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Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Environment and Conservation
Division:	Radiological Health
Contact Person:	Beth Murphy
Address:	3rd Floor L & C Annex 401 Church Street Nashville, Tennessee 37243-1532
Phone:	(615) 532-0392
Email:	Beth.Murphy@state.tn.us

Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	ADA Coordiantor
Address:	12th Floor, L&C Tower 401 Church Street Nashville, Tennessee 37243
Phone:	1-866-253-5827 (toll free) or (615) 532-0200 Hearing impaired callers may use the TN Relay Service at 1-800-848-0298.
Email:	beverly.evans@state.tn.us

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	17th Floor Conference Room, L & C Tower		
Address 2:	401 Church Street		
City:	Nashville, Tennessee		
Zip:	37243		
Hearing Date :	02/23/09		
Hearing Time:	1:00 p.m.	☒ CST ☐ EST	

Additional Hearing Information:

Oral or written comments are invited at the hearing. In addition, written comments may be submitted to Beth Murphy at the Division of Radiological health, Central Office, address below, prior to or following the public hearing. However, the Division must receive comments in its Central Office by 4:30 p.m. (CST), February 27, 2009, in order to assure consideration.

Copies of draft rules are available for review in the Public Access Areas of the following Departmental Environmental Assistance Centers:

Nashville Field Office
711 R. S.Gass Boulevard
Nashville, TN 37243
(615) 687-7000 / 1-888-891-8332

Knoxville Field Office
3711 Middlebrook Pike
Knoxville, TN 37921
(865) 594-6035 / 1-888-891-8332

Chattanooga Field Office
State Office Building
540 McCallie Avenue, Suite 550
Chattanooga, TN 37402-2013
(423) 634-5781 / 1-888-891-8332

Memphis Field Office
Perimeter Park
2510 Mt Moriah Road, Suite E-645
Memphis, TN 38115-1520
(901) 368-7939 / 1-888-891-8332

Copies are available for review also at the Division of Radiological Health, Central Office:

Division of Radiological Health
L & C Annex, Third Floor
401 Church Street
Nashville, TN 37243-1532
(615) 532-0364

The "DRAFT" rules may be accessed for review also at the Department's World Wide Web Site located at http://www.state.tn.us/environment/rad.

Revision Type (check all that apply):

X Amendment
X New
X Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here.)

Chapter Number	**Chapter Title**
1200-02-04	General Provisions
Rule Number	**Rule Title**
1200-02-04-.04	Definitions
1200-02-04-.05	Units of Radiation Dose
1200-02-04-.06	Units of Radioactivity

Chapter Number	**Chapter Title**
1200-02-05	Standards for Protection Against Radiation
Rule Number	**Rule Title**
1200-02-05-.32	Definitions
1200-02-05-.60	Dose Limits for Individual Members of the Public
1200-02-05-.71	Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
1200-02-05-.110	Caution Signs
1200-02-05-.111	Posting Requirements
1200-02-05-.115	Procedures for Receiving and Opening Packages
1200-02-05-.137	Records of Waste Disposal
1200-02-05-.142	Reports to Individuals of Exposure to Radiation
1200-02-05-.145	Notifications, Records and Reports of Misadministration
1200-02-05-.161	Schedules
1200-02-05-.163	Reports of Transactions Involving Nationally Tracked Sources
1200-02-05-.164	Nationally Tracked Source Thresholds

1200-02-05-.165	Report, Notification, and Records of a Dose to an Embryo/Fetus or a Nursing Child

Chapter Number	**Chapter Title**
1200-02-06	Use of X-Ray Apparatus
Rule Number	**Rule Title**
1200-02-06-.03	Definitions

Chapter Number	**Chapter Title**
1200-02-07	Use of Radionuclides in the Healing Arts
Rule Number	**Rule Title**
1200-02-07-.01	Purpose
1200-02-07-.02	Scope
1200-02-07-.03	Repealed
1200-02-07-.04	Repealed
1200-02-07-.05	Definitions
1200-02-07-.06	Other Federal and State Requirements
1200-02-07-.07	Provisions for the Protection of Human Research Subjects
1200-02-07-.08	Maintenance of Records
1200-02-07-.09	Implementation
1200-02-07-.10	License Required
1200-02-07-.11	Application for License, Amendment, or Renewal
1200-02-07-.12	Reserved
1200-02-07-.13	License Amendments
1200-02-07-.14	Notifications
1200-02-07-.15	Exemptions Regarding Specific Licenses of Broad Scope
1200-02-07-.16	License Issuance and Specific Exemptions
1200-02-07-.17	Authority and Responsibilities for the Radiation Protection Program
1200-02-07-.18	Radiation Protection Program Changes
1200-02-07-.19	Supervision
1200-02-07-.20	Written Directives
1200-02-07-.21	Procedures for Administrations Requiring a Written Directive
1200-02-07-.22	Suppliers for Sealed Sources or Devices for Medical Use
1200-02-07-.23	Training for Radiation Safety Officer
1200-02-07-.24	Training for an Authorized Medical Physicist
1200-02-07-.25	Training for an Authorized Nuclear Pharmacist
1200-02-07-.26	Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist
1200-02-07-.27	Recentness of Training
1200-02-07-.28	Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material
1200-02-07-.29	Calibration of Survey Instruments
1200-02-07-.30	Determination of Dosages of Unsealed Radioactive Material for Medical Use
1200-02-07-.31	Authorization for Calibration, Transmission, and Reference Sources
1200-02-07-.32	Requirements for Possession of Sealed Sources and Brachytherapy Sources
1200-02-07-.33	Labeling of Vials and Syringes
1200-02-07-.34	Surveys of Ambient Radiation Dose Rate and Contamination
1200-02-07-.35	Release of Individuals Containing Radioactive Drugs or Implants
1200-02-07-.36	Provision of Mobile Medical Service
1200-02-07-.37	Decay-in-Storage
1200-02-07-.38	Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is not Required
1200-02-07-.39	Training for Uptake, Dilution, and Excretion Studies
1200-02-07-.40	Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a

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1200-02-07-.41	Radionuclide Contaminants
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1200-02-07-.43	Training for Imaging and Localization Studies
1200-02-07-.44	Use of Unsealed Radioactive Material for Which a Written Directive is Required
1200-02-07-.45	Safety Instruction
1200-02-07-.46	Safety Precautions
1200-02-07-.47	Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required
1200-02-07-.48	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicurries)
1200-02-07-.49	Training for the Oral Administration of Sodium Iodide I-131 requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicurries)
1200-02-07-.50	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive
1200-02-07-.51	Use of Sealed Sources for Manual Brachytherapy
1200-02-07-.52	Surveys After Source Implant and Removal
1200-02-07-.53	Brachytherapy Source Accountability
1200-02-07-.54	Safety Instruction
1200-02-07-.55	Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy
1200-02-07-.56	Calibration Measurements of Brachytherapy Sources
1200-02-07-.57	Decay of Strontium-90 Sources for Ophthalmic Treatments
1200-02-07-.58	Therapy-Related Computer Systems
1200-02-07-.59	Training for Use of Manual Brachytherapy Sources
1200-02-07-.60	Training for Ophthalmic Use of Strontium-90
1200-02-07-.61	Use of Sealed Sources for Diagnosis
1200-02-07-.62	Training for Use of Sealed Sources for Diagnosis
1200-02-07-.63	Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit
1200-02-07-.64	Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit
1200-02-07-.65	Installation, Maintenance, Adjustment and Repair
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1200-02-07-.68	Dosimetry Equipment
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1200-02-07-.81	Other Medical Uses of Radioactive Material or Radiation from Radioactive Material
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1200-02-07-.84	Records of Written Directives
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1200-02-07-.86	Reserved
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1200-02-07-.93	Records of Administrative and Technical Requirements That Apply to the Provisions of Mobile Services
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1200-02-07-.96	Records of Safety Instruction and Training
1200-02-07-.97	Records of Radiation Surveys of Patients and Human Research Subjects
1200-02-07-.98	Records of Brachytherapy Source Accountability
1200-02-07-.99	Records of Calibration Measurements of Brachytherapy Sources
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1200-02-07-.101	Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
1200-02-07-.102	Records of Safety Procedures
1200-02-07-.103	Records of Dosimetry Equipment
1200-02-07-.104	Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations
1200-02-07-.105	Records of Periodic Spot-Checks for Teletherapy Units
1200-02-07-.106	Records of Periodic Spot-Checks for Remote Afterloader Units
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1200-02-07-.110	Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
1200-02-07-.111	Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources
1200-02-07-.112	Report of Procedures for Administrations Requiring a Written Directive
1200-02-07-.113	Report of a Leaking Source

Chapter Number	**Chapter Title**
1200-02-08	Radiation Safety Requirements for Industrial Radiography Operations
Rule Number	**Rule Title**
1200-02-08-.03	Definitions
1200-02-08-.05	Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants
1200-02-08-.07	Minimum Subjects to be Covered in Training Radiographers
1200-02-08-.11	Shielded Room X-Ray Radiography

Chapter Number	**Chapter Title**
1200-02-09	Requirements for Accelerators
Rule Number	**Rule Title**
1200-02-09-.03	Definitions
1200-02-09-.04	Requirements for Registration
1200-02-09-.06	Specific Requirements for the Issuance of a Certified Registration
1200-02-09-.17	General Safety Provisions

Chapter Number	**Chapter Title**
1200-02-10	Licensing and Registration

Rule Number	Rule Title
1200-02-10-.03	Exemptions: Source Material
1200-02-10-.04	Exemptions: Radioactive Materials Other Than Source Materials
1200-02-10-.10	General Licenses – Radioactive Material Other Than Source Materials
1200-02-10-.13	Special Requirements for Issuance of Specific Licenses
1200-02-10-.14	Specific Licenses for Certain Groups of Medical Uses of Radioactive Materials
1200-02-10-.16	Specific Terms and Conditions of Licenses
1200-02-10-.18	Renewal of License
1200-02-10-.23	Modification, Revocation, and Termination of Licenses
1200-02-10-.26	Records
1200-02-10-.27	Inspections
1200-02-10-.31	Fees for Licenses
1200-02-10-.32	Licensing of Shippers of Radioactive Material into or Within Tennessee
1200-02-10-.33	Acceptable Training and Experience for Medical Uses of Radioactive Material
1200-02-10-.35	Training for an Authorized Number Pharmacist

Chapter Number	Chapter Title
1200-02-11	Licensing Requirements for Land Disposal of Radioactive Waste
Rule Number	**Rule Title**
1200-02-11-.15	Termination of License

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Chapter 1200-02-04
General Provisions

Amendments

Paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (1) shall read as follows:

(1) As used in these regulations, these terms have the definitions set forth below. (For additional definitions used only in Chapters 1200-02-05, 1200-02-06, 1200-02-07, 1200-02-08 and 1200-02-09, see Rules 1200-02-05-.32, 1200-02-06-.03, 1200-02-07-.05, 1200-02-08-.03 and 1200-02-09-.03.)

Subparagraph (e) of paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (e) shall read as follows:

(e) Authorized nuclear pharmacist. Defined in 1200-02-07-.05(4).

Subparagraph (f) of paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (f) shall read as follows:

(f) Authorized. Defined in 1200-02-07-.05(5).

Subparagraph (pp) of paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting "1200-02-07-.04(4) and" from the subparagraph so that, as amended, subparagraph (pp) shall read as follows:

(pp) Qualified expert means, for purposes of 1200-02-09-.21(2)(g) and (m), a person:

Subparagraph (tt) of paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (tt) shall read as follows:

(tt) Radiological Safety Officer means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

Subparagraph (yy) of paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (yy) shall read as follows:

(yy) Sealed source. Defined in Rule 1200-02-07-.05(32).

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Repeals

Rule 1200-02-04-.05 Units of Radiation Dose is repealed and the table of contents is modified by deleting the previous title of the rule and replacing it with the word "Repealed".

1200-02-04-.05 Repealed.

Authority: T.C.A. §§ 68–202–201 et seq.

Rule 1200-02-04-.06 Units of Radioactivity is repealed and the table of contents modified by deleting the previous title of the rule and replacing it with the word “Repealed”.

1200-02-04-.06 Repealed.

Authority: T.C.A. §§ 68–202–201 et seq., and 68–202–206.

Chapter 1200-02-05
Standards for Protection Against Radiation

Amendments

Paragraph (50) of Rule 1200-02-05-.32 Definitions is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (50) shall read as follows:

(50) Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from registered, unregistered, licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 1200-02-07-.35, from voluntary participation in medical research programs, or as a member of the public.

Paragraph (53) of Rule 1200-02-05-.32 Definitions is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (53) shall read as follows:

(53) Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee or registrant. Public Dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 1200-02-07-.35, or from voluntary participation in medical research programs.

Paragraph (70) of Rule 1200-02-05-.32 Definitions is amended by deleting the word "deep-dose" from the sentence and replacing it with "effective dose" so that, as amended, paragraph (70) shall read as follows:

(70) Total effective dose equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Paragraph (79) of Rule 1200-02-05-.32 Definitions is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (79) shall read as follows:

(79) Misadministration means an event that meets the criteria in 1200-02-05-.145.

Rule 1200-02-05-.32 Definitions is amended by adding paragraph (102) so that paragraph (102) shall read as follows:

(102) Nationally tracked sources means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 1200-02-05-.164. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Rule 1200-02-05-.60 Dose Limits for Individual Members of the Public is amended by deleting the Rule in its entirety and substituting the following so that, as amended, Rule 1200-02-05-.60 shall read as follows:

(1) Each licensee and registrant shall conduct operations so that:

(a) The total effective dose equivalent received by any individual member of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year. This limit is exclusive of the dose contribution from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 1200-02-07-.35, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 1200–02–05–.122; and

(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 1200-02-07-.35, does not exceed 0.002 rem (0.02 mSv) in any one hour.

(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limit for members of the public continues to apply to those individuals.

(3) Notwithstanding paragraph (1)(a) of this rule, a licensee or registrant may permit visitors to an individual who cannot be released, under 1200-02-07-.35, to receive a radiation dose greater than 0.1 rem (1mSv) if:

(a) The radiation dose received does not exceed 0.5 rem (5 msv); and

(b) The authorized user, as defined in 1200-02-07-.05(5), has determined before the visit that it is appropriate.

(4) A licensee, registrant or applicant may apply for prior authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application by the licensee, registrant or applicant shall include the following:

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (1) of this rule;

(b) The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(c) The procedures to be followed to maintain the dose as low as is reasonably achievable (ALARA).

(5) In addition to the requirements of this chapter, a licensee or registrant subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

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

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Part 1 of subparagraph (a) of paragraph (1) of rule 1200-02-05-.71 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose is amended by adding the word “one” between the word “in” and “(1)” so that, as amended, part 1 shall read as follows:

1. Adults likely to receive, in one (1) year from sources external to the body, a dose in excess of 10 percent (10%) of the limits in 1200-02-05-.50;

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (1) of Rule 1200-02-05-.110 Caution Signs is amended by deleting the letter “c” from the word “chapter” and replacing it with “C” so that, as amended, paragraph (1) shall read as follows:

(1) Unless otherwise authorized by the Division, the standard radiation symbol prescribed by this Chapter shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed by this chapter is the three–bladed design:

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (11) of Rule 1200-02-05-.111 Posting Requirements is amended by deleting the letters “ed” from the word “switched” so that, as amended, paragraph (1) shall read as follows:

(11) All radiation machines shall be clearly labeled at the control panel near the switch that energizes the apparatus, and at any remote switch that energize the apparatus, with the words “CAUTION – RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED” or “DANGER – RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED”.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (6) of Rule 1200-02-05-.115 Procedures for Receiving and Opening Packages is amended by adding the word “paragraph” between the word “in” and “(2)” in the second sentence so that, as amended, paragraph (6) shall read as follows:

(6) Licensees transferring special form sources to or from a work site in licensee owned or operated vehicles are exempt from the contamination monitoring requirements of paragraph (2) of this rule. Licensees are not exempt from the requirement in paragraph (2) for surveying radiation levels to ensure that the source is still properly secured in its shield.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (2) of Rule 1200-02-05-.137 Records of Waste Disposal is amended by deleting the paragraph and substituting the following so that paragraph (2) shall read as follows:

(2) The licensee shall retain the records required by paragraph (1) of this rule until the Division terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in 1200-02-10-.26 for activities licensed under these parts.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (6) of Rule 1200-02-05-.142 Reports to Individuals of Exposure to Radiation is amended by deleting the paragraph in its entirety and substituting the following so that, as amended, paragraph (6) shall read as follows:

(6) Reports submitted under this rule shall:

(a) Be in writing;

(b) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual and the individual's social security number;

(c) Include the individual's radiation exposure information;

(d) Include data and results obtained under Division regulations, or conditions, as shown in records maintained by the licensee or registrant under Division regulations; and

(e) Contain the following statement:

This report is furnished to you under the provisions of the Division of Radiological Health of the Tennessee Department of Environment and Conservation regulations entitled "State Regulations for Protection Against Radiation." You should preserve this report for future reference.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Rule 1200-02-05-.145 Notifications, Records and Reports of Misadministration is amended by deleting the Rule in its entirety and substituting the following so that, as amended the Rule shall read as follows:

(1) Other than events that result from intervention by a patient or human research subject, a licensee or registrant shall report any event in which the administration of radioactive material or radiation from radioactive material results in:

(a) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and

1. The total dose delivered differs from the prescribed dose by 20 percent or more;

2. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(b) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

1. An administration of a wrong radioactive drug;

2. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

3. An administration of a dose or dosage to the wrong individual or human research subject;

4. An administration of a dose or dosage delivered by the wrong mode of treatment; or

5. A leaking sealed source.

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(d) A therapeutic radiation machine dose:

1. Involving the wrong individual, wrong mode of treatment or wrong treatment site,

2. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent (10%) of the total prescribed dose,

3. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent (30%) or more of the weekly prescribed dose, or

4. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent (20%) of the total prescribed dose.

(e) A diagnostic x–ray radiation machine exposure involving the wrong individual.

(2) A licensee or registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee or registrant shall notify the Division at the number given in 1200-02-04-.07 no later than the next calendar day after discovery of the misadministration.

(4) The licensee or registrant shall submit a written report to the Division at the address listed in 1200-02-04-.07(1)(c) within fifteen days after discovery of the misadministration.

(a) The written report must include:

1. The licensee or registrant's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the individual(s) who received the administration;

6. What actions, if any, have been taken or are planned to prevent recurrence; and

7. Certification that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The licensee or registrant shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that they will inform the individual or that, based on medical judgment, telling the

individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee or registrant shall provide a written description if requested.

(6) Aside from the notification requirement, nothing in this rule affects any rights or duties of licensees, registrants, and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

(7) A licensee or registrant shall retain a record of a misadministration in accordance with this rule for 3 years. A copy of the record shall be provided to the referring physician if other than the licensee or registrant, within 15 days after discovery of the misadministration. The record must contain the licensee or registrant's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee or registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Endnote 2 of Schedule RHS 8-30 of Rule 1200-02-05-.161 Schedules is amended by deleting "LAC 33:XV.412" from the end of the paragraph and replacing it with "1200-02-05-.52" so that, as amended, endnote 2 shall read as follows:

[2] These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do not include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 µCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See 1200-02-05-.52.)

Endnote 3 of Schedule RHS 8-30 of Rule 1200-02-05-.161 Schedules is amended by deleting "LAC 33:XV.410.E" from the end of the first sentence and replacing it with "1200-02-05-.50(5)" so that, as amended, endnote 2 shall read as follows:

[3] For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see 1200-02-05-.50(5)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) µCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

$$SA = 3.6E\text{-}7 \text{ curies/gram U} \quad \text{U-depleted}$$

$$SA = [0.4 + 0.38\,(\text{enrichment}) + 0.0034\,(\text{enrichment})^2]\ E\text{-}6, \quad \text{enrichment} \geq 0.72$$

where enrichment is the percentage by weight of U-235, expressed as percent.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

New Rules

Chapter 1200-02-05 is amended by adding new Rules 1200-02-05-.163 Reports of Transactions Involving Nationally Tracked Sources, 1200-02-05-.164 Nationally Tracked Source Thresholds, and 1200-02-05-.165 Report, Notification and Records of a Dose to an Embryo/Fetus or a Nursing Child. The new rules shall read as follows:

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1200-02-05-.163 Reports of Transactions Involving Nationally Tracked Sources

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit to the NRC a National Source Tracking Transaction Report as specified in paragraphs (1) through (5) of this rule for each type of transaction.

(1) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source;

(d) The radioactive material in the source;

(e) The initial source strength in becquerels (curies) at the time of manufacture; and

(f) The manufacture date of the source.

(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name and license number of the recipient facility and the shipping address;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The shipping date;

(i) The estimated arrival date; and

(j) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name, address, and license number of the person that provided the source;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The date of receipt; and

(i) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the source;

(e) The initial or current source strength in becquerels (curies);

(f) The date for which the source strength is reported;

(g) The disassemble date of the source.

(5) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The waste manifest number;

(d) The container identification with the nationally tracked source;

(e) The date of disposal; and

(f) The method of disposal.

(6) The National Source Tracking Transaction Report discussed in paragraphs (1) through (5) of this rule must be submitted to the U.S. NRC by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(a) The on-line National Source Tracking System;

(b) Electronically using a computer-readable format;

(c) By facsimile;

(d) By mail to the address on the NRC Form 748 National Source Tracking Transaction Report Form; or

(e) By telephone with followup by facsimile or mail.

(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (1) through (5) of this rule. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by subparagraphs (6)(a) through (e) of this rule. The initial inventory report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the sealed source;

(e) The initial or current source strength in becquerels (curies); and

(f) The date for which the source strength is reported.

Authority: T.C.A. §§ 68–202–201 et seq.

1200-02-05-.164 Nationally tracked source Thresholds.

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

Authority**:** T.C.A. §§ 68–202–201 et seq.

1200-02-05-.165 Report, Notification, and Records of a Dose to an Embryo/Fetus or a Nursing Child

(1) A licensee or registrant shall report to the Division at the address listed in 1200-02-04-.07(1)(c), any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee or registrant shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast-feeding individual that:

(a) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee or registrant shall notify the Division at the number given in 1200-02-04-.07 no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraph (1) or (2) of this rule.

(4) The licensee or registrant shall submit a written report to the Division within fifteen days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraph (1) or (2) of this rule.

(a) The written report must include:

1. The licensee or registrant's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the embryo/fetus or the nursing child;

6. What actions, if any, have been taken or are planned to prevent recurrence; and

7. Certification that the licensee or registrant notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee or registrant shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty-four hours after discovery of an event that would require reporting under paragraph (1) or (2) of this rule, unless the referring physician personally informs the licensee or registrant either that they will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee or registrant is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within twenty-four hours, the licensee or registrant shall make the appropriate notifications as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee or registrant shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee or registrant shall provide a written description if requested.

(6) A licensee or registrant shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with this rule for 3 years. A copy of the record required shall be provided to the referring physician, if other than the licensee or registrant, no later than fifteen days after the discovery of the event. The record must contain the licensee or registrant's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief

description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee or registrant notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

Authority: T.C.A. §§ 68–202–201 et seq.

Chapter 1200-02-06
Use of X-Ray Apparatus

Amendment

Rule 1200-02-06-.03 Definitions is amended by adding paragraph (74) so that paragraph (74) shall read as follows:

(74) 'Misadministration'. An event that meets the criteria in 1200-02-05-.145.

Authority: T.C.A §§ 68-202-203 and 68-202-206.

Chapter 1200-02-07
Use of Sealed Radioactive Sources in the Healing Arts

Repeal

Chapter 1200-02-07 Use of Sealed Radioactive Sources in the Healing Arts is repealed in its entirety and replaced with the following:

Authority: T.C.A §§ 68-202-203 and 68-202-206.

New Rules

Chapter 1200-02-07
Use of Radionuclides in the Healing Arts

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1200-02-07-.01 Purpose

This Chapter contains the requirements and provisions for the medical use of radionuclides and for issuance of specific licenses authorizing the medical use of this material. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

1200-02-07-.02 Scope

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

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

1200-02-07-.03 Repealed

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

1200-02-07-.04 Repealed

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

1200-02-07-.05 Definitions

(1) Address of use means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

(2) Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

(3) Authorized medical physicist means an individual who:

(a) Meets the requirements in 1200-02-07-.24(1) and 1200-02-07-.27; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use license or permit issued by the Division, U.S. Nuclear Regulatory Commission, or Agreement State;

2. A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee;

3. A permit issued by a Division, U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

4. A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(4) Authorized nuclear pharmacist means a pharmacist who:

(a) Meets the requirements in 1200-02-07-.25(1) and 1200-02-07-.27; or

(b) Is identified as an authorized nuclear pharmacist on:

1. A specific license or equivalent permit issued by the Division, U.S. Nuclear Regulatory Commission, or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

2. A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

3. A permit issued by a Division, U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4. A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(c) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(d) Is designated as an authorized nuclear pharmacist in accordance with 1200-02-10-.13(10)(b)4.

(5) Authorized user means a physician, dentist, or podiatrist who:

(a) Meets the requirements in 1200-02-07-.27 and 1200-02-07-.39(1)(a), 1200-02-07-.43(1)(a), 1200-02-07-.47(1)(a), 1200-02-07-.48(1)(a), 1200-02-07-.49(1)(a), 1200-02-07-.59(1)(a), 1200-02-07-.60, 1200-02-07-.62(1)(a), or 1200-02-07-.80(1)(a); or

(b) Is identified as an authorized user on:

1. A Division, U.S. Nuclear Regulatory Commission, or Agreement State license that authorizes the medical use of radioactive material;

2. A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

3. A permit issued by a Division, U.S. Nuclear Regulatory Commission, or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

4. A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

(6) Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

(7) Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(8) Client's address means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with 1200-02-07-.36.

(9) Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

(10) Dentist means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

(11) Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

(12) High dose-rate remote afterloader means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

(13) Low dose-rate remote afterloader means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

(14) Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or that person's delegate or delegates.

(15) Manual brachytherapy means a type of therapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed or inserted.

(16) Medical institution means an organization in which more than one medical discipline is practiced.

(17) Medical use means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(18) Medium dose-rate remote afterloader means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(19) Misadministration means an event that meets the criteria in 1200-02-05-.145.

(20) Mobile medical service means the transportation of radioactive material to and its medical use at the client's address**.**

(21) Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(22) Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(23) Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the commonwealth of Puerto Rico to practice pharmacy.

(24) Physician means a doctor of medicine or doctor of osteopathy licensed by the State or Territory of the United States, the District of Columbia, or the commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

(25) Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

(26) Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

(27) Prescribed dosage means the specified activity or range of activity of unsealed radioactive material as documented:

(a) In a written directive as specified in 1200-02-07-.20; or

(b) In accordance with the directions of the authorized user for procedures performed under 1200-02-07-.38 and 1200-02-07-.40.

(28) Prescribed dose means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(c) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(29) Pulsed dose-rate remote afterloader means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(a) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(b) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

(30) Radiation safety officer means an individual who meets the requirements in 1200-02-07-.23(1) or (3)(a) and 1200-02-07-.27 or is named as a Radiation Safety Officer on a specific medical use license or equivalent permit issued by the Division, U.S. Nuclear Regulatory Commission or Agreement State or a medical use permit issued by a Commission master material licensee.

(31) Reserved.

(32) Sealed source means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(33) Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both the U.S. Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(34) Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

(35) Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(36) Teletherapy, as used in this Chapter, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(37) Temporary job site means a location where mobile medical services are conducted other than hose location(s) of use authorized on the license.

(38) Therapeutic dosage means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(39) Therapeutic dose means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(40) Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(41) Type of use means use of radioactive material under 1200-02-07-.38, 1200-02-07-.40, 1200-02-07-.44, 1200-02-07-.51, 1200-02-07-.61, 1200-02-07-.63 or 1200-02-07-.81.

(42) Unit dosage means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(43) Written directive means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 1200-02-07-.20.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.06 Other Federal and State Requirements

Nothing in this Chapter relieves the licensee from complying with applicable Food and Drug Administration (FDA), or other federal and state requirements governing radioactive drugs or devices.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

1200-02-07-.07 Provisions for the Protection of Human Research Subjects

(1) A licensee may conduct research involving human subjects using radioactive material provided:

(a) That the research is conducted, funded, supported, or regulated by a federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. In both instances, the licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(b) The research involving human subjects authorized in 1200-02-07-.07(1)(a) shall be conducted using radioactive material authorized for medical use in the license; and

(c) Nothing in 1200-02-07-.07 relieves licensees from complying with the other requirements in this rule.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.08 Maintenance of Records

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

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.09 Implementation

(1) A licensee shall implement the provisions in this rule on [the effective date of these rules].

(2) When a requirement in this rule differs from the requirement in an existing license condition, the requirement in this rule shall govern.

(3) Any existing license condition that is not affected by a requirement in this rule remains in effect until there is a license amendment or license renewal.

(4) If a license condition exempted a licensee from a provision of this rule on [the effective date of these rules], it will continue to exempt a licensee from the corresponding provision in this rule.

(5) If a license condition cites provisions in this rule that will be deleted on [the effective date of these rules], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(6) Licensees shall continue to comply with any license condition that requires it to implement procedures required by 1200-02-07-.66, 1200-02-07-.72, 1200-02-07-.73 and 1200-02-07-.74 until there is a license amendment or renewal that modifies the license condition.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.10 License Required

(1) A person shall only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Division, or as allowed in 1200-02-07-.10(2) or 1200-02-07-.10(3).

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in this rule under the supervision of an authorized user as provided in 1200-02-07-.19, unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in this rule under the supervision of an authorized nuclear pharmacist or authorized user as provided in 1200-02-07-.19 unless prohibited by license condition.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.11 Application for License, Amendment, or Renewal

(1) An application must be signed by the applicant's or licensee's management.

(2) An application for a license for medical use of radioactive material as described in 1200-02-07-.38, 1200-02-07-.40, 1200-02-07-.44, 1200-02-07-.51, 1200-02-07-.61, 1200-02-07-.63, and 1200-02-07-.81 must be made by:

(a) Filing the original Application in duplicate on a form prescribed by the Division, and

(b) Submitting applicable procedures required by 1200-02-07-.66, 1200-02-07-.72, 1200-02-07-.73, and 1200- 02-07-.74.

(3) A request for a license amendment or renewal must be made by:

(a) Submitting an original in letter format to the Division, and

(b) Submitting applicable procedures required by 1200-02-07-.21, 1200-02-07-.66, 1200-02-07-.72, 1200-02-07-.73, and 1200-02-07-.74.

(4) In addition to the requirements in paragraphs (2) and (3) of this rule, an application for a license or amendment for medical use of radioactive material as described in 1200-02-07-.81 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in this Chapter.

(a) The applicant shall also provide specific information on:

1. Radiation safety precautions and instructions;

2. Training and experience of proposed users;

3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(5) The applicant or licensee shall also provide any other information requested by the Division in its review of the application.

(6) An applicant that satisfies the requirements specified in 1200-10-.13(4) may apply for a specific license of broad scope.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.12 Reserved

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.13 License Amendments

(1) A licensee shall apply for and must receive a license amendment:

(a) Before it receives, prepares or uses radioactive material for a type of use that is permitted under this rule, but that is not authorized on the licensee's current license issued pursuant to this rule;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or an authorized medical physicist under the license, except an individual who is:

1. For an authorized user, an individual who meets the requirements in 1200-02-07-.27 and 1200-02-07-.39(1)(a), 1200-02-07-.43(1)(a), 1200-02-07-.47(1)(a), 1200-02-07-.48(1)(a), 1200-02-07-.49(1)(a), 1200-02-07-.59(1)(a), 1200-02-07-.62(1)(a), 1200-02-07-.80(1)(a);

2. For an authorized nuclear pharmacist, an individual who meets the requirements in 1200-02-07-.25(1) and 1200-02-07-.27;

3. For an authorized medical physicist, an individual who meets the requirements in 1200-02-07-.24(1) and 1200-02-07-.27;

4. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a U.S. Nuclear Regulatory Commission or Agreement State license or Licensing State or other equivalent permit or license recognized by the Division that authorizes the use of radioactive material in medical use in the practice of nuclear pharmacy; or

5. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy.

(c) Before it changes Radiation Safety Officers, except as provided in 1200-02-07-.17(3);

(d) Before it receives radioactive material in excess of the amount or in a different physical or chemical form than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license;

(f) Before it changes the address(es) of use identified in the application or on the license;

(g) Before it changes statements, representations, and procedures which are incorporated into the license: and

(h) Before it releases licensed facilities for unrestricted use.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.14 Notifications

(1) A licensee shall notify the Division no later than thirty days after:

(a) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee's mailing address changes;

(c) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 1200-02-10-.16(2); or

(d) The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used under either 1200-02-07-.38 or 1200-02-07-.40.

(2) The licensee shall send the documents required in this rule to the Division at the address listed in 1200-02-04-.07(1)(c).

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.15 Exemptions Regarding Specific Licenses of Broad Scope

A licensee possessing a specific license of broad scope for medical use is exempt from:

(1) The provisions of 1200-02-07-.11(4) regarding the need to file an amendment to the license for medical use of radioactive material, as described in 1200-02-07-.81;

(2) The provisions of 1200-02-07-.13(1)(b) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;

(3) The provisions of 1200-02-07-.13(1)(e) regarding additions to or changes in the areas of use at the addresses specified in the license;

(4) The provisions of 1200-02-07-.14(1)(a) regarding notification to the Division for new authorized users, new authorized medical physicists and new authorized nuclear pharmacists;

(5) The provisions of 1200-02-07-.22(1) regarding suppliers for sealed sources.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.16 License Issuance and Specific Exemptions

(1) The Division shall issue a license for the medical use of radioactive material if:

(a) The applicant has filed an application with the Division in accordance with the instructions in 1200-02-07-.11;

(b) The applicant has paid applicable fee under 1200-02-10-.31;

(c) The Division finds the applicant equipped and committed to observe the safety standards established by the Division in these regulations for the protection of the public health and safety; and

(d) The applicant meets the requirements of Chapter 1200-02-10.

(2) The Division shall issue a license for mobile medical service if the applicant:

a) Meets the requirements in paragraph (1) of this rule; and

(b) Assures that individuals or human research subjects to whom unsealed radioactive material, or radiation from implants containing radioactive material, will be administered may be released following treatment in accordance with 1200-02-07-.35.

(3) The Division may, upon application of any interested person or upon its own initiative, grant exemptions from this Chapter that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.17 Authority and Responsibilities for the Radiation Protection Program

(1) In addition to the radiation protection program requirements of 1200-02-05-.40, a licensee's management shall approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal to the Division;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted under 1200-02-07-.18;

(2) A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(3) For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, under paragraph (7) of this rule, if the licensee takes the actions required in paragraphs (2), (5), (7), and (8) of this rule.

(4) A licensee may simultaneously appoint more than one temporary radiation safety officer under paragraph (3) of this rule, if needed to ensure that the licensee has a temporary radiation safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

(5) A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

(6) Licensees that are authorized for two or more different types of use of radioactive material under 1200-02-07-.44, 1200-02-07-.51, 1200-02-07-.63, and 1200-02-07-.81, or two or more types of units under 1200-02-07-.63 shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. The committee may include other members the licensee considers appropriate.

(7) A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide corrective actions;

(c) Stop unsafe operations; and

(d) Verify implementation of corrective actions.

(8) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 6 months. The licensee shall maintain minutes of each meeting in accordance with 1200-02-07-.82.

(9) A licensee shall retain a record of actions taken under paragraphs (1), (2), and (5) of this rule in accordance with 1200-02-07-.82.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.18 Radiation Protection Program Changes

(1) A licensee may revise its radiation protection program without Division approval if:

(a) The revision does not require a license amendment under 1200-02-07-.13;

(b) The revision is in compliance with this Chapter and the license;

(c) The revision has been reviewed and approved by the radiation safety officer and licensee management; and

(d) The affected individuals are instructed on the revised program before the changes are implemented.

(2) A licensee shall retain a record of each change in accordance with 1200-02-07-.83.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.19 Supervision

(1) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by 1200-02-07-.10(2), shall:

(a) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and

(b) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this Chapter, and license conditions with respect to the medical use of radioactive material.

(2) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, asallowed by 1200-02-07-.10(3), shall:

(a) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(b) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, this Chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (1) and (2) of this rule is responsible for the acts and omissions of the supervised individual.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.20 Written Directives

(1) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within forty-eight hours of the oral directive.

(2) The written directive must contain the patient or human research subject's name and the following information:

(a) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(b) For an administration of a therapeutic dosage of radioactive drug containing radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: The total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(d) For teletherapy: The total dose, dose per fraction, number of fractions, and treatment site;

(e) For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(f) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: Treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: The radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(a) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within forty-eight hours of the oral revision.

(4) The licensee shall retain a copy of the written directive in accordance with 1200-02-07-.84.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.21 Procedures for Administrations Requiring a Written Directive

(1) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(a) The patient's or human research subject's identity is verified before each administration; and

(b) Each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by paragraph (1) of this rule must address the following items that are applicable to the licensee's use of radioactive material:

(a) Verifying the identity of the patient or human research subject;

(b) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(c) Checking both manual and computer-generated dose calculations; and

(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 1200-02-07-.63 or 1200-02-07-.81.

(3) A licensee shall retain a copy of the procedures required under paragraph (1) of this rule in accordance with 1200-02-07-.112.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.22 Suppliers for Sealed Sources or Devices for Medical Use

For medical use, a licensee may only use:

(1) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 1200-02-10 of these regulations or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State;

(2) Sealed sources or devices non-commercially transferred from a Division, Nuclear Regulatory Commission or Agreement State licensee; or

(3) Teletherapy sources manufactured and distributed in accordance with a license issued under Chapter 1200-02-10 of these regulations or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State;

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.23 Training fro Radiation Safety Officer

Except as provided in 1200-02-07-.26, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer under 1200-02-07-.17 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State, and who meets the requirements of paragraphs (4) and (5) of this rule. (Specialty boards whose certification processes have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(a) 1. Hold a bachelor’s or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of twenty college credits in physical science;

2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

3. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b) 1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the U.S. Nuclear Regulatory Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users under 1200-02-07-.43 or 1200-02-07-.47; and

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) (a) Has completed a structured educational program consisting of both:

1. Two hundred hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiation dosimetry; and

2. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a Division, U.S. NRC or Agreement State license or a permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(iii) Securing and controlling radioactive material;

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material;

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(vi) Using emergency procedures to control radioactive material; and

(vii) Disposing of radioactive material; or

(3) (a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State under 1200-02-07-.24(1) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as radiation safety officer and who meets the requirements in paragraphs (4) and (5) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and

(4) Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in paragraph (5) of this rule, and in subparagraph (1)(a), (1)(b), (2)(a), (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

(5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an authorized medical physicist, authorized user, authorized nuclear pharmacist, or radiation safety officer, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.24 Training for an Authorized Medical Physicist

Except as provided in 1200-02-07-.26, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in subparagraph (2)(b) and paragraph (3) of this rule. To be recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and/or supervised experience in medical physics:

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the U.S. Nuclear Regulatory Commission or an Agreement State; or

2. In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 1200-02-07-.59 or 1200-02-07-.80; and

(c) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration,

quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) (a) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use modalities for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;

3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (1)(a) and (b) and paragraph (3), or subparagraph (2)(a) and paragraph (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 1200-02-07-.24 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type(s) of use in the modalities for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.25 Training for an Authorized Nuclear Pharmacist

Except as provided in 1200-02-07-.26, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified by a specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in subparagraph (2)(b) of this rule. To be recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(b) Hold a current, active license to practice pharmacy;

(c) Provide evidence of having acquired at least four thousand hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than two thousand hours of the required training and experience; and

(d) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2) (a) Has completed 700 hours in a structured educational program consisting of both:

1. 200 hours of classroom and laboratory 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

2. Supervised practical experience in a nuclear pharmacy involving:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid misadministrations in the administration of radioactive material; and

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subparagraphs (1)(a) through (d) or subparagraph (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.26 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist

(1) An individual identified as a radiation safety officer, a teletherapy physicist or medical physicist, an authorized medical physicist, or a nuclear pharmacist or authorized nuclear pharmacist on a Division, U.S. Nuclear Regulatory Commission, or Agreement State license, or a permit issued by

the Division, U.S. Nuclear Regulatory Commission, or an Agreement State broad scope licensee or master material license permit, or by a master material license permittee of broad scope before effective date of these rules, need not comply with the training requirements of 1200-02-07-.23, 1200-02-07-.24, or 1200-02-07-.25, respectively.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Division, U.S. Nuclear Regulatory Commission, an Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by the Division, U.S. Nuclear Regulatory Commission, or Agreement State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee issued before the effective date of these rules, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of 1200-02-07-.39, 1200-02-07-.43, 1200-02-07-.47, 1200-02-07-.48, 1200-02-07-.49, 1200-02-07-.59, 1200-02-07-.60, 1200-02-07-.62 and 1200-02-07-.80.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.27 Recentness of Training

The training and experience specified in 1200-02-07-.17 through 1200-02-07-.27 and 1200-02-07-.38 through 1200-02-07-.80 must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.28 Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material

(1) For direct measurements performed in accordance with 1200-02-07-.30, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

(2) A licensee shall calibrate the instrumentation required in paragraph (1) of this rule in accordance with nationally recognized standards or the manufacturer's instructions.

(3) A licensee shall retain a record of each instrument calibration required by this rule in accordance with 1200-02-07-87.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.29 Calibration of Survey Instruments

(1) A licensee shall calibrate the survey instruments used to show compliance with this Chapter and Chapter 1200-02-05 before first use, annually, and following a repair that affects the calibration.

(2) To satisfy the requirements of 1200-02-07-.29(1), the licensee shall:

(a) Calibrate all required scale readings up to 10 millisieverts (1000 millirem) per hour with a radiation source;

(b) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(c) Conspicuously note on the instrument the date of calibration.

(3) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.

(4) The licensee shall retain a record of each survey instrument calibration in accordance with 1200-02-07-.88.

(5) Calibration of all survey instruments shall be in accordance with an approved procedure or preformed by persons specifically licenses to provide calibration services.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.30 Determination of Dosages of Unsealed Radioactive Material for Medical Use

(1) A licensee shall determine and record the activity of each dosage before medical use.

(2) For a unit dosage, this determination must be made by:

(a) Direct measurement of radioactivity; or

(b) A decay correction, based on the activity or activity concentration determined by:

1. A manufacturer or preparer licensed under 1200-02-10-.13(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

2. An Agreement State or U.S. Nuclear Regulatory Commission licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA).

(3) For other than unit dosages, this determination must be made by:

(a) Direct measurement of radioactivity;

(b) Combination of measurement of radioactivity and mathematical calculations; or

(c) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under 1200-02-10-.13(10) or equivalent Agreement State requirements.

(4) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty percent.

(5) A licensee shall retain a record of the dosage determination required by this rule in accordance with 1200-02-07-.89.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.31 Authorization for Calibration, Transmission, and Reference Sources

(1) Any person authorized by 1200-02-07-.10 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to Chapter 1200-02-10 or equivalent provisions of the U.S. Nuclear Regulatory

Commission or an Agreement State and that do not exceed 1.11 gigabecquerels (30 millicuries) each;

(b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 1200-02-10-.13(12) of these regulations, or equivalent provisions of the U.S. Nuclear Regulatory Commission or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(c) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 millicuries);

(d) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

1. 7.4 megabecquerels (200 µCi); or

2. 1000 times the quantities in Schedule RHS 8-30 Chapter 1200-02-10; and

(e) Technetium-99m in amounts as needed.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.32 Requirements for Possession of Sealed Sources and Brachytherapy Sources

(1) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(2) A licensee in possession of a sealed source shall:

(a) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(b) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State in the sealed source and device registry.

(3) If the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, the licensee shall:

(a) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in chapters 1200-02-05 and 1200-02-10; and

(b) File a report within five days of the leak test in accordance with 1200-02-07-.113.

(4) A licensee need not perform a leak test on the following sources:

(a) Sources containing only radioactive material with a half-life of less than 30 days;

(b) Sources containing only radioactive material as a gas;

(c) Sources containing 3.7 MBq (100 µCi) or less of beta or gamma-emitting material or 0.37 MBq (10 µCi) or less of alpha-emitting material;

(d) Seeds of iridium-192 encased in nylon ribbon; and

(e) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(5) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with 1200-02-07-.111.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.33 Labeling of Vials and Syringes

Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.34 Surveys of Ambient Radiation Dose Rate and Contamination

(1) Except as provided in paragraph (2) of this rule, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs were prepared for use or administered.

(2) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

(3) A licensee shall conduct the surveys required by paragraphs (1) and (2) of this rule so as to able to measure dose rates as low as 1 microsievert (0.1 millirem) per hour.

(4) A licensee shall establish dose rate action levels for the surveys required by paragraphs (1) and (2) of this rule and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(5) A licensee shall survey for removable contamination at the end of each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.

(6) A licensee shall conduct the surveys required by paragraph (5) of this rule so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).

(7) A licensee shall establish removable contamination action levels for the surveys required by paragraph (5) of this rule and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(8) A licensee does not need to perform the surveys required by paragraph (1) of this rule in area(s) where patients or human research subjects are confined when they cannot be released pursuant to 1200-02-07-.35.

(9) A licensee shall retain a record of each survey in accordance with 1200-02-07-.91.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.35 Release of Individuals Containing Radioactive Drugs or Implants

(1) A licensee may authorize the release from its control of any individual who has been administered radioactive drugs or 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).[1]

[1] The current revision of NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(2) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

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

(b) Information on the potential consequences, if any, of failure to follow the guidance.

(3) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 1200-02-07-.92.

(4) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 1200-02-07-.92.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.36 Provision of Mobile Medical Service

(1) A licensee providing mobile medical service shall:

(a) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(b) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

(c) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(d) Before leaving a client's address, survey all areas of use, to ensure compliance with Chapter 1200-02-05; and

(2) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

(3) A licensee providing mobile medical services shall retain the letter required in paragraph (1)(a) of this rule and the record of each survey required in paragraph (1)(d) of this rule in accordance with 1200-02-07-.93(1) and (2), respectively.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.37 Decay-in-Storage

(1) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:

(a) Monitors radioactive material at the surface before disposal and determines that its Radioactivity cannot be distinguished from the background radiation level with an appropriate calibrated radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(b) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

(2) A licensee shall retain a record of each disposal permitted under paragraph (1) of this rule in accordance with 1200-02-07-.94.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.38 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required

(1) Except for quantities that require a written directive under 1200-02-07-.20(2), a licensee may use any unsealed radioactive material, prepared for medical use for uptake, dilution, or excretion that is:

(a) Obtained from a manufacturer or preparer licensed under 1200-02-10-.13(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 1200-02-07-.43 or 1200-02-07-.47 and 1200-02-07-.43(1)(c)1(ii)(VII), or an individual under the supervision, as specified in 1200-02-07-.19; or

(c) Obtained from and prepared by an Agreement State or U.S. Nuclear Regulatory Commission licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA); or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee approved application or an Investigational New Drug (IND) protocol accepted by Food and Drug Administration (FDA) for use in research.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.39 Training for Uptake, Dilution, and Excretion Studies

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 1200-02-07-.38 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements of subparagraph (1)(c) of this rule. To be recognized, a specialty board shall require all candidates for certification to:

1. Has completed 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in subparts (1)(c)1(i) and (ii) of this rule; and

2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under 1200-02-07-.43 or 1200-02-07-.47 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(i) Classroom and laboratory 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) Work experience, under the supervision of an authorized user who meets the requirements in 1200-02-07-.39, 1200-02-07-.43, or 1200-02-07-.47 or equivalent U.S. Nuclear Regulatory Commission or agreement State requirements, involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 1200-02-07-.39, 1200-02-07-.43, or 1200-02-07-.47 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in parts (1)(a)1 or (1)(c)1 of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 1200-02-07-.38.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.40 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required

(1) A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 1200-02-07-.20(2) that is:

(a) Obtained from a manufacturer or preparer licensed under Chapter 1200-02-10-.13(10) or equivalent regulations of another Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 1200-02-07-.43, or 1200-02-07-.47 and 1200-02-07-.43(1)(c)1(ii)(VII), or an individual under the supervision of either as specified in 1200-02-07-.19; or

(c) Obtained from and prepared by an Agreement State or U.S. Nuclear Regulatory Commission licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA); or

(d) Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA).

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.41 Radionuclide Contaminants

(1) A licensee shall not administer to humans a radioactive drug containing:

(a) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of Mo-99 per mCi of Tc-99m);

(b) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride);

(c) More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82).

(2) To demonstrate compliance with paragraph (1) of this rule, the licensee preparing radioactive drugs from radionuclide generators shall:

(a) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;

(b) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

(3) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 1200-02-07-.95.

(4) A licensee shall report immediately to the Division each occurrence of radionuclide contaminant concentration exceeding the limits specified in paragraph (1) of this rule.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.42 Reserved

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.43 Training for Imaging and Localization Studies

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 1200-02-07-.40 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in part (c)2 of this paragraph. To be recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in subparts (c)1(i) and (ii) of this paragraph; and

2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under 1200-02-07-.47 and meets the requirements in item (c)1(ii)(VII) of this paragraph or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

(i) Classroom and laboratory 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;

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in this rule or item (VII) of this subpart and 1200-02-07-.47 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

(VII) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or 1200-02-07-.47 and item 1(ii)(VII) of this subparagraph or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in parts (a)1 or (c)1 of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 1200-02-07-.38 and 1200-02-07-.40.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.44 Use of Unsealed Radioactive Material for Which a Written Directive is Required

(1) A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

(a) Obtained from a manufacturer or preparer licensed under 1200-02-07-10-.13(10) or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 1200-02-07-.43, 1200-02-07-.47, or an individual under the supervision of either as specified in 1200-02-07-.19; or

(c) Obtained from and prepared by an Agreement State or U.S. Nuclear Regulatory Commission licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA) for use in research; or

(d) Prepared by the licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA).

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.45 Safety Instructions

(1) In addition to the requirements of 1200-02-04-.12:

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released under 1200-02-07-.35. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control; and

2. Visitor control to include the following:

(i) Routine visitation to hospitalized individuals in accordance with Chapter 1200-02-05;

(ii) Contamination control;

(iii) Waste control; and

(iv) Notification of the radiation safety officer, or their designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with 1200-02-07-.96.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.46 Safety Precautions

(1) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 1200-02-07-.35, a licensee shall:

(a) Quarter the patient or the human research subject either in:

1. A private room with a private sanitary facility; or

2. A room, with a private sanitary facility, with another individual who also has received radiopharmaceutical therapy and who also cannot be released under 1200-02-07-.35;

(b) Visibly post the patient's or the human research subject's room with a "Caution Radioactive Materials" sign.

(c) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(d) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(2) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.47 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 1200-02-07-.44 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission an Agreement State and who meets the requirements in subparagraph (1)(b) of this rule. (Specialty boards whose certification processes have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in subpart (b)1(i) through item (b)1(ii)(V) of this paragraph. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed by-product material; or

(b) 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(i) Classroom and laboratory 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) Work experience, under the supervision of an authorized user who meets the requirements of this rule, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in this subparagraph, must also have experience in administering dosages in the same dosage category or categories (i.e., item (VI) of this subpart) as the individual requesting authorized user status. The work experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

I. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

II. Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. Experience with at least three cases in this also satisfies the requirement in subitem I of this item;

III. Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

IV. Parenteral administration of any other radionuclide for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraph (a) and item (b)1(ii)(VI) of this paragraph or subparagraph (b) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 1200-02-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The

preceptor authorized user, who meets the requirements in this subparagraph, must have experience in administering dosages in the same dosage category or categories (i.e., item 1(ii)(VI) of this subparagraph) as the individual requesting authorized user status.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.48 Training for the Oral Administration of Sodium Iodine I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicurries)

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (c) of this paragraph and whose certification has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State; (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.); or

(b) Is an authorized user under 1200-02-07-.47 for uses listed in 1200-02-07-.47(1)(b)1(ii)(VI)I or II, 1200-02-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(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

2. Has work experience, under the supervision of an authorized user who meets the requirements in 1200-02-07-.47, 1200-02-07-.48, 1200-02-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements in 1200-02-07-.47(1)(b), must also have experience in administering dosages as specified in 1200-02-07-.47(1)(b)1(ii)(VI)I and II. The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in parts 1 and 2 of this subparagraph and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 1200-02-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in 1200-02-07-.47, 1200-02-07-.48, 1200-02-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirement in 1200-02-07-.47(1)(b), must also have experience in administering dosages as specified in 1200-02-07-.47(1)(b)1(ii)(VI)I and II.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.49 Training for the Oral Administration of Sodium Iodine I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicurries)

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in parts (c)1 and 2 of this paragraph and whose certification has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.); or

(b) Is an authorized user under 1200-02-07-.47 for uses listed in 1200-02-07-.47(1)(b)1(ii)(VI)II, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(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

2. Has work experience, under the supervision of an authorized user who meets the requirements in 1200-02-07-.47, 1200-02-07-.49 or equivalent Agreement State

or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in 1200-02-07-.47(1)(b), must have experience in administering dosages as specified in 1200-02-07-.47(1)(b)1(ii)(VI)II. The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in parts 1 and 2 of this subparagraph and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 1200-02-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in 1200-02-07-.47, 1200-02-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in 1200-02-07-.47(1)(b), must have experience in administering dosages as specified in 1200-02-07-.47(1)(b)1(ii)(VI)II.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.50 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under 1200-02-07-.47 for uses listed in 1200-02-07-.47(1)(b)1(ii)(VI)III or 1200-02-07-.47(1)(b)1(ii)(VI)IV, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(b) Is an authorized user under 1200-02-07-.59 or 1200-02-07-.80, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who meets the requirements in subparagraph (d) of this paragraph; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under 1200-02-07-.59 or 1200-02-07-.80, and who meets the requirements in subparagraph (d) of this paragraph.

(d) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

(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

2. Has work experience, under the supervision of an authorized user who meets the requirements in 1200-02-07-.47 or 1200-02-07-.50, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 1200-02-07-.47 must have experience in administering dosages as specified in 1200-02-07-.47(1)(b)1(ii)(VI)III and/or IV. The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(e) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (b) or (c) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 1200-02-07-.47, 1200-02-07-.50, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the

requirements in 1200-02-07-.47, must have experience in administering dosages as specified in 1200-02-07-.47(1)(b)1(ii)(VI)III and/or IV.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.51 Use of Sealed Sources for Manual Brachytherapy

(1) A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active investigational device exemption (IDE) application accepted by the Food and Drug Administration (FDA) provided the requirements of 1200-02-07-.22 are met.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.52 Surveys After Source Implants and Removal

(1) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(2) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(3) A licensee shall retain a record of the surveys in accordance with 1200-02-07-.97.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.53 Brachytherapy Source Accountability

(1) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(2) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(3) A licensee shall maintain a record of the brachytherapy source accountability in accordance with 1200-02-07-.98.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.54 Safety Instructions

(1) In addition to the requirements of 1200-02-04-.12:

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under 1200-02-07-.35. Instruction must be commensurate with the duties of the personnel and include the:

1. Size and appearance of the brachytherapy sources;

2. Safe handling and shielding instructions;

3. Patient or human research subject control;

4. Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with 1200-02-05-.60(1)(a); and

(ii) Visitation authorized in accordance with 1200-02-05-.60(2); and

5. Notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with 1200-02-07-.96.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.55 Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy

(1) For each patient or human research subject who is receiving brachytherapy and cannot be released under 1200-02-07-.35, a licensee shall:

(a) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(b) Visibly post the patient's or human research subject's room with a "Caution- Radioactive Materials" sign; and

(c) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(2) A licensee shall have emergency response equipment available near each treatment room to respond to a source:

(a) Dislodged from the patient; and

(b) Lodged within the patient following removal of the source applicators.

(3) The radiation safety officer, or their designee, and an authorized user shall be notified immediately if the patient or human research subject has a medical emergency or dies.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.56 Calibration Measurements of Brachytherapy Sources

(1) Before the first medical use of a brachytherapy sealed source on or after the effective date of this rule, a licensee shall have:

(a) Determined the source output or activity using a dosimetry system that meets the requirements of 1200-02-07-.68;

(b) Determined source positioning accuracy within applicators; and

(c) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subparagraphs (a) and (b) of this paragraph.

(2) Instead of a licensee making its own measurements as required in paragraph (1) of this rule, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (1) of this rule.

(3) A licensee shall mathematically correct the outputs or activities determined in paragraph (1) of this rule for physical decay at intervals consistent with 1 percent physical decay.

(4) A licensee shall retain a record of each calibration in accordance with 1200-02-07-.99.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.57 Decay of Strontium-90 Sources for Ophthalmic Treatments

(1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 1200-02-07-.56.

(2) A licensee shall retain a record of the activity of each strontium-90 source in accordance with 1200-02-07-.100.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.58 Therapy-Related Computer Systems

(1) The licensee shall perform or shall verify and maintain documentation of acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.59 Training for Use of Manual Brachytherapy Sources

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 1200-02-07-.51 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements at a medical institution, involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Checking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of material on hand;

(V) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(VI) Using emergency procedures to control radioactive material; and

2. Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this rule or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subpart 1(ii) of this subparagraph; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in part (a)1, or parts (b)1 and 2 of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 1200-02-07-.51.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.60 Training for Ophthalmic Use of Strontium-90

(1) Except as provided in 1200-02-07-.26, the licensee shall require the authorized user of strontium-90 for ophthalmic uses authorized under 1200-02-07-.51 to be a physician who:

(a) Is an authorized user under 1200-02-07-.59 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(b) 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 1200-02-07-.59, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in subparagraphs (a) and (b) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.61 Use of Sealed Sources for Diagnosis

A licensee shall use only sealed sources for diagnostic medical uses as approved in the sealed source and device registry.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.62 Training for Use of Sealed Sources for Diagnosis

(1) Except as provided in 1200-02-07-.26, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 1200-02-07-.61 to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in subparagraphs (b) and (c) of this paragraph and whose certification has been recognized by the Division, the U.S Nuclear Regulatory Commission, or an Agreement State (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.); or

(b) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

(c) Has completed training in the use of the device for the uses requested.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.63 Use of Sealed Source in Remote Afterloader Unit, Teletheraphy Unit, or Gamma Stereotactic Radiosurgery Unit

(1) A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the sealed source and device registry; or

(b) In research in accordance with an active investigational device exemption (IDE) application accepted by the Food and Drug Administration (FDA) provided the requirements of 1200-02-07-.22(1) are met.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.64 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit

(1) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(2) A licensee shall retain a record of these surveys in accordance with 1200-02-07-.97.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.65 Installation, Maintenance, Adjustment, and Repair

(1) Only a person specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(4) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 1200-02-07-.101.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.66 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) A licensee shall:

(a) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(b) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(c) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(d) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by subparagraph (1)(d) of this rule must be physically located at the unit console.

(3) A licensee shall post instructions at the unit console to inform the operator of:

(a) The location of the procedures required by subparagraph (1)(d) of this rule; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(4) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(a) The procedures identified in subparagraph (1)(d) of this rule; and

(b) The operating procedures for the unit.

(5) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee shall retain a record of individuals receiving instruction required by paragraph (4) of this rule, in accordance with 1200-02-07-.96.

(7) A licensee shall retain a copy of the procedures required by subparagraphs (1)(d) and (4)(b) of this rule in accordance with 1200-02-07-.102.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.67 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source(s) to be shielded when an entrance door is opened; and

(c) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in paragraphs (1) through (5) of this rule, a licensee shall:

(a) For low dose rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For high dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(c) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the radiation safety officer, or their designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently:

(a) Remains in the unshielded position; or

(b) Lodges within the patient following completion of the treatment.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.68 Dosimetry Equipment

(1) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

(a) The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(b) The system must have been calibrated within the previous four years. 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past twenty-four months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(2) The licensee shall have available for use a dosimetry system available for use for spot- check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (1) of this rule. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (1) of this rule.

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with 1200-02-07-.103.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.69 Full Calibration Measurements on Teletherapy Units

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(a) Before the first medical use of the unit; and

(b) Before medical use under the following conditions:

1. Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

2. Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

3. 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

(c) At intervals not exceeding one year.

(2) To satisfy the requirement of paragraph (1) of this rule, full calibration measurements must include determination of:

(a) The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error; and

(f) The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in 1200-02-07-.68(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (2)(a) of this rule may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by paragraph (1) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in subparagraph (2)(a) of this rule for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

(6) Full calibration measurements required by paragraph (1) of this rule and physical decay corrections required by paragraph (5) of this rule must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 1200-02-07-.104.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.70 Full Calibration Measurements on Remote Afterloader Units

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

1. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

2. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding one calendar quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(d) At intervals not exceeding one year for low dose-rate remote afterloader units.

(2) To satisfy the requirement of paragraph (1) of this rule, full calibration measurements must include, as applicable, determination of:

(a) The output within ±5 percent;

(b) Source positioning accuracy to within ±1 millimeter;

(c) Source retraction with backup battery upon power failure;

(d) Length of the source transfer tubes;

(e) Timer accuracy and linearity over the typical range of use;

(f) Length of the applicators; and

(g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in 1200-02-07-.68(1) to measure the output.

(4) A licensee shall make full calibration measurements required by paragraph (1) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (2) of this rule, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one calendar quarter.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (1) through (5) of this rule.

(7) A licensee shall mathematically correct the outputs determined in subparagraph (2)(a) of this rule for physical decay at intervals consistent with one percent physical decay.

(8) Full calibration measurements required by paragraph (1) of this rule and physical decay corrections required by paragraph (7) of this rule must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with 1200-02-07-.104.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.71 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

1. Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

2. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

3. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(c) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirements of paragraph (1) of this rule, full calibration measurements must include determination of:

(a) The output within ±3 percent;

(b) Relative helmet factors;

(c) Isocenter coincidence;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error;

(f) Trunnion centricity;

(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(h) Helmet microswitches;

(i) Emergency timing circuits; and

(j) Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in 1200-02-07-.68(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (2)(a) of this rule may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by paragraph (1) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in subparagraph (2)(a) of this rule at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by paragraph (1) of this rule and physical decay corrections required by paragraph (5) of this rule must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 1200-02-07-.104.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.72 Periodic Spot-Checks for Teletherapy Units

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(a) Timer accuracy, and timer linearity over the range of use;

(b) On-off error;

(c) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) The accuracy of all distance measuring and localization devices used for medical use;

(e) The output for one typical set of operating conditions measured with the dosimetry system described in 1200-02-07-.68(2); and

(f) The difference between the measurement made in subparagraph (e) of this paragraph 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).

(2) A licensee shall perform measurements required by paragraph (1) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee as soon as possible in writing of the results of each spot-check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(a) Electrical interlocks at each teletherapy room entrance;

(b) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(c) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(d) Viewing and intercom systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the checks required in paragraph (4) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain a record of each spot-check required by paragraphs (1) and (4) of this rule, in accordance with 1200-02-07-.105.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.73 Periodic Spot-Checks for Remote Afterloader Units

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(a) At the beginning of each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;

(b) Before each patient treatment with a low dose-rate remote afterloader unit; and

(c) After each source installation.

(2) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in paragraph (1) of this rule. The authorized medical physicist need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) To satisfy the requirements of paragraph (1) of this rule, spot-checks must, at a minimum, assure proper operation of:

(a) Electrical interlocks at each remote afterloader unit room entrance;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(d) Emergency response equipment;

(e) Radiation monitors used to indicate the source position;

(f) Timer accuracy;

(g) Clock (date and time) in the unit's computer; and

(h) Decayed source(s) activity in the unit's computer.

(5) If the results of the checks required in paragraph (4) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain a record of each check required by paragraph (4) of this rule in accordance with 1200-02-07-.106.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.74 Periodic Spot-Checks for Gamma Steriotactic Radiosursery Units

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(a) Monthly;

(b) At the beginning of each day of use; and

(c) After each source installation.

(2) A licensee shall have the authorized medical physicist:

(a) Establish written procedures for performing the spot-checks required in paragraph (1) of this rule; and

(b) Review the results of each spot-check required by paragraph (1) of this rule within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

(3) To satisfy the requirements of subparagraph (1)(a) of this rule, spot-checks must, at a minimum:

(a) Assure proper operation of:

1. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

2. Helmet microswitches;

3. Emergency timing circuits; and

4. Stereotactic frames and localizing devices (trunnions).

(b) Determine:

1. The output for one typical set of operating conditions measured with the dosimetry system described in 1200-02-07-.68(2);

2. The difference between the measurement made in part 1 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);

3. Source output against computer calculation;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. Trunnion centricity.

(4) To satisfy the requirements of subparagraphs (1)(b) and (c) of this rule, spot-checks must assure proper operation of:

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(f) Emergency off buttons.

(5) A licensee shall arrange for the repair of any system identified in paragraph (3) of this rule that is not operating properly as soon as possible.

(6) If the results of the checks required in paragraph (4) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain a record of each check required by paragraphs (3) and (4) of this rule in accordance with 1200-02-07-.107.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.75 Additional Technical Requirements for Mobile Remote Afterloader Units

(1) A licensee providing mobile remote afterloader service shall:

(a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(b) Account for all sources before departure from a client's address of use.

(2) In addition to the periodic spot-checks required by 1200-02-07-.73, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

(a) Electrical interlocks on treatment area access points;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(e) Radiation monitors used to indicate room exposures;

(f) Source positioning (accuracy); and

(g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(3) In addition to the requirements for checks in paragraph (2) of this rule, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in paragraph (2) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) A licensee shall retain a record of each check required by paragraph (2) of this rule in accordance with 1200-02-07-.108.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.76 Radiation Surveys

(1) In addition to the survey requirement in Rule 1200-02-05-.70, a person licensed under this Chapter shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the sealed source and device registry.

(2) The licensee shall make the survey required by paragraph (1) of this rule at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding round the source(s), or compromise the radiation safety of the unit or the source(s).

(3) A licensee shall retain a record of the radiation surveys required by paragraph (1) of this rule in accordance with 1200-02-07-.109.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.77 Five Year Inspection for Teletherapy Units and Gamma Stereotactic Radiosurgery Units

(1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit 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.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) A licensee shall keep a record of the inspection and servicing in accordance with 1200-02-07-.110.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.78 Therapy-Related Computer Systems

(1) The licensee shall perform or shall verify and maintain documentation of acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.79 Reserved

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.80 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) Except as provided in 1200-02-07-.26, the licensee shall require an authorized user of a sealed source for a use authorized under 1200-02-07-.63 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in part (b)3 and subparagraph (c) of this paragraph. To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

(b) 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements at a medical institution, involving:

(I) Reviewing full calibration measurements and periodic spot-checks;

(II) Preparing treatment plans and calculating treatment doses and times;

(III) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(V) Checking and using survey meters; and

(VI) Selecting the proper dose and how it is to be administered; and

2. Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this rule or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subpart 1(ii) of this subparagraph; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in part (a)1 of this paragraph or part 1 of this subparagraph, and part 2 of this subparagraph and subparagraph (c) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.81 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

(1) A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in this rule if:

(a) The applicant or licensee has submitted the information required by 1200-02-07-.11(2), 1200-02-07-.11(3), and 1200-02-07-.11(4); and

(b) The applicant or licensee has received written approval from the Division in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Division considers necessary for the medical use of the material.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.82 Records of Authority and Responsibilities for Radiation Protection Programs

(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with 1200-02-07-.17(1) for five years. The record must include a summary of the actions taken and a signature of licensee management.

(2) The licensee shall retain a copy of both authority, duties, and responsibilities of the radiation safety officer as required by 1200-02-07-.17(5), and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required

by 1200-02-07-.17(2). The records must include the signature of the radiation safety officer and licensee management.

(3) The minutes of each Radiation Safety Committee meeting held in accordance with 1200-02-07-.17(8) shall include:

(a) The date of the meeting;

(b) Members present;

(c) Members absent; and

(d) Summary of deliberations and discussions.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.83 Records of Radiation Protection Program Changes

A licensee shall retain a record of each radiation protection program change made in accordance with 1200-02-07-.18(1) for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.84 Records of Written Directives

A licensee shall retain a copy of each written directive as required by 1200-02-07-.20 for three years.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.85 Reserved

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.86 Reserved

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.87 Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material

A licensee shall maintain a record of instrument calibrations required by 1200-02-07-.28 for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.88 Records of Survey Instrument Calibrations

A licensee shall maintain a record of radiation survey instrument calibrations required by 1200-02-07-.29 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.89 Records of Dosages of Unsealed Radioactive Material for Medical Use

A licensee shall maintain a record of dosage determinations required by 1200-02-07-.30 for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.90 Reserved

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.91 Records of Surveys for Ambient Radiation Exposure Rate

A licensee shall retain a record of each survey required by 1200-02-07-.34 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.92 Records of the Release of Individuals containing Unsealed Radioactive Material or Implants Containing Radioactive Material

(1) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release.

(2) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by 1200-02-07-.35(2) were provided to a breast-feeding woman.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.93 Records of Mobile Medical Services

(1) A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by 1200-02-07-.36(1)(a), Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(2) A licensee shall retain the record of each survey required by 1200-02-07-.36(1)(d) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.94 Records of Decay-in-Storage

A licensee shall maintain records of the disposal of licensed materials, as required by 1200-02-07-.37, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.95 Records of Radionuclide Contaminants

A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 1200-02-07-.41 for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.96 Records of Safety Instruction and Training

A licensee shall maintain a record of safety instructions and training required by 1200-02-07-.45, 1200-02-07-.54, and 1200-02-07-.66(4) for three years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.97 Records of Radiation Surveys of Patients and Human Research Subjects

A licensee shall maintain a record of the surveys required by 1200-02-07-.52 and 1200-02-07-.64 for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.98 Records of Brachytherapy Source Accountability

(1) A licensee shall maintain a record of brachytherapy source accountability required by 1200-02-07-.53 for three years.

(2) For temporary implants, the record must include:

(a) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(b) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(3) For permanent implants, the record must include:

(a) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(b) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(c) The number and activity of sources permanently implanted in the patient or human research subject.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.99 Records of Calibration Measurements of Brachytherapy Sources

A licensee shall maintain a record of the calibrations of brachytherapy sources required by 1200-02-07-.56 for three years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the signature of the authorized medical physicist.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.100 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments

A licensee shall maintain a record of the activity of a strontium-90 source required by 1200-02-07-.56 for the life of the source. The record must include the date and initial activity of the source as determined under 1200-02-07-.56, and for each decay calculation, the date, the source activity, and the signature of the authorized medical physicist.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.101 Records of Installation, Maintenance, Adjustment, and Repair or Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 1200-02-07-.65 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.102 Records of Safety Procedures

A licensee shall retain a copy of the procedures required by subparagraphs (1)(d) and (4)(b) of 1200-02-07-.66 until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.103 Records of Dosimetry Equipment

(1) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 1200-02-07-.68 for the duration of the license.

(2) For each calibration, intercomparison, or comparison, the record must include:

(a) The date;

(b) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 1200-02-07-.68(1) and (2);

(c) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(d) The names of the individuals who performed the calibration, intercomparison, or comparison.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.104 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations

(1) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by 1200-02-07-.69, 1200-02-07-.70, and 1200-02-07-.71 for three years.

(2) The record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(c) The results and an assessment of the full calibrations;

(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) The signature of the authorized medical physicist who performed the full calibration.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.105 Records of Periodic Spot-Checks for Teletherapy Units

(1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 1200-02-07-.72 for three years.

(2) The record must include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(c) An assessment of timer linearity and constancy;

(d) The calculated on-off error;

(e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(f) The determined accuracy of each distance measuring and localization device;

(g) The difference between the anticipated output and the measured output;

(h) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.106 Records of Periodic Spot-Checks for Remote Afterloader Units

(1) A licensee shall retain a record of each spot-check for remote afterloader units required by 1200-02-07-.73 for three years.

(2) The record must include, as applicable:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(c) An assessment of timer accuracy;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.107 Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units

(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 1200-02-07-.74 for three years.

(2) The record must include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(c) An assessment of timer linearity and accuracy;

(d) The calculated on-off error;

(e) A determination of trunnion centricity;

(f) The difference between the anticipated output and the measured output;

(g) An assessment of source output against computer calculations;

(h) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.108 Records of Additional Technical Requirements for Mobile Remote Afterloader Units

(1) A licensee shall retain a record of each check for mobile remote afterloader units required by 1200-02-07-.75 for three years.

(2) The record must include:

(a) The date of the check;

(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(c) Notations accounting for all sources before the licensee departs from a facility;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(e) The signature of the individual who performed the check.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.109 Records of Surveys of Therapeutic Treatment Units

(1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 1200-02-07-.76 for the duration of use of the unit.

(2) The record must include:

(a) The date of the measurements;

(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) The signature of the individual who performed the test.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.110 Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

(1) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 1200-02-07-.77 for the duration of use of the unit.

(2) The record must contain:

(a) The inspector's radioactive materials license number;

(b) The date of inspection;

(c) The manufacturer's name and model number and serial number of both the treatment unit and source;

(d) A list of components inspected and serviced, and the type of service; and

(e) The signature of the inspector.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.111 Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources

(1) A licensee shall retain records of leak tests required by 1200-02-07-.32(2) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(2) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 1200-02-07-.32(5) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.112 Records for Procedures for Administrations Requiring a Written Directive

A licensee shall retain a copy of the procedures required by 1200-02-07-.21(1) for the duration of the license.

Authority: T.C.A. §§ 68-202-201 et seq.

1200-02-07-.113 Report of a Leaking Source

A licensee shall file a report within five days if a leak test required by 1200-02-07-.32 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The report must be filed with the Division, and sent to the Division at the address listed in 1200-02-04-.07(1)(c). The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Authority: T.C.A. §§ 68-202-201 et seq.

Chapter 1200-02-08
Radiation Safety Requirements for Industrial Radiography Operations

Amendments

Rule 1200-02-08-.03 Definitions is amended by adding a new paragraph (30) so that paragraph (30) shall read as follows:

(30) 'Industrial Radiography' means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Subparagraph (a) of paragraph (3) of rule 1200-02-08-.05 Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants is amended by adding the words "or registrant" between the words "licensee" and "shall" in the first sentence so that, as amended, subparagraph (a) shall read as follows:

(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 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 installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraphs (1) through (4) of Rule 1200-02-08-.07 Minimum Subjects to be Covered in Training Radiographers is amended by deleting the paragraphs in their entirety and substituting the following so that, as amended, paragraphs (1) through (4) shall read as follows:

(1) A licensee or registrant shall not permit any individual to act as a radiographer until the individual:

(a) Has received training in the subjects in paragraph (7) of this rule, 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 1200–02–08–.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.) and

(2) In addition, the licensee or registrant 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 1200-02-05 and 1200-02-10, 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 in subparagraphs (a) and (c) of this paragraph by successful completion of a practical examination covering this material.

(3) The licensee or registrant 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 1200-02-05 and 1200-02-10, 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 in subparagraph (a) of this paragraph by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described above in subparagraph (b) of this paragraph by successful completion of a practical examination on the use of such hardware.

(4) The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Subparagraph (b) of paragraph (1) of Rule 1200-02-08-.11 Shielded Room X-Ray Radiography is amended by deleting the words “paragraph (5)” from the end of the first sentence and replacing it with “subparagraph (e) of this paragraph” so that, as amended, subparagraph (b) shall read as follows:

(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 subparagraph (e) of this paragraph. 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.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Chapter 1200–02–09
Requirements for Accelerators

Amendments

Paragraph (1) of Rule 1200-02-09-.03 Definitions is amended deleting the words "*A*ccelerator. Means" from the beginning of the paragraph and replacing it with "Accelerator means" so that, as amended, paragraph (1) shall read as follows:

(1) Accelerator means any device used to impart kinetic energy to electrically charged particles including but not limited to electrons, protons, deuterons, and helium ions. For the purpose of this chapter "accelerator" includes equipment designed for and used only for the production of x–rays of 0.9 MeV or greater and equipment capable of discharging nuclear particles into a medium external to the accelerating device.

Paragraph (2) of Rule 1200-02-09-.03 Definitions is amended deleting the words "Operator. Means" from the beginning of the paragraph and replacing it with "Operator means" so that, as amended, paragraph (2) shall read as follows:

(2) Operator means a person who manipulates the controls of an accelerator and who is responsible to the registrant for assuring compliance with the requirements of these regulations and all Certified Registration Conditions during operation of the accelerator.

Rule 1200-02-09-.03 Definitions is amended by added paragraph (3) so that paragraph (3) shall read as follows:

(3) Misadministration means an event that meets the criteria in 1200-02-05-.145.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Rule 1200-02-09-.04 Requirements for Registration is amended by deleting the Rule in its entirety and substituting the following to read as follows:

(1) No person shall activate an accelerator, until the registration has been certified pursuant to the information supplied by the applicant and 1200–02–09–.05.

(2) Application for a Certified Registration shall be made to the Division as follows:

(a) Application for a Certified Registration shall be filed on a form prescribed by the Division.

(b) The Division may at any time after the filing of the original application or before the expiration of the Certified Registration require further statements in order to enable the Division to determine whether certification should be granted or denied or whether the Certified Registration should be modified or revoked.

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

(3) Possession of a Certified Registration is not required in order to transfer, own, receive, acquire, or possess an accelerator when such devices are in storage or disassembled or otherwise incapable of operation. However, each person receiving such accelerator shall within ten (10) days after the receipt of the accelerator submit an application for Certified Registration pursuant to 1200-02-10-.24.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Subparagraph (c) of Paragraph (1) of Rule 1200-02-09-.06 Specific Requirements for the Issuance of a Certified Registration is amended by deleting the words “and, where applicable, the clinical management of radioactive patients” from the end of the sentence and adding footnote “1” after the period of the sentence with the correspondent text in the footnote so that, as amended, subparagraph (c) and correspondent footnote shall read as follows:

(c) The physician designated on the application as the responsible individual shall be a radiologist or therapeutic radiologist certified by the American Board of Radiology in radiology or therapeutic radiology and has experience in the use of accelerators to treat humans.[1]

[1] Certified registrants that desire to utilize physician(s) who do not meet these criteria for minimum training and experience may request a variance excepting the physician from the requirements for a limited time period. The variance request should include:

1. The name of the proposed individual,
2. A description of his or her training and experience including information similar to that specified in 1200-02-09-.06(1)(c),
3. Information to substantiate that the physician is currently engaged in the certification process,
4. Written endorsement of the technical qualifications of the proposed physician from personal knowledge by a physician certified by the American Board of Radiology in radiology or therapeutic radiology. This should be a letter from the proposed physician's Residency Director where the physician in question completed the Residency program in radiology or therapeutic radiology.

Upon receipt of acceptable information, the Division will grant a specific variance to 1200-02-09-.06(1)(c). This variance will be for a time period not to exceed one (1) year. The Division will entertain a request to extend this variance for no more than a two (2) additional one (1) year time periods provided the certified registrant can support that the physician remains currently engaged in the certification process.

Subparagraph (n) of paragraph (4) of rule 1200-02-09-.17 General Safety Provisions is amended by deleting the word “are” after the word “the” and before the word “may” and substituting in its place the word “area” so that, as amended, subparagraph (n) shall read as follows:

(n) All high radiation areas shall be so constructed that persons within the area may at all times able to escape.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Chapter 1200-02-10
Licensing and Registration

Amendments

Subparagraph (f) of paragraph (3) of Rule 1200-02-10-.03 Exemptions: Source Material is amended by deleting the word "or" appearing after the word "metal" and before the word "minimum" and replacing it with the word "of" so that, as amended, subparagraph (f) shall read as follows:

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

Subparagraph (b) of paragraph (1) of Rule 1200-02-10-.04 Exemptions: Radioactive Material Other Than Source Material is amended by adding "1200-02-10-.10 and" after the word "in" and before "1200-02-10-.29" so that, as amended, subparagraph (b) shall read as follows:

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

Part 1 of subparagraph (i) of paragraph (2) of Rule 1200-02-10-.04 Exemptions: Radioactive Materials Other Than Source Material is amended by deleting "1200-02-10-.23(15)" after the word "to" and before the word "that" and replacing it with "1200-02-10-.13(15)" so that, as amended, part 1 shall read as follows:

1. Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred[2] in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.26 of 10 CFR Part 32 or a licensing state pursuant to regulations equivalent to 1200–2–10–.13(15) that authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

Part 3 of subparagraph (i) of paragraph (2) of Rule 1200-02-10-.04 Exemptions: Radioactive Materials Other Than Source Material is amended by deleting "1200-2-1-.04(2)(i)1" after the word "under" and before the word "provided" and replacing it with "1200-02-10-.04(2)(i)1" so that, as amended, part 3 shall read as follows:

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 1200-02-10-.04(2)(i)1, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 1200–02–10–.13(15).

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Subparagraph (f) of paragraph (4) of Rule 1200-02-10-.10 General Licenses-Radioactive Material Other Than Source Material is amended by deleting the word “license” after the word “general” and before the word “do” and replacing it with the word “licenses” so that, as amended, subparagraph (f) shall read as follows:

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

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (1) of Rule 1200-02-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (1) shall read as follows:

(1) Reserved

Paragraph (2) of Rule 1200-02-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (2) shall read as follows:

(2) Reserved

Paragraph (3) of Rule 1200-02-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (3) shall read as follows:

(3) Reserved

Subparagraph (d) of paragraph (5) of Rule 1200-02-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting “10 CFR 31.5(c)(13)(i)” after the word “of” and before the word “bears” and replacing it with “1200-02-10-.10” so that, as amended, subparagraph (d) shall read as follows:

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

Paragraph (10) of Rule 1200-02-10-.13 Requirements for Issuance of Specific Licenses is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (10) shall read as follows:

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

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons authorized pursuant to 1200-02-07 will be approved if:

1. The applicant satisfies the general requirements specified in 1200-02-10-.12;

2. The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in

the manufacture, preparation, propagation, compounding, or processing of a drug;

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

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

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

4. The applicant satisfies the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half–life greater than 100 days, the time may be omitted.

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

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

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

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

(i) This individual qualifies as an authorized nuclear pharmacist as defined in subparagraph 1200-02-07-.05(4),

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

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

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

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

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

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

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

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

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

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

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

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

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

Paragraph (11) of Rule 1200-02-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting “1200-02-10-.14” from the last sentence after the word “to” and before the word “will” and replacing it with “1200-02-07” so that, as amended, paragraph (11) shall read as follows:

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

[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 1200-02-07 may submit the pertinent information specified in this paragraph (10).

Part 2 of subparagraph (e) of Paragraph (11) of Rule 1200-02-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting "1200-02-10-.14, Group III" after the word "to" and before the word "or: replacing it with "1200-02-07 of these regulations" so that, as amended, part 2 shall read as follows:

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

Paragraph (12) of Rule 1200-02-10-.13 Requirements for Issuance of Specific Licenses is amended by deleting the introductory language to paragraph (12) and substituting the following so that, as amended, the introductory language to paragraph (12) shall read as follows:

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

Subparagraph (a) of paragraph (12) of Rule 1200-02-10-.13 Requirements for Issuance of Specific Licenses is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (a) shall read as follows:

(a) The applicant satisfies the general requirements in 1200-02-10-.12 of these regulations.

Subparagraph (c) of paragraph (12) of Rule 1200-02-10-.13 Requirements for Issuance of Specific Licenses is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (c) shall read as follows:

(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 Division has approved distribution of the (name of the source or device) to persons licensed to use radioactive material identified in 1200-02-07-.31, 1200-02-07-.51, 1200-02-07-.61, and 1200-02-07-.63 as appropriate, and to persons who hold an equivalent license issued by the U.S. NRC or an Agreement State.

Footnote 11 of part 8 of subparagraph (d) of Paragraph (17) of Rule 1200-02-10-.13 Requirements for Issuance of Specific Licenses is amended by deleting "99-^{4} 99" from the footnote and replacing it with "99-499" so that, as amended, footnote 11 shall read:

[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 99–499 or other state or federal reporting requirements.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (6) of Rule 1200-02-10-.16 Specific Terms and Conditions of Licenses is amended by deleting "1200–2–10–.14(2)(b)2" from the end of the paragraph and replacing it with "1200-02-07-.41" so that, as amended, paragraph (6) shall read as follows:

(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 1200-02-07-.41.

Paragraph (7) of Rule 1200-02-10-.16 Specific Terms and Conditions of Licenses is amended by deleting "1200-2-10-.10(2)(b)14" after the word "part" and before the word "shall" and replacing it with "1200-02-10-.10(2)(c)14" so that, as amended, the introductory language of paragraph (7) shall read as follows:

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

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (2) of Rule 1200-02-10-.18 Renewal of License is amended by deleting the word "Divisionepartment" from the end of the paragraph and replacing it with the word "Division" so that, as amended, paragraph (2) shall read as follows:

(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.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (2) of Rule 1200-02-10-.23 Modification, Revocation, and Termination of Licenses is amended by deleting ", or of the Act" from the paragraph so that, as amended, paragraph (2) shall read as follows:

(2) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule or regulation of the Department. This action will be taken pursuant to Tennessee Code Annotated Chapter 23.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Rule 1200-02-10-.26 Records is amended by deleting the Rule in its entirety and substituting the following to read as follows:

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

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

(b) The licensee who transferred the material shall retain each record of transfer for three years after each transfer, unless a specific requirement in another part of these rules dictate otherwise.

(c) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Division terminates each license that authorizes disposal of the material.

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

(3) Records which must be maintained pursuant to this Rule may be the original or a reproduced copy. The record may also be stored in electronic media with the capability for producing legible,

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

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

(a) Records of disposal of licensed material made under 1200-02-05-.121 (including burials authorized before January 28, 1981), 1200-02-05-.122, 1200-02-05-.123, 1200-02-05-.124; and

(b) Records required by 1200-02-05-.132(2)(d).

(5) If licensed activities are transferred or assigned in accordance with 1200-02-10-.16(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(a) Records of disposal of licensed material made under 1200-02-05-.121 (including burials authorized before January 28, 1981), 1200-02-05-.122, 1200-02-05-.123, 1200-02-05-.124; and

(b) Records required by 1200-02-05-.132(2)(d).

(6) Prior to license termination, each licensee shall forward the records required by 1200-02-10 to the Division.

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

Subparagraph (f) of paragraph (5) of Rule 1200-02-10-.27 Inspections is amended by deleting the word “and” after the word “they” and before the word “were” from the paragraph so that, as amended, subparagraph (f) shall read as follows:

(f) If as a result of inadvertent error or excusable neglect a tube(s) is not inspected, the Commissioner or the Commissioner's designee may grant the 18 percent (18%) fee for all other tubes provided they were timely inspected by a qualified individual.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Subparagraph (a) of paragraph (5) of Rule 1200-02-10-.31 Fees for Licenses is amended by deleting the words “Nashville office” from the paragraph and replacing it with “Central Office” so that, as amended, subparagraph (a) shall read as follows:

(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 Central Office. All items on the application form shall be completed in sufficient detail to allow the Division to determine that the applicant’s equipment, facilities and radiation protection program are adequate to protect health and minimize danger to life and property.

Subparagraph (c) of paragraph (5) of Rule 1200-02-10-.31 Fees for Licenses is amended by deleting the “.” after “application” and replacing it with “,” so that, as amended, subparagraph (c) shall read as follows:

(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.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (3) of Rule 1200-02-10-.32 Licensing of Shippers of Radioactive Material into or Within Tennessee is amended by deleting the paragraph and substituting the following so that, as amended, paragraph (3) shall read as follows:

(3) Definitions used in this rule.

(a) Carrier means any person who transports radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities.

(b) Disposal means isolation of radioactive waste from the biosphere.

(c) Disposal/Processing Facility means any facility located within Tennessee that accepts radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities for packaging, repackaging, processing, refurbishing, storage pending disposal or disposal.

(d) (Reserved)

(e) (Reserved)

(f) License for delivery means an authorization issued by the Division to any shipper of radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities to transport such radioactive material or offer such material for transport to a disposal/processing facility.

(g) Shipper means any person, whether a resident of Tennessee or a non–resident:

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.

(h) Transport means the movement of radioactive waste and/or items contaminated or potentially contaminated with licensable quantities of radioactive material or from licensable activities into or within the State of Tennessee on waterways, roadways, railways or other transportation facilities upon which USDOT regulations are applicable.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Schedule RHS 8–3 Exempt Quantities is amended by deleting “Praseodymium-147 (Pr 147) 100” so that, as amended, Schedule RHS 8-3 shall read as follows:

SCHEDULE RHS 8–3

EXEMPT QUANTITIES

Radioactive Material	Micro–curies
Antimony–122 (Sb 122)	100
Antimony–124 (Sb 124)	10
Antimony–125 (Sb 125)	10
Arsenic–73 (As 73)	100
Arsenic–74 (As 74)	10
Arsenic–76 (As 76)	10
Arsenic–77 (As 77)	100
Barium–13l (Ba 131)	10
Barium–133 (Ba 133)	10
Barium–140 (Ba 140)	10
Bismuth–210 (Bi 210)	1
Bromine–82 (Br 82)	10
Cadmium–l09 (Cd 109)	10
Cadmium–115m (Cd 115m)	10
Cadmium–115 (Cd 115)	100
Calcium–45 (Ca 45)	10
Calcium–47 (Ca 47)	10
Carbon–14 (C 14)	100
Cerium–141 (Ce 141)	100
Cerium–143 (Ce 143)	100
Cerium–144 (Ce 144)	1
Cesium–129 (Cs 129)	100
Cesium–131 (Cs 131)	1,000
Cesium–134m (Cs 134m)	100
Cesium–134 (Cs 134)	1
Cesium–135 (Cs 135)	10
Cesium–136 (Cs 136)	10
Cesium–137 (Cs 137)	10
Chlorine–36 (Cl 36)	10
Chlorine–38 (Cl 38)	10
Chromium–51 (Cr 51)	1,000
Cobalt–57 (Co 57)	100
Cobalt–58m (Co 58m)	10
Cobalt–58 (Co 58)	10
Cobalt–60 (Co 60)	1
Copper–64 (Cu 64)	100
Dysprosium–165 (Dy 165)	10
Dysprosium–166 (Dy 166)	100
Erbium–169 (Er 169)	100
Erbium–171 (Er 171)	100
Europium–152 (Eu 152)9.2 h	100
Europium–152 (Eu 152)13 yr	1
Europium–154 (Eu 154)	1
Europium–155 (Eu 155)	10
Fluorine–18 (F 18)	1,000
Gadolinium–153 (Gd 153)	10
Gadolinium–159 (Gd 159)	100
Gallium–67 (Ga 67)	100
Gallium–72 (Ga 72)	10
Germanium–68 (Ge 68)	10
Germanium–71 (Ge 71)	100
Gold–195 (Au 195)	10
Gold–198 (Au 198)	100
Gold–l99 (Au 199)	100
Hafnium–181 (Hf 181)	10
Holmium–166 (Ho 166)	100
Hydrogen–3 (H 3)	1,000
Indium–111 (In 111)	100
Indium–113m (In 113m)	100
Indium–114m (In 114m)	10
Indium–115m (In 115m)	100
Indium–115 (In 115)	10
Iodine–123 (I 123)	100
Iodine–125 (I 125)	1
Iodine–126 (I 126)	1
Iodine–129 (I 129)	0.1
Iodine–131 (I 131)	1
Iodine–132 (I 132)	10
Iodine–133 (I 133)	1
Iodine–134 (I 134)	10
Iodine–135 (I 135)	10
Iridium–192 (Ir 192)	10
Iridium–194 (Ir 194)	100
Iron–52 (Fe 52)	10
Iron–55 (Fe 55)	100
Iron–59 (Fe 59)	10
Krypton–85 (Kr 85)	100
Krypton–87 (Kr 87)	10
Lanthanum–140 (La 140)	10
Lutetium–177 (Lu 177)	100

Radioactive Material	Micro–curies
Manganese–52 (Mn 52)	10
Manganese–54 (Mn 54)	10
Manganese–56 (Mn 56)	10
Mercury–197m (Hg 197m)	100
Mercury–197 (Hg 197)	100
Mercury–203 (Hg 203)	10
Molybdenum–99 (Mo 99)	100
Neodymium–147(Nd 147)	100
Neodymium–149 (Nd 149)	100
Nickel–59 (Ni 59)	100
Nickel–63 (Ni 63)	10
Nickel–65 (Ni 65)	100
Niobium–93m (Nb 93m)	10
Niobium–95 (Nb 95)	10
Niobium–97 (Nb 97)	10
Osmium–185 (Os 185)	10
Osmium–191m (Os 191m)	100
Osmium–191 (Os 191)	100
Osmium–193 (Os 193)	100
Palladium–103 (Pd 103)	100
Palladium–109 (Pd 109)	100
Phosphorus–32 (P 32)	10
Platinum–191 (Pt 191)	100
Platinum–193m (Pt 193m)	100
Platinum–193 (Pt 193)	100
Platinum–197m (Pt 197m)	100
Platinum–197 (Pt 197)	100
Polonium–210 (Po 210)	0.1
Potassium–42 (K 42)	10
Potassium–43 (K 43)	10
Praseodymium–142 (Pr 142)	100
Praseodymium–l43 (Pr 143)	100
Promethium–147 (Pm 147)	10
Promethium–149 (Pm 149)	10
Rhenium–186 (Re 186)	100
Rhenium–188 (Re 188)	100
Rhodium–103m (Rh 103m)	100
Rhodium–105 (Rh 105)	100
Rubidium–81 (Rb 81)	10
Rubidium–86 (Rb 86)	10
Rubidium–87 (Rb 87)	10
Ruthenium–97 (Ru 97)	100
Ruthenium–103 (Ru 103)	10
Ruthenium–105 (Ru 105)	10
Ruthenium–106 (Ru 106)	1
Samarium–151 (Sm 151)	10
Samarium–153 (Sm 153)	100
Scandium–46 (Sc 46)	10
Scandium–47 (Sc 47)	100
Scandium–48 (Sc 48)	10
Selenium–75 (Se 75)	10
Silicon–31 (Si 31)	100
Silver–105 (Ag 105)	10
Silver–110m (Ag 110m)	1
Silver–111 (Ag 111)	100
Sodium–22 (Na 22)	10
Sodium–24 (Na 24)	10
Strontium–85 (Sr 85)	10
Strontium–89 (Sr 89)	1
Strontium–90 (Sr 90)	0.1
Strontium–91 (Sr 91)	10
Strontium–92 (Sr 92)	10
Sulfur–35 (S 35)	100
Tantalum–182 (Ta 182)	10
Technetium–96 (Tc 96)	10
Technetium–97m (Tc 97m)	100
Technetium–97 (Tc 97)	100
Technetium–99m (Tc 99m)	100
Technetium–99 (Tc 99)	10
Tellurium–125m (Te 125m)	10
Tellurium–127m (Te 127m)	10
Tellurium–127 (Te 127)	100
Tellurium–129m (Te 129m)	10
Tellurium–129 (Te 129)	100
Tellurium–131m (Te 131m)	10
Tellurium–132 (Te 132)	10
Terbium–160 (Tb 160)	10
Thallium–200 (Tl 200)	100
Thallium–201 (Tl 201)	100
Thallium–202 (Tl 202)	100
Thallium–204 (Tl 204)	10
Thulium–170 (Tm 170)	10
Thulium–171 (Tm 171)	10
Tin–113 (Sn 113)	10
Tin–125 (Sn 125)	10
Tungsten–181 (W 181)	10
Tungsten–185 (W 185)	10
Tungsten–187 (W 187)	100
Vanadium–48 (V 48)	10
Xenon–131m (Xe 131m)	1,000
Xenon–133 (Xe 133)	100
Xenon–135 (Xe 135)	100
Ytterbium–175 (Yb 175)	100
Yttrium–87 (Y 87)	10
Yttrium–88 (Y 88)	10
Yttrium–90 (Y 90)	10
Yttrium–91 (Y 91)	10
Yttrium–92 (Y 92)	100
Yttrium–93 (Y 93)	100
Zinc–65 (Zn 65)	10
Zinc–69m (Zn 69m)	100
Zinc–69 (Zn 69)	1,000
Zirconium–93 (Zr 93)	10
Zirconium–95 (Zr 95)	10
Zirconium–97 (Zr 97)	10
Any radioactive material not	

Radioactive Material	Micro–curies
listed above other than alpha–emitting radioactive material	0.1
Any alpha emitting radioactive material not listed above other than transuranic radioactive material	0.01

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Repeals

Rule 1200-02-10-.14 Specific Licenses for Certain Groups of Medical Uses of Radioactive Material is repealed and the table of Contents amended by deleting the previous title of the rule and replacing it with the word "Repealed".

1200–02–10–.14 REPEALED

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Rule 1200-02-10-.33 Acceptable Training and Experience for Medical Uses of Radioactive Material is repealed and the table of Contents amended by deleting the previous title of the rule and replacing it with the word "Repealed".

1200–02–10–.33 REPEALED

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Rule 1200-02-10-.35 Training for an Authorized Nuclear Pharmacist is repealed and the table of Contents amended by deleting the previous title of the rule and replacing it with the word "Repealed".

1200–02–10–.35 REPEALED

Authority: T.C.A. §§ 68–202–203 and 68–202–206.

Paragraph (3) of Rule 1200-02-11-.15 Termination of License is amended by adding subparagraph (c) so that subparagraph (c) shall read as follows:

(c) That the records required by have been sent to the party responsible for institutional control of the disposal site and a copy has been sent to the Division immediately prior to license termination.

Authority: T.C.A. §§ 68–202–203 and 68–202–206.