentially contaminated with radioactive material or on low-level radioactive waste received, of-----	\$0.005/lb
	Notwithstanding the requirements of paragraph 1200-2-10-.31(8) and Rule 1200-2-10-.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 1200-2-10-.31.	

Authority: T.C.A. §§4-5-201 et seq., 68-202-201 et seq. and 68-203-201 et seq. **Administrative History:** Original rule filed April 11, 2001; effective June 25, 2001.

1200-2-10-.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. 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 of 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 1200-2-10-.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 1200-2-10-24 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 1200-2-10-27(4), except as provided by paragraph 1200-2-10-24(3)(c)-----	\$ 200.00

- (b) In addition to the fees established in paragraphs (6) through (19) of Rule 1200-2-10-31 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:

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
Notwithstanding the requirements of paragraph 1200-2-10-31(8) and Rule 1200-2-10-32, 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

Schedule II	
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 1200-2-10-.31.	

Authority: T.C.A. §§4-5-201 et seq., 68-202-201 et seq. and 68-203-201 et seq. **Administrative History:** Original rule filed April 11, 2001; effective June 25, 2001.

1200-2-10-.35 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;

(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 (effective date of amendment), 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. and 68-202-101 and 206

Formatted

1200-2-10-.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 1200-2-10 and Chapters 1200-2-7, 1200-2-8, 1200-2-9, 1200-2-11 and 1200-2-12. For low-level waste disposal facilities (Chapter 1200-2-11), 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.
- (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 1200-2-10-.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 1200-2-10-.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:
 - 1. Are not technically achievable,
 - 2. Would be prohibitively expensive or
 - 3. 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 1200-2-10-.36(3)(b). Acceptable financial assurance mechanisms are those in subparagraph 1200-2-10-.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 1200-2-10-.36(2) and subparagraph 1200-2-10-.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 1200-2-5-.60 and 1200-2-5-.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 1200-2-10-.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 1200-2-10-.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.

Authority: T.C.A. §§4-5-201 et seq. and 68-202-101 et seq.

Formatted

1200-2-10-.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_2 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 radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity	
						(TBq/g)	(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
Ag-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	54.1	20	54.1	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	54.1	0.5	13.5	3.9×10^4	1.0×10^6
At-211	Astatine(85)	30	81.1	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	1.4×10^3	3.7×10^4
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	54.1	20	54.1	1.3×10^4	3.5×10^5
Be-10		20	54.1	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^{-3}	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
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	9.4×10^6	2.5×10^8
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		0.2	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	54.1	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	1.9×10^3	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

Symbol of radio-nuclide	Element and atomic number	Specific activity					
		Δ_1 (TBq)	Δ_1 (Ci)	Δ_2 (TBq)	Δ_2 (Ci)	(TBq/g)	(Ci/g)
Ce-143		0.6	16.2	0.5	13.5	2.5×10^4	6.6×10^3
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^{-5}	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	4.9×10^2	1.3×10^3
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	24.3	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
Es-253	Einsteinium(99) *	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	3.5×10^3	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	2.9×10^3	5.5×10^4
F-18	Fluorine(9)	1	27.0	0.5	13.5	3.5×10^6	9.5×10^7

Symbol of radio-nuclide	Element and atomic number	Specific activity					
		Δ_1 (TBq)	Δ_1 (Ci)	Δ_2 (TBq)	Δ_2 (Ci)	(TBq/g)	(Ci/g)
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^{24}	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	Holmium(67)	4	108	0.9	24.3	5.1×10^2	1.4×10^4
Ho-163		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	7.1×10^2	1.9×10^4
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	4.2×10^2	1.1×10^4
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	1.3×10^3	3.5×10^5
In-111	Indium(49)	2	54.1	2	54.1	1.5×10^4	4.2×10^5
In-113m		4	108	4	108	6.2×10^2	1.7×10^4
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	1.9×10^2	5.2×10^4
Ir-190		0.7	18.9	0.7	18.9	2.3×10^3	6.2×10^4
Ir-192		1	27.0	0.5	13.5	3.4×10^4	9.2×10^5
Ir-193m		10	270	10	270	2.4×10^2	6.4×10^4
Ir-194		0.2	5.41	0.2	5.41	3.1×10^3	8.4×10^5
K-40	Potassium(19)	0.6	16.2	0.6	16.2	2.4×10^{-2}	6.4×10^{-5}
K-42		0.2	5.41	0.2	5.41	2.2×10^2	6.0×10^6
K-43		1.0	27.0	0.5	13.5	1.2×10^2	3.3×10^6
Kr-81	Krypton(36)	40	1080	40	1080	7.8×10^{-1}	2.1×10^{-2}
Kr-85m		6	162	6	162	3.0×10^3	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	1.0×10^2	2.8×10^2
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	4.2×10^2	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

Symbol of radio-nuclide	Element and atomic number	Specific activity						
		Δ_1 (TBq)	Δ_1 (Ci)	Δ_2 (TBq)	Δ_2 (Ci)	(TBq/g)	(Ci/g)	
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^{-3}	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^{-1}	3.9×10^{-3}	
Pu-244		0.3	8.11	2×10^{-4}	5.41×10^{-3}	6.7×10^{-2}	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	5.9×10^1	1.6×10^3
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	4×10^0	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	6.8×10^5	1.8×10^7	
Rb-84		1	27.0	0.9	24.3	1.8×10^5	4.7×10^6	
Rb-86		0.3	8.11	0.3	8.11	3.0×10^5	8.1×10^6	
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	3.2×10^7	8.6×10^8	
Rb (natural)		Unlimited	Unlimited	Unlimited	Unlimited	6.7×10^6	1.8×10^7	
Rc-183	Rhenium(75)	5	135	5	135	3.8×10^2	1.0×10^4	
Rc-184m		3	81.1	3	81.1	1.6×10^2	4.3×10^3	
Rc-184		1	27.0	1	27.0	6.9×10^2	1.9×10^4	
Rc-186		4	108	0.5	13.5	6.9×10^3	1.9×10^5	
Rc-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4×10^{-9}	3.8×10^{-8}	
Rc-188		0.2	5.41	0.2	5.41	3.6×10^4	9.8×10^5	
Rc-189		4	108	0.5	13.5	2.5×10^4	6.8×10^5	
Rc (natural)		Unlimited	Unlimited	Unlimited	Unlimited	2.4×10^{-8}		
Rh-99		Rhodium(45)	2	54.1	2	54.1	3.0×10^1	8.2×10^4
Rh-101	4		108	4	108	4.1×10^1	1.1×10^4	
Rh-102m	2		54.1	0.9	24.3	2.3×10^2	6.2×10^4	
Rh-102	0.5		13.5	0.5	13.5	4.5×10^1	1.2×10^4	
Rh-103m	40		1080	40	1080	1.2×10^6	3.3×10^7	
Rh-105	10		270	0.9	24.3	3.1×10^1	8.4×10^3	
Rn-222	Radon(86)		0.2	5.41	4×10^{-2}	0.108	3.7×10^3	1.5×10^5
Ru-97	Ruthenium(44)	4	108	4	108	1.7×10^4	4.6×10^5	
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	2.5×10^3	6.7×10^5	
Ru-106		0.2	5.41	0.2	5.41	1.2×10^4	3.3×10^5	
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	1.5×10^3	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	3.9×10^4	1.0×10^6	
Sb-126		0.4	10.8	0.4	10.8	3.1×10^4	8.4×10^5	
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	9.8×10^4	2.6×10^6	
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	

Symbol of radio-nuclide	Element and atomic number	Specific activity				Specific activity	
		Δ_1 (TBq)	Δ_1 (Ci)	Δ_2 (TBq)	Δ_2 (Ci)	(TBq/g)	(Ci/g)
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	6.2×10^3
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	1.1×10^2	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	4.7×10^2	1.3×10^4
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	4.1×10^7	1.1×10^9
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^{-1}	1.7×10^{-2}
Tc-118	Tellurium(52)	0.2	5.41	0.2	5.41	6.8×10^3	1.8×10^5
Tc-121m		5	135	5	135	2.6×10^2	7.0×10^3
Tc-121		2	54.1	2	54.1	2.4×10^3	6.4×10^4
Tc-123m		7	189	7	189	3.3×10^2	8.9×10^3
Tc-125m		30	811	9	243	6.7×10^2	1.8×10^4
Tc-127m		20	541	0.5	13.5	3.5×10^2	9.4×10^3
Tc-127		20	541	0.5	13.5	9.8×10^2	2.6×10^4
Tc-129m		0.6	16.2	0.5	13.5	1.1×10^3	3.0×10^4
Tc-129		0.6	16.2	0.5	13.5	7.7×10^5	2.1×10^7
Tc-131m		0.7	18.9	0.5	13.5	3.0×10^4	8.0×10^5
Tc-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^{-5}	2.1×10^{-1}
Th-230		2	54.1	2×10^{-4}	5.41×10^{-3}	7.9×10^{-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^{-7}	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	2.0×10^7	5.3×10^8
Tl-204		4	108	0.5	13.5	1.7×10^7	4.6×10^8
Tm-167	Thulium(69)	7	189	7	189	3.1×10^7	8.5×10^8
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	4.0×10^7	1.1×10^8
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^{-2}	8.3×10^{-1}	2.2×10^1
U-233		10	270	1×10^{-3}	2.70×10^{-2}	3.6×10^{-1}	9.7×10^{-3}
U-234		10	270	1×10^{-3}	2.70×10^{-2}	2.3×10^{-1}	6.2×10^{-3}
U-235		Unlimited	Unlimited	Unlimited	Unlimited	5.0×10^{-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)	

Symbol of radionuclide	Element and atomic number	Specific activity					
		A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	(TBq/g)	(Ci/g)
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	6.3 x 10 ³	1.7 x 10 ⁵
V-49		40	1080	40	1080	3.0 x 10 ²	8.1 x 10 ³
W-178	Tungsten(74)	1	27.0	1	27.0	1.3 x 10 ³	3.4 x 10 ⁴
W-181		30	811	30	811	2.2 x 10 ²	6.0 x 10 ³
W-185		40	1080	0.9	24.3	3.5 x 10 ²	9.4 x 10 ³
W-187		2	54.1	0.5	13.5	2.6 x 10 ⁴	7.0 x 10 ⁵
W-188		0.2	5.41	0.2	5.41	3.7 x 10 ²	1.0 x 10 ⁴
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	4.8 x 10 ⁴	1.3 x 10 ⁶
Xe-123		0.2	5.41	0.2	5.41	4.4 x 10 ⁵	1.2 x 10 ⁷
Xe-127		4	108	4	108	1.0 x 10 ³	2.8 x 10 ⁴
Xe-131m		40	1080	40	1080	3.1 x 10 ³	8.4 x 10 ⁴
Xe-133		20	541	20	541	6.9 x 10 ³	1.9 x 10 ⁵
Xe-135		4	108	4	108	9.5 x 10 ⁴	2.6 x 10 ⁶
Y-87	Yttrium(39)	2	54.1	2	54.1	1.7 x 10 ⁴	4.5 x 10 ⁵
Y-88		0.4	10.8	0.4	10.8	5.2 x 10 ²	1.4 x 10 ⁴
Y-90		0.2	5.41	0.2	5.41	2.0 x 10 ⁴	5.4 x 10 ⁵
Y-91m		2	54.1	2	54.1	1.5 x 10 ⁵	4.2 x 10 ⁷
Y-91		0.3	8.11	0.3	8.11	9.1 x 10 ²	2.5 x 10 ³
Y-92		0.2	5.41	0.2	5.41	3.6 x 10 ²	9.6 x 10 ³
Y-93		0.2	5.41	0.2	5.41	1.2 x 10 ³	3.3 x 10 ⁴
Yb-169	Ytterbium(70)	3	81.1	3	81.1	8.9 x 10 ²	2.4 x 10 ⁴
Yb-175		30	811	0.9	24.3	6.6 x 10 ³	1.8 x 10 ⁵
Zn-65	Zinc(30)	2	54.1	2	54.1	3.0 x 10 ²	8.2 x 10 ³
Zn-69m		2	54.1	0.5	13.5	1.2 x 10 ³	3.3 x 10 ⁴
Zn-69		4	108	0.5	13.5	1.8 x 10 ⁶	4.9 x 10 ⁷
Zr-88	Zirconium(40)	3	81.1	3	81.1	6.6 x 10 ²	1.8 x 10 ⁴
Zr-93		40	1080	0.2	5.41	9.3 x 10 ⁻³	2.5 x 10 ⁻³
Zr-95		1	27.0	0.9	24.3	7.9 x 10 ⁻²	2.1 x 10 ¹
Zr-97		0.3	8.11	0.3	8.11	7.1 x 10 ¹	1.9 x 10 ³

a International shipments of einsteinium require multilateral approval of A₁ and A₂ values.

b International shipments of fermium require multilateral approval of A₁ and A₂ values.

c 20 Ci for Mo-99 for domestic use.

Table A-2: General Values for A₁ and A₂

Contents	A ₁ (TBq)	A ₂ (TBq)
Only beta- or gamma-emitting nuclides are known to be present.	0.2	5
Alpha-emitting nuclides are known to be present, or no relevant data are available	0.10	2.70
		2 x 10 ⁻⁵
		5.41 x 10 ⁻⁴

Table A-3: Activity-mass Relationships for Uranium

Uranium Enrichment ¹ wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8 x 10 ⁻³	5.0 x 10 ⁻⁷
0.72	2.6 x 10 ⁻³	7.1 x 10 ⁻⁷
1.0	2.8 x 10 ⁻³	7.6 x 10 ⁻⁷
1.5	3.7 x 10 ⁻³	1.0 x 10 ⁻⁶

	Specific Activity	
<u>5.0</u>	1.0×10^{-8}	2.7×10^{-6}
<u>10.0</u>	1.8×10^{-8}	4.8×10^{-6}
<u>20.0</u>	3.7×10^{-8}	1.0×10^{-5}
<u>35.0</u>	7.4×10^{-8}	2.0×10^{-5}
<u>50.0</u>	9.3×10^{-8}	2.5×10^{-5}
<u>90.0</u>	2.2×10^{-6}	5.8×10^{-5}
<u>93.0</u>	2.6×10^{-6}	7.0×10^{-5}
<u>95.0</u>	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.

Formatted

**RULES
OF
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH**

**CHAPTER 1200-2-12
RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING**

TABLE OF CONTENTS

1200-2-12-.01	Purpose	1200-2-12-.15	Radioactive Markers
1200-2-12-.02	Scope	1200-2-12-.16	Uranium Sinker Bars
1200-2-12-.03	Definitions	1200-2-12-.17	Use of a Sealed Source in a Well without a Surface Casing
1200-2-12-.04	Registration or Application for a License		Training
1200-2-12-.05	Registration and License for Well Logging	1200-2-12-.18	Operating and Emergency Procedures
1200-2-12-.06	Agreement with Well Owner or Operator	1200-2-12-.19	Personnel Monitoring
1200-2-12-.07	Labels, Security, and Transportation	1200-2-12-.20	Radiation Surveys
	Precautions	1200-2-12-.21	Radioactive Contamination Control
1200-2-12-.08	Radiation Detection Instruments	1200-2-12-.22	Security
1200-2-12-.09	Leak Testing of Sealed Sources	1200-2-12-.23	Documents and Records Required at Field Stations
1200-2-12-.10	Physical Inventory	1200-2-12-.24	Documents and Records Required at Temporary Job-sites
1200-2-12-.11	Records of Material Use		Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources
1200-2-12-.12	Design and Performance Criteria for Sealed Sources	1200-2-12-.25	
1200-2-12-.13	Inspection, Maintenance, and Operation of Sources of Radiation	1200-2-12-.26	
1200-2-12-.14	Subsurface Tracer Studies		

1200-2-12-.01 PURPOSE.

This Chapter prescribes requirements for the issuance of a license or acceptance of registration authorizing the use of sources of radiation including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. This Chapter also prescribes radiation safety requirements for persons using sources of radiation in these operations.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.02 SCOPE

The provisions and requirements of this Chapter are in addition to, and not in substitution for, other requirements of these regulations. The requirements set out in this Chapter are not to be used to apply for the issuance of a license authorizing the use of radioactive material in tracer studies involving multiple wells, such as field flooding studies, or the use of sealed sources auxiliary to well logging but not lowered into wells.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.03 DEFINITIONS

As used in this Chapter, 1200-2-12, certain terms have the definitions set forth below: (Additional definitions may be found in Chapters 1200-2-4, 1200-2-5, 1200-2-6, 1200-2-8, 1200-2-9 and 1200-2-11.)

- (1) *Aquifer* means a formation, group of formations, or part of a formation that contains a sufficient quantity of permeable material to yield significant quantities of water for wells and springs.
- (2) *Field station* means a facility where sources of radiation may be stored or used and from which equipment is dispatched to temporary job-sites.
- (3) *Fresh water aquifer* means, for the purpose of this Chapter, a geologic formation that is capable of yielding fresh water to a well or spring.
- (4) *Injection tool* means a device used for controlled subsurface injection of radioactive tracer material.
- (5) *Irretrievable well logging source* means any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.
- (6) *Logging assistant* means any individual who, under the personal supervision of a logging supervisor, handles sources of radiation or radioactive tracers that are not in logging tools or shipping containers or who performs surveys required by 1200-2-12-.21.
- (7) *Logging supervisor* means an individual who uses sources of radiation or provides personal supervision in the use of sources of radiation at a temporary job-site and who is responsible to the licensee or registrant for assuring compliance with the requirements of these regulations and the conditions of the license or registration.
- (8) *Logging tool* means a device used subsurface to perform well logging.
- (9) *Personal supervision* means guidance and instruction by a logging supervisor who is physically present at a temporary job-site, who is in personal contact with logging assistants, an who can give immediate assistance.
- (10) *Radioactive marker* means radioactive material used for depth determination or direction orientation. For purposes of this Chapter, this term includes radioactive collar markers and radioactive iron nails.
- (11) *Safety review* means a periodic review provided by the licensee or registrant for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.
- (12) *Sealed source*. See 1200-2-4-.04(1)(yy).
- (13) *Source holder* means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.
- (14) *Subsurface tracer study* means the release of unsealed radioactive material or a substance labeled with radioactive material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.
- (15) *Surface casing for protecting fresh water aquifers* means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

Deleted: ll

- (16) *Temporary job-site* means a place where sources of radiation are present for the purpose of performing well logging including subsurface tracer studies.
- (17) *Uranium sinker bar* means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.
- (18) *Well* means a bored, drilled, driven or dug shaft or hole whose depth is greater than the largest surface dimension.
- (19) *Well logging* means all operations involving the lowering and raising of measuring devices or tools which contain sources of radiation or are used to detect radioactive materials in wells for the purpose of obtaining information about the well or adjacent formations.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.04 REGISTRATION OR APPLICATION FOR A LICENSE

A person, as defined in Chapter 1200-2-4, shall file an application for a license authorizing the use of radioactive material in well logging or register radiation producing machines for use in well logging with the Division of Radiological Health at the address given in 1200-2-4-.07.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.05 REGISTRATION AND LICENSE FOR WELL LOGGING

- (1) The Department may approve an application for a license for the use of radioactive material in well logging or a registration if the following requirements are met:
 - (a) The applicant shall satisfy the general requirements specified in 1200-2-10-.12 and 1200-2-10-.24 and any special requirements contained in this Chapter;
 - (b) The applicant or registrant shall develop a program for training logging supervisors and logging assistants and submit a description of this program which specifies the:
 - 1. Initial training;
 - 2. On-the-job training;
 - 3. Annual safety reviews provided by the licensee or registrant;
 - 4. Means the applicant or registrant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the regulations, license, and the applicant's or registrant's operating and emergency procedures; and
 - 5. Means the applicant or registrant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating an emergency procedures;
 - (c) The applicant or registrant shall submit written operating and emergency procedures as described in 1200-2-12-.19 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures;

- (d) The applicant or registrant shall establish and submit its program for annual inspections of the job performance of each logging supervisor to ensure that the regulations, license, and the applicant's or registrant's operating and emergency procedures are followed. Inspection records must be retained for three (3) years after each annual internal inspection;
- (e) The applicant or registrant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility; and
- (f) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures. The description must include the:
 - 1. Instruments to be used;
 - 2. Methods of performing the analysis; and
 - 3. Experience of the person who will analyze the wipe samples. Experience shall be commensurate with the analysis to be made.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.06 AGREEMENT WITH WELL OWNER OR OPERATOR

- (1) A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will met the following requirements:
 - (a) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;
 - (b) A person may not attempt to recover a sealed source in a manner which is reasonably expected to result in its rupture;
 - (c) The radiation monitoring required in 1200-2-12-.22(1) will be performed;
 - (d) If the environment, any equipment, or personnel are contaminated with radioactive material, they must be decontaminated before release for unrestricted use or release from the site; and
 - (e) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:
 - 1. Each irretrievable well logging source must be immobilized and sealed in place with a cement plug.
 - 2. A mechanical device to prevent inadvertent intrusion on the source must be set at some point in the well above the cement plug, unless the cement plug and source are not accessible to any subsequent drilling operations. And,

3. A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 7 inches (17 cm) square and 1/8-inch (3 mm) thick. The plaque must contain:
 - (i) The word "CAUTION";
 - (ii) The radiation symbol (the color requirement in 1200-2-5-.12(1)(a) need not be met);
 - (iii) The date the source was abandoned;
 - (iv) The name of the well owner or well operator, as appropriate;
 - (v) The well name and well identification number(s) or other designation;
 - (vi) An identification of the sealed source(s) by radionuclide and quantity;
 - (vii) The depth of the source and depth to the top of the plug; and
 - (viii) An appropriate warning, depending on the specific circumstances of each abandonment.¹
- (2) The licensee shall retain a copy of the written agreement for 3 years after the completion of the well logging operation.
- (3) A licensee may apply for approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in (1)(e) of this Rule.
- (4) A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in (1)(a) through (1)(e) of this Rule.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.07 LABELS, SECURITY, AND TRANSPORTATION PRECAUTIONS

- (1) Labels.
 - (a) The licensee may not use a source, source holder, or logging tool that contains radioactive material unless the smallest component that is transported as a separate piece of equipment with the radioactive material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in 1200-2-5-.12(1) without the conventional color requirements and the wording "DANGER (or CAUTION) RADIOACTIVE MATERIAL."

¹ Appropriate warnings may include: (a) "Do not drill below plug-back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole" followed by the words, "before contacting the Division of Radiological Health."

- (b) The licensee may not use a container to store radioactive material unless the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in 1200-2-5-12(1) and the wording "CAUTION (or DANGER), RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."
 - (c) The licensee may not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with 1200-2-10-30.
- (2) Security precautions during storage and transportation.
- (a) The licensee or registrant shall store each source of radiation in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of sources of radiation from storage by unauthorized personnel. The licensee shall store radioactive material in a manner which will minimize danger from explosion or fire.
 - (b) The licensee or registrant shall lock and physically secure the transport packages containing sources of radiation in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the sources of radiation from the vehicle.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.08 RADIATION DETECTION INSTRUMENTS

- (1) The licensee or registrant shall keep a calibrated and operable radiation survey instrument capable of detecting, as appropriate, beta, gamma and x-ray radiation at each field station and temporary job-site to make the radiation surveys required by this Chapter and by Chapter 1200-2-5. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.1 milliroentgen (2.58×10^{-8} C/kg) per hour through at least 50 milliroentgens (1.29×10^{-5} C/kg) per hour. Survey instruments acquired before the effective date of this Chapter and capable of measuring 0.1 milliroentgen (2.58×10^{-8} C/kg) per hour through at least 20 milliroentgens (5.16×10^{-6} C/kg) per hour also satisfy this requirement until July 14, 1992.
- (2) The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured.
- (3) The licensee or registrant shall have each radiation survey instrument required under (1) of this Rule calibrated:
 - (a) At intervals not to exceed 6 months and after instrument servicing;
 - (b) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and
 - (c) So that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

- (4) The licensee or registrant shall retain calibration records for a period of 3 years after the date of calibration for inspection by the Division.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.09 LEAK TESTING OF SEALED SOURCES

- (1) Each licensee who uses a sealed source shall have the source tested for leakage periodically. The licensee shall keep a record of leak test results in units of microcuries and retain the record for inspection by the Division for 3 years after the leak, test is performed.
- (2) The wipe of a sealed source must be performed using a leak test kit or method approved by the Division, U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and must be performed by a person approved by the Division, U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State to perform the analysis.
- (3) Each sealed source must be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source shall not be used until tested.
- (4) Removal of leaking source from service:
 - (a) If the test conducted pursuant to (1) and (2) of this Rule reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by an Agreement State, U.S. Nuclear Regulatory Commission, or a Licensing State licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by a Department, U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State licensee that is authorized to perform these functions. ***
 - (b) The licensee shall submit a report to the Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, TN 37243-1532, within five (5) days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.
- (5) The following sealed sources are not subject to the periodic leak test requirements set out in (1) through (4) of this Rule:
 - (a) Hydrogen-3 sources;
 - (b) Sources containing radioactive material with a half-life of 30 days or less;
 - (c) Sources containing radioactive material in gaseous form;
 - (d) Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3,700,000 Bq) or less; and

- (e) Sources of alpha- or neutron-emitting radioactive material with an activity of 10 microcuries (370,000 Bq) or less.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.10 PHYSICAL INVENTORY

Each licensee or registrant shall conduct a semi-annual physical inventory to account for all sources of radiation received and possessed. The licensee or registrant shall retain records of the inventory for 3 years from the date of the inventory for inspection by the Division. The inventory must indicate the quantity and kind of sources of radiation, the location of the sources of radiation, the date of the inventory, and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.11 RECORDS OF MATERIAL USE

- (1) Each licensee or registrant shall maintain records for each use of sources of radiation showing:
 - (a) The make, model number, and a serial number or a description of each source of radiation used;
 - (b) In the case of unsealed material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer material;
 - (c) The identity of the logging supervisor who is responsible for the sources of radiation and the identity of logging assistants present; and
 - (d) The location and date of use of the sources or radiation.
- (2) The licensee or registrant shall make the records required by (1) of this Rule available for inspection by the Division. The licensee or registrant shall retain the records for 3 years from the date of the recorded event.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.12 DESIGN AND PERFORMANCE CRITERIA FOR SEALED SOURCES

- (1) A licensee may not use a sealed source in well logging unless the sealed source:
 - (a) Is doubly encapsulated;
 - (b) Contains radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and
 - (c) The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

1. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.
 2. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.
 3. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.
 4. A 1 gram hammer and pin, 0.3 cm pin diameter must be dropped from a height of 1 m onto the test source.
 5. The test source must be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals).
- (2) The requirements in (1) of the Rule do not apply to sealed sources that contain radioactive material in gaseous form.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.13 INSPECTION, MAINTENANCE, AND OPENING OF SOURCES OF RADIATION

- (1) Each licensee or registrant shall visually check sources of radiation including source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing:
 - (a) The date of check;
 - (b) Name of inspector;
 - (c) Equipment involved;
 - (d) Defects found; and
 - (e) Repairs made.
- (2) The required records in (1) of this Rule must be maintained for 3 years after the defect is found.
- (3) Each licensee or registrant shall have a program for semiannual visual inspection and routine maintenance of sources of radiation including source holder, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing:
 - (a) The date of check;
 - (b) Equipment involved;

- (c) Inspection and maintenance operations performed;
 - (d) Any defects found; and
 - (e) Any actions taken to correct the defects.
- (4) The records required in (3) of this Rule must be retained for 3 years after the defect is found.
 - (5) Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to Rule 1200-2-12-.19 has been approved either by the Division pursuant to Rule 1200-2-12-.05(1)(c) or by the U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State.
 - (6) If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Division, U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State to perform this operation.
 - (7) The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the Division, U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.14 SUBSURFACE TRACER STUDIES

- (1) The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary job-sites.
- (2) A licensee may not knowingly inject radioactive material into aquifers unless specifically authorized to do so by the Division of Radiological Health and any other appropriate State agency.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.15 RADIOACTIVE MARKERS.

The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in Schedule RHS 8-2, Chapter 1200-2-5.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.16 URANIUM SINKER BARS.

The licensee may use a uranium sinker bar in well logging only if it is legibly impressed with the words "CAUTION - RADIOACTIVE - DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.17 USE OF A SEALED SOURCE IN A WELL WITHOUT A SURFACE CASING.

The licensee may use a sealed source in a well without a surface casing for protecting aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Division pursuant to Rule 1200-2-12-.05(1)(c) or by the U.S. Nuclear Regulatory Commission, a Licensing State or another Agreement State.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.18 TRAINING

- (1) The licensee or registrant may not permit an individual to act as a logging supervisor until that person:
 - (a) Has completed training in the subjects outlined in (5) of this Rule;
 - (b) Has received copies of, and instruction in:
 1. These regulations;
 2. The license or registration under which the logging supervisor will perform well logging; and
 3. The licensee's or registrant's operating and emergency procedures required by Rule 1200-2-12-.19;
 - (c) Has completed on-the-job training and demonstrated competence in the use of sources of radiation, remote handling tools and radiation survey instruments by a field evaluation; and
 - (d) Has demonstrated understanding of the requirements in (1)(a) and (b) of this Rule by successfully completing a written test.
- (2) The licensee or registrant may not permit an individual to act as a logging assistant until that person:
 - (a) Has received instruction in applicable sections of these regulations;
 - (b) Has received copies of, and instruction in, the licensee's or registrant's operating and emergency procedures required by Rule 1200-2-12-.19;
 - (c) Has demonstrated understanding of these regulations and of the licensee's or registrant's operating and emergency procedures listed in (2)(a) and (b) of this Rule by successfully completing a written or oral test; and
 - (d) Has received instruction in the use of sources of radiation, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

- (3) The licensee or registrant shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.
- (4) The licensee shall maintain a record on each logging supervisor's and logging assistant's training and annual safety review. The training records must include copies of written tests and dates of oral tests. The training records must be retained until 3 years following the termination of employment. Records of annual safety reviews must list the topics discussed and be retained for 3 years.
- (5) The licensee or registrant shall include the following subjects in the training required in (1)(a) of this Rule:
 - (a) Fundamentals of radiation safety including:
 1. Characteristics of radiation;
 2. Units of radiation dose and quantity of radioactivity;
 3. Hazards of exposure to radiation;
 4. Levels of radiation from sources of radiation;
 5. Methods of controlling radiation dose (time, distance, and shielding); and
 6. Radiation safety practices, including prevention of contamination, and methods of decontamination.
 - (b) Radiation detection instruments including:
 1. Use, operation, calibration, and limitations of radiation survey instruments;
 2. Survey techniques; and
 3. Use of personnel monitoring equipment.
 - (c) Equipment to be used including:
 1. Operation of equipment, including source handling equipment and remote handling tools;
 2. Storage, control, and disposal of radioactive material; and
 3. Maintenance of equipment;
 - (d) The requirements of pertinent regulations; and
 - (e) Case histories of accidents in well logging.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.19 OPERATING AND EMERGENCY PROCEDURES

- (1) Each licensee or registrant shall develop and follow written operating and emergency procedures that cover:
 - (a) The handling and use of sources of radiation including the use of sealed sources in wells without surface casing for protecting aquifers, if appropriate;
 - (b) The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;
 - (c) Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by Rule 1200-2-12-.21(3) through (5);
 - (d) Minimizing personnel exposure including exposures from inhalation and ingestion of radioactive tracer materials;
 - (e) Methods and occasions for locking and securing stored sources of radiation;
 - (f) Personnel monitoring and the use of personnel monitoring equipment;
 - (g) Transportation of radioactive materials to field stations or temporary job-sites, packaging of radioactive materials for transport in vehicles, placarding of vehicles when needed, and physically securing sources of radiation in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;
 - (h) Picking up, receiving, and opening packages containing radioactive materials, in accordance with Rule 1200-2-5-.16;
 - (i) For the use of tracers, decontamination of the environment, equipment, and personnel;
 - (j) Maintenance of records generated by logging personnel at temporary job-sites;
 - (k) The inspection and maintenance of sources of radiation including sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by Rule 1200-2-12-.13;
 - (l) Identifying and reporting to the Division defects and noncompliance as required;
 - (m) Actions to be taken if a sealed source is lodged in a well;
 - (n) Instructions for notifying responsible persons in the event of an accident; and
 - (o) Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive materials and actions to obtain suitable radiation survey instruments as required by Rule 1200-2-12-.08(2).

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.20 PERSONNEL MONITORING

- (1) The licensee or registrant shall not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of sources of radiation, either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLDs replaced at least quarterly. After replacement each film badge or TLD must be promptly processed.
- (2) The licensee shall provide bioassay services to individuals using radioactive materials in subsurface tracer studies if required by the license.
- (3) The licensee or registrant shall retain records of film badge, TLD and bioassay results for inspection until the Division authorizes disposition of the records.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.21 RADIATION SURVEYS

- (1) The licensee or registrant shall make all radiation surveys necessary, including the surveys required under (2) through (5) of this Rule, to ensure protection of health and safety of each area where radioactive materials and other sources of radiation are used and stored.
- (2) Before transporting radioactive materials, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the radioactive materials.
- (3) If the sealed source assembly is removed from the logging tool before departure from the temporary job-site, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.
- (4) If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.
- (5) The licensee shall make a radiation survey at the temporary job-site before and after each subsurface tracer study to confirm the absence of contamination.
- (6) The results of surveys required under (1) through (5) of this Rule must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey instrument used, and the location of the survey. The licensee or registrant shall retain records of surveys for inspection by the Division for 3 years after they are made.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.22 RADIOACTIVE CONTAMINATION CONTROL

- (1) If the licensee detects evidence that a sealed source has ruptured or radioactive materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by 1200-2-12-.19.

- (2) If contamination results from the use of radioactive material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.
- (3) During efforts to recover a sealed source lodged in the well, a licensee shall continuously monitor, with an appropriate radiation detection instrument or logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-23 SECURITY

- (1) A logging supervisor must be physically present at a temporary job-site whenever sources of radiation are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the job-site in order to obtain assistance if a source becomes lodged in a well.
- (2) During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in Rule 1200-2-5-.32(62).

Deleted: 1200-2-4-.04(1)(j)

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-24 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS

- (1) Each licensee or registrant shall maintain the following documents and records at the field station:
 - (a) A copy of these regulations;
 - (b) The license authorizing the use of radioactive material or registration;
 - (c) Operating and emergency procedures required by 1200-2-12-.19;
 - (d) The record of radiation survey instrument calibrations required by 1200-2-12-.08;
 - (e) The record of leak test results required by 1200-2-12-.09;
 - (f) Physical inventory records required by 1200-2-12-.10;
 - (g) Utilization records required by 1200-2-12-.11;
 - (h) Records of inspection and maintenance required by 1200-2-12-.13;
 - (i) Training records required by 1200-2-12-.18(4); and
 - (j) Survey records required by 1200-2-12-.21(6).

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.25 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOB-SITES

- (1) Each licensee or registrant conducting operations at a temporary job-site shall maintain the following documents and records at the temporary job-site until the well logging operation is completed:
 - (a) Operating and emergency procedures required by 1200-2-12-.19;
 - (b) Evidence of latest calibration of the radiation survey instruments in use at the site required by 1200-2-12-.08;
 - (c) Latest survey records required by 1200-2-12-.21(2), (3), and (5);
 - (d) The shipping papers for the transportation of radioactive materials; and
 - (e) When operating under reciprocity pursuant to 1200-2-10-.29, a copy of the license authorizing use of radioactive materials or a copy of registration for other sources of radiation.

Authority: T.C.A. §68-23-101 et seq. *Administrative History:* Original rule filed October 9, 1992; effective November 23, 1992.

1200-2-12-.26 NOTIFICATION OF INCIDENTS AND LOST SOURCES; ABANDONMENT PROCEDURES FOR IRRETRIEVABLE SOURCES

- (1) The licensee shall immediately notify the Division of Radiological Health by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. The letter must designate the well or other location, describe the magnitude and extent of the escape of radioactive materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.
- (2) The licensee or registrant shall notify the Division of Radiological Health of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by 1200-2-5-.23, 1200-2-5-.24, and 1200-2-5-.26.
- (3) If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall:
 - (a) Notify the Division of Radiological Health by telephone of the circumstances that resulted in the inability to retrieve the source and obtain approval to implement abandonment procedures;
 - (b) Advise the well owner or operator as appropriate, of the abandonment procedures under 1200-2-12-.06(1) or (3); and
 - (c) Either ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.
- (4) The licensee shall, within 30 days after a sealed source has been classified as irretrievable, make a report in writing to the Division of Radiological Health. The licensee shall send a

copy of the report to each state or Federal agency that issued permits or otherwise approved of the drilling operation. The report must contain the following information:

- (a) Date of occurrence;
- (b) A description of the irretrievable well logging source involved including the radionuclide and its quantity, chemical, and physical form;
- (c) Surface location and identification of the well;
- (d) Results of efforts to immobilize and seal the source in place;
- (e) A brief description of the attempted recovery effort;
- (f) Depth of the source;
- (g) Depth of the top of the cement plug;
- (h) Depth of the well;
- (i) Any other information, such as a warning statement, contained on the permanent identification plaque; and
- (j) State and Federal agencies receiving a copy of this report.

Authority: T.C.A. §68-23-101 et seq. **Administrative History:** Original rule filed October 9, 1992; effective November 23, 1992.