

## G.O.C. STAFF RULE ABSTRACT

DEPARTMENT: Environment and Conservation

DIVISION: Radiological Health

SUBJECT: Rule Reorganization

STATUTORY AUTHORITY: Tennessee Code Annotated, Section 68-202-101 et seq.

EFFECTIVE DATES: May 22, 2012 through June 30, 2013

FISCAL IMPACT: Minimal

STAFF RULE ABSTRACT:

These rulemaking changes reflect a reorganization of all TDEC rules in order to be more logical and user friendly. This rulemaking affects Chapters 1200-02-04, 1200-02-05, 1200-02-06, 1200-02-07, 1200-02-08, 1200-02-09, 1200-02-10, 1200-02-11 and 1200-02-12. Its various additions and modifications will incorporate:

- a. Changes to the numbering designation of Radiological Health rules from 1200-02 to 0400-20;
- b. Correcting typographical errors throughout all Chapters; and
- c. Deleting obsolete language.

## Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

No comments were received during the comment period.

### Regulatory Flexibility Addendum

Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

- (1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule:

This rulemaking that changes the rule numbers from Chapter 1200-20-07 and that makes other housekeeping changes makes no substantive changes. Therefore, there is no impact on small business.

- (2) The projected reporting, recordkeeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

There are no projected additional reporting, recordkeeping or administrative costs as a result of this rulemaking.

- (3) A statement of the probable effect on impacted small businesses and consumers:

There is no expected adverse affect on small businesses as a result of this rulemaking.

- (4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business:

The Department is unaware of alternatives to the proposed rules.

- (5) A comparison of the proposed rule with any federal or state counterparts:

There is no exact match with any federal or state counterparts.

- (6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

Due to the administrative nature of this rulemaking small businesses could not be exempt from this rulemaking.

## Impact on Local Governments

Pursuant to T.C.A. 4-5-220 and 4-5-228 “any rule to proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The Department does not anticipate that these amended rules will have a financial impact on local governments.

DEADLINE

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Sequence Number: 02-18-12  
Rule ID(s): 5159-5/60  
File Date: 02/22/2012  
Effective Date: 05/22/2012

# Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

<b>Agency/Board/Commission:</b>	Environment and Conservation
<b>Division:</b>	Radiological Health
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**Revision Type (check all that apply):**

- Amendment
- New
- Repeal

**Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)**

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0400-20-07	Use of Radionuclides in the Healing Arts
Rule Number	Rule Title
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0400-20-07-.03	Reserved
0400-20-07-.04	Reserved
0400-20-07-.05	Definitions
0400-20-07-.06	Other Federal and State Requirements
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0400-20-07-.08	Maintenance of Records
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1200-02-07-.113	Report of a Leaking Source

(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://fn.gov/sos/rules/1360/1360.htm>)

Repeal

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

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

New Rules

Chapter 0400-20-07  
Use of Radionuclides in the Healing Arts

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0400-20-07-.71	Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units	0400-20-07-.97	Records of Radiation Surveys of Patients and Human Research Subjects
0400-20-07-.72	Periodic Spot-Checks for Teletherapy Units	0400-20-07-.98	Records of Brachytherapy Source Accountability
0400-20-07-.73	Periodic Spot-Checks for Remote Afterloader Units	0400-20-07-.99	Records of Calibration Measurements of Brachytherapy Sources
0400-20-07-.74	Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units	0400-20-07-.100	Records of Decay of Strontium-90 Sources for Ophthalmic Treatments
0400-20-07-.75	Additional Technical Requirements for Mobile Remote Afterloader Units	0400-20-07-.101	Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
0400-20-07-.76	Radiation Surveys	0400-20-07-.102	Records of Safety Procedures
0400-20-07-.77	Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units	0400-20-07-.103	Records of Dosimetry Equipment
0400-20-07-.78	Therapy-Related Computer Systems	0400-20-07-.104	Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations
0400-20-07-.79	Reserved	0400-20-07-.105	Records of Periodic Spot-Checks for Teletherapy Units
0400-20-07-.80	Training for Use of Remote Afterloader Unit, Teletherapy Units and Gamma Stereotactic Radiosurgery Units	0400-20-07-.106	Records of Periodic Spot-Checks for Remote Afterloader Units
0400-20-07-.81	Other Medical Uses of Radioactive Material or Radiation from Radioactive Material	0400-20-07-.107	Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Unit
0400-20-07-.82	Records of Authority and Responsibilities for Radiation Protection Programs	0400-20-07-.108	Records of Additional Technical Requirements for Mobile Remote Afterloader Units
0400-20-07-.83	Records of Radiation Protection Program Changes	0400-20-07-.109	Records of Surveys of Therapeutic Treatment Units
0400-20-07-.84	Records of Written Directives	0400-20-07-.110	Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
0400-20-07-.85	Reserved	0400-20-07-.111	Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources
0400-20-07-.86	Reserved	0400-20-07-.112	Report of Procedures for Administrations Requiring a Written Directive
0400-20-07-.87	Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material	0400-20-07-.113	Report of a Leaking Source
0400-20-07-.88	Records of Radiation Survey Instrument Calibrations		
0400-20-07-.89	Records of Dosages of Unsealed Radioactive Material for Medical Use		
0400-20-07-.90	Reserved		
0400-20-07-.91	Records of Surveys for Ambient Radiation Exposure Rate		

~~4200-02-07-.01~~ 0400-20-07-.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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~4200-02-07-.02~~ 0400-20-07-.02 Scope.

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

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

~~4200-02-07-.03~~ 0400-20-07-.03 Reserved.

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

~~4200-02-07-04~~ ~~0400-20-07-04~~ Reserved.

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

~~4200-02-07-05~~ ~~0400-20-07-05~~ Definitions.

When used in this Rule Chapter, the following terms have the meanings given below unless otherwise specified:

- (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 ~~4200-02-07-24~~ paragraph (1) of Rule 0400-20-07-24 and ~~4200-02-07-27~~ Rule 0400-20-07-27; 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 ~~4200-02-07-25~~ paragraph (1) of Rule 0400-20-07-25 and ~~4200-02-07-27~~ Rule 0400-20-07-27; 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 ~~4200-02-10-13~~ part (10)(b)4 of Rule 0400-20-10-13.
- (5) "Authorized user" means a physician, dentist, or podiatrist who:
- (a) Meets the requirements in ~~4200-02-07-27~~ Rule 0400-20-07-27 and ~~4200-02-07-39~~ subparagraph (1)(a) of Rule 0400-20-07-39, 4200-02-07-43 subparagraph (1)(a) of Rule 0400-20-07-43, 4200-02-07-47 subparagraph (1)(a) of Rule 0400-20-07-47, 0400-20-07-48 subparagraph (1)(a) of Rule 0400-20-07-48, 4200-02-07-49 subparagraph (1)(a) of Rule 0400-20-07-49, 0400-20-07-59 subparagraph (1)(a) of Rule 0400-20-07-59, 4200-02-07-60 Rule 0400-20-07-60, 4200-02-07-62 subparagraph (1)(a) of Rule 0400-20-07-62, or 4200-02-07-80 subparagraph (1)(a) of Rule 0400-20-07-80; 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 ~~4200-02-07-36~~ Rule 0400-20-07-36.
- (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) "Division" means the Division of Radiological Health.
- (13) "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.
- (14) "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.

- (15) "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.
- (16) "Manual brachytherapy" means a type of therapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed or inserted.
- (17) "Medical institution" means an organization in which more than one medical discipline is practiced.
- (18) "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.
- (19) "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.
- (20) "Misadministration" means an event that meets the criteria in ~~4200-02-05-145~~ Rule 0400-20-05-145.
- (21) "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.
- (22) "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.
- (23) "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.
- (24) "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.
- (25) "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.
- (26) "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.
- ~~(45)~~(27) "Positron Emission Tomography (PET) radionuclide production facility" is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.
- ~~(27)~~(28) "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.
- ~~(28)~~(29) "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:
- (a) In a written directive as specified in ~~4200-02-07-20~~ Rule 0400-20-07-20; or
  - (b) In accordance with the directions of the authorized user for procedures performed under ~~4200-02-07-38~~ Rules 0400-20-07-38 and ~~4200-02-07-40~~ 0400-20-07-40.
- ~~(29)~~(30) "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.
- ~~(30)~~(31) "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.
- ~~(31)~~(32) "Radiation safety officer" means an individual who meets the requirements in ~~4200-02-07-23~~ paragraph (1) or subparagraph (3)(a) of Rule 0400-20-07-23 and ~~4200-02-07-27~~ Rule 0400-20-07-27, 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.
- ~~(32)~~(33) "Radioactive drug" means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.
- ~~(33)~~(34) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
- ~~(34)~~(35) "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.
- ~~(35)~~(36) "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.
- ~~(36)~~(37) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
- ~~(37)~~(38) "Teletherapy," for the purpose of 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.
- ~~(38)~~(39) "Temporary job site" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.
- ~~(39)~~(40) "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.
- ~~(40)~~(41) "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.
- ~~(41)~~(42) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
- ~~(42)~~(43) "Type of use" means use of radioactive material under ~~4200-02-07-38~~ Rule 0400-20-07-38, 4200-02-07-40, 0400-20-07-40, 4200-02-07-44, 0400-20-07-44, 4200-02-07-51, 0400-20-07-51, 4200-02-07-61, 0400-20-07-61, 4200-02-07-63, 0400-20-07-63 or 4200-02-07-81, 0400-20-07-81.

~~(43)~~(44) "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.

~~(44)~~(45) "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~~ Rule 0400-20-07-20.

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

~~1200-02-07-06~~ 0400-20-07-06 Other Federal and State Requirements.

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

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

~~1200-02-07-07~~ 0400-20-07-07 Provisions for the Protection of Human Research Subjects.

- (1) A licensee may conduct research involving human subjects using radioactive material provided that:
  - (a) 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)~~ subparagraph (a) of this paragraph shall be conducted using radioactive material authorized for medical use in the license; and
  - (c) Nothing in ~~1200-02-07-07~~ this rule relieves licensees from complying with the other requirements in this rule.

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

~~1200-02-07-08~~ 0400-20-07-08 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. A licensee shall maintain adequate safeguards against tampering with and loss of records.

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

~~1200-02-07-09~~ 0400-20-07-09 Implementation.

- (1) A licensee shall implement the provisions in this rule on ~~(the effective date of these rules)~~ March 21, 2010.
- (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]~~ March 21, 2010, 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]~~ March 21, 2010, 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 0400-20-07-66, 1200-02-07-72 0400-20-07-72, 1200-02-07-73 0400-20-07-73~~ and ~~1200-02-07-74 0400-20-07-74~~ until there is a license amendment or renewal that modifies the license condition.

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

~~1200-02-07-10 0400-20-07-10~~ 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, the U.S. Nuclear Regulatory Commission, or an Agreement State or as allowed in paragraphs (2) and (3) of this rule.
- (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~~ Rule 0400-20-07-19, unless prohibited by a 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~~ Rule 0400-20-07-19 unless prohibited by a license condition.

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

~~1200-02-07-11 0400-20-07-11~~ 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 Rules 0400-20-07-38, 1200-02-07-40 0400-20-07-40, 1200-02-07-44 0400-20-07-44, 1200-02-07-51 0400-20-07-51, 1200-02-07-61 0400-20-07-61, 1200-02-07-63 0400-20-07-63, and 1200-02-07-81 0400-20-07-81~~ must be made by:
  - (a) Filing with the Division the original application in duplicate on a form prescribed by the Division; and
  - (b) Submitting applicable procedures required by ~~1200-02-07-66 Rules 0400-20-07-66, 1200-02-07-72 0400-20-07-72, 1200-02-07-73 0400-20-07-73, and 1200-02-07-74 0400-20-07-74.~~
- (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 ~~1200-02-07-66 Rules 0400-20-07-66, 1200-02-07-72 0400-20-07-72, 1200-02-07-73 0400-20-07-73, and 1200-02-07-74 0400-20-07-74.~~
- (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~~ Rule 0400-20-07-81 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;

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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) An 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 ~~4200-10-13~~ paragraph (4) of Rule 0400-20-10-13 may apply for a specific license of broad scope.

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

~~4200-02-07-12~~ 0400-20-07-12 Reserved.

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

~~4200-02-07-13~~ 0400-20-07-13 License Amendments.

- (1) A licensee shall apply for and must receive a license amendment:
- (a) Before the licensee 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 the licensee 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 ~~4200-02-07-27~~ Rule 0400-20-07-27 and ~~4200-02-07-39~~ subparagraph (1)(a) of Rule 0400-20-07-39, ~~4200-02-07-43~~ subparagraph (1)(a) of Rule 0400-20-07-43, ~~4200-02-07-47~~ subparagraph (1)(a) of Rule 0400-20-07-47, ~~4200-02-07-48~~ subparagraph (1)(a) of Rule 0400-20-07-48, ~~4200-02-07-49~~ subparagraph (1)(a) of Rule 0400-20-07-49, ~~4200-02-07-59~~ subparagraph (1)(a) of Rule 0400-20-07-59, ~~4200-02-07-62~~ subparagraph (1)(a) of Rule 0400-20-07-62, ~~4200-02-07-80~~ subparagraph (1)(a) of Rule 0400-20-07-80;
    2. For an authorized nuclear pharmacist, an individual who meets the requirements in ~~4200-02-07-25~~ paragraph (1) of Rule 0400-20-07-25 and ~~4200-02-07-27~~ Rule 0400-20-07-27;
    3. For an authorized medical physicist, an individual who meets the requirements in ~~4200-02-07-24~~ paragraph (1) of Rule 0400-20-07-24 and ~~4200-02-07-27~~ Rule 0400-20-07-27;
    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 the licensee changes Radiation Safety Officers, except as provided in ~~1200-02-07-17~~ paragraph (3) of Rule ~~0400-20-07-17~~;
- (d) Before the licensee receives radioactive material in excess of the amount or in a different physical or chemical form than is authorized on the license;
- (e) Before the licensee adds to or changes the areas of use identified in the application or on the license;
- (f) Before the licensee changes the address(es) of use identified in the application or on the license;
- (g) Before the licensee changes statements, representations, and procedures which are incorporated into the license; and
- (h) Before the licensee releases licensed facilities for unrestricted use.

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

~~1200-02-07-14~~ ~~0400-20-07-14~~ Notifications.

- (1) A licensee shall provide to the Division a copy of the board certification, the Nuclear Regulatory Commission, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual no later than ~~thirty~~ 30 days after the date that the Licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist, pursuant to ~~Rule 1200-02-07-13~~ subparagraph (1)(b) of Rule ~~0400-20-07-13~~;
- (2) A licensee shall notify the Division no later than ~~thirty~~ 30 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 ~~Rule 1200-02-10-16~~ paragraph (2) of Rule ~~0400-20-10-16~~; 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 Rule ~~1200-02-07-38~~ ~~0400-20-07-38~~ or ~~1200-02-07-40~~ ~~0400-20-07-40~~;
- (3) The licensee shall send the documents required in this rule to the Division at the address listed in Rule ~~1200-02-04-07~~ ~~0400-20-04-07~~.

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

~~1200-02-07-15~~ ~~0400-20-07-15~~ 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~~ paragraph (4) of Rule ~~0400-20-07-11~~ regarding the need to file an amendment to the license for medical use of radioactive material, as described in ~~1200-02-07-81~~ Rule ~~0400-20-07-81~~;
- (2) The provisions of ~~1200-02-07-13~~ subparagraph (1)(b) of Rule ~~0400-20-07-13~~ 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~~ subparagraph (1)(e) of Rule ~~0400-20-07-13~~ regarding additions to or changes in the areas of use at the addresses specified in the license;

- (4) The provisions of ~~Rule 1200-02-07-14~~ subparagraph (2)(a) of Rule 0400-20-07-14 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~~ paragraph (1) of Rule 0400-20-07-22 regarding suppliers for sealed sources.

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

~~1200-02-07-16~~ 0400-20-07-16 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 ~~1200-02-07-14~~ Rule 0400-20-07-11;
  - (b) The applicant has paid applicable fee under ~~1200-02-10-31~~ Rule 0400-20-10-31;
  - (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~~ 0400-20-10.
- (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~~ Rule 0400-20-07-35.
- (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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-17~~ 0400-20-07-17 Authority and Responsibilities for the Radiation Protection Program.

- (1) In addition to the radiation protection program requirements of ~~1200-02-05-40~~ Rule 0400-20-05-40, 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~~ Rule 0400-20-07-18.
- (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~~ 60 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 2~~ or more different types of use of radioactive material under ~~4200-02-07-44 Rule 0400-20-07-44~~, ~~4200-02-07-51~~ ~~0400-20-07-51~~, ~~4200-02-07-63~~ ~~0400-20-07-63~~, and ~~4200-02-07-81~~ ~~0400-20-07-81~~, or ~~two 2~~ or more types of units under ~~4200-02-07-63~~ ~~Rule 0400-20-07-63~~ 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 ~~4200-02-07-82~~ ~~Rule 0400-20-07-82~~.
- (9) A licensee shall retain a record of actions taken under paragraphs (1), (2), and (5) of this rule in accordance with ~~4200-02-07-82~~ ~~Rule 0400-20-07-82~~.

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

~~4200-02-07-18~~ ~~0400-20-07-18~~ 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 ~~4200-02-07-13~~ ~~Rule 0400-20-07-13~~;
  - (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 ~~4200-02-07-83~~ ~~Rule 0400-20-07-83~~.

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

~~4200-02-07-19~~ ~~0400-20-07-19~~ 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 ~~4200-02-07-10~~ paragraph (2) of Rule 0400-20-07-10, 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, as allowed by ~~4200-02-07-10~~ paragraph (3) of Rule 0400-20-07-10, 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.
- (3) 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~4200-02-07-20~~ 0400-20-07-20 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 ( $\mu$ Ci)), 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~~ 48 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  $\mu$ Ci) 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:

- (1) Before implantation: Treatment site, the radionuclide, and dose; and
  - (2) 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~~ 48 hours of the oral revision.
- (4) The licensee shall retain a copy of the written directive in accordance with ~~1200-02-07-84~~ Rule 0400-20-07-84.

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

~~1200-02-07-21~~ 0400-20-07-21 Procedures for Administrations Requiring a Written Directive.

- (1) For any administration requiring a written directive, a 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 activities 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~~ Rule 0400-20-07-63 or ~~1200-02-07-81~~ 0400-20-07-81.
- (3) A licensee shall retain a copy of the procedures required under paragraph (1) of this rule in accordance with ~~1200-02-07-112~~ Rule 0400-20-07-112.

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

~~1200-02-07-22~~ 0400-20-07-22 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~~ Chapter 0400-20-10 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~~ 0400-20-10 of these regulations or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State;

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

~~1200-02-07-23~~ 0400-20-07-23 Training for Radiation Safety Officer.

Except as provided in ~~1200-02-07-26~~ Rule 0400-20-07-26, a licensee shall require an individual fulfilling the responsibilities of the radiation safety officer under ~~1200-02-07-47~~ Rule 0400-20-07-17 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~~ 20 college credits in physical science;
    - 2. Have ~~five~~ 5 or more years of professional experience in health physics (graduate training may be substituted for no more than ~~two~~ 2 years of the required experience) including at least ~~three~~ 3 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~~ 2 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 Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-43~~ 0400-20-07-43 or ~~1200-02-07-47~~ 0400-20-07-47; 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~~ 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) Radiation biology; and
  - (v) Radiation dosimetry; and
2. ~~One~~ 1 year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a Division, U.S. Nuclear Regulatory Commission 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 ~~4200-02-07-24~~ paragraph (1) of Rule ~~0400-20-07-24~~ 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~4200-02-07-24~~ ~~0400-20-07-24~~ Training for an Authorized Medical Physicist.

Except as provided in ~~4200-02-07-26~~ Rule ~~0400-20-07-26~~, 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~~ 2 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 Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-59~~ 0400-20-07-59 or ~~1200-02-07-80~~ 0400-20-07-80; 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~~ 1 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 (1)(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 Rule ~~1200-02-07-24~~ this rule, Rule ~~1200-02-07-26~~ 0400-20-07-26 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-25~~ 0400-20-07-25 Training for an Authorized Nuclear Pharmacist.

Except as provided in ~~1200-02-07-25~~ Rule 0400-20-07-25, a 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~~ 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than ~~two thousand~~ 2,000 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-26~~ ~~0400-20-07-26~~ 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 March 21, 2010~~, need not comply with the training requirements of ~~1200-02-07-23 Rule 0400-20-07-23~~, ~~1200-02-07-24 0400-20-07-24~~, or ~~1200-02-07-25 0400-20-07-25~~, 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 March 21, 2010~~, 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 Rules 0400-20-07-39~~, ~~1200-02-07-43 0400-20-07-43~~, ~~1200-02-07-47 0400-20-07-47~~, ~~1200-02-07-48 0400-20-07-48~~, ~~1200-02-07-49 0400-20-07-49~~, ~~1200-02-07-59 0400-20-07-59~~, ~~1200-02-07-60 0400-20-07-60~~, ~~1200-02-07-62 0400-20-07-62~~ and ~~1200-02-07-80 0400-20-07-80~~.
- (3) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on Division or NRC licenses for the same uses for which these individuals are authorized.

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

~~1200-02-07-27~~ ~~0400-20-07-27~~ Recentness of Training.

The training and experience specified in ~~1200-02-07-17 Rules 0400-20-07-17~~ through ~~1200-02-07-27 this rule~~ and ~~1200-02-07-38 Rules 0400-20-07-38~~ through ~~1200-02-07-80 0400-20-07-80~~ must have been obtained within the seven (7) 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-28~~ ~~0400-20-07-28~~ 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 Rule 0400-20-07-30~~, 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 Rule 0400-20-07-87~~.

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

~~1200-02-07-29~~ ~~0400-20-07-29~~ Calibration of Survey Instruments.

- (1) A licensee shall calibrate the survey instruments used to show compliance with this Chapter and Chapter ~~1200-02-05 0400-20-05~~ before first use, annually, and following a repair that affects the calibration.

- (2) To satisfy the requirements of ~~1200-02-07-29~~ paragraph (1) of Rule 0400-20-07-29, the licensee shall:
- (a) Calibrate all required scale readings up to 10 millisieverts (1000 millirem) per hour with a radiation source;
  - (b) Calibrate ~~two~~ 2 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) A 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) A licensee shall retain a record of each survey instrument calibration in accordance with ~~1200-02-07-88~~ Rule 0400-20-07-88.
- (5) Calibration of all survey instruments shall be in accordance with an approved procedure or preformed by persons specifically licensed to provide calibration services.

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

~~1200-02-07-30~~ 0400-20-07-30 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 ~~Rule 1200-02-10-13~~ paragraph (10) of Rule 0400-20-10-13 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. A PET radioactive drug producer licensed under ~~Rule 1200-02-10-14~~ paragraph (8) of Rule 0400-20-10-11 or equivalent Agreement State Requirements.
- (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:
    1. A manufacturer or preparer licensed under ~~Rule 1200-02-10-13~~ paragraph (10) of Rule 0400-20-10-13 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, or
    2. A PET radioactive drug producer licensed under ~~Rule 1200-02-10-14~~ paragraph (8) of Rule 0400-20-10-11 or equivalent U.S. Nuclear Regulatory Commission or 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~~ 20 percent.
- (5) A licensee shall retain a record of the dosage determination required by this rule in accordance with ~~4200-02-07-89~~ Rule 0400-20-07-89.

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

~~4200-02-07-31~~ 0400-20-07-31 Authorization for Calibration, Transmission, and Reference Sources.

- (1) Any person authorized by ~~4200-02-07-10~~ Rule 0400-20-07-10 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 ~~4200-02-10~~ 0400-20-10 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 ~~4200-02-10-13~~ paragraph (12) of these regulations Rule 0400-20-10-13, 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  $\mu$ Ci); or
    - 2. 1000 times the quantities in Schedule RHS 8-30 Chapter ~~4200-02-10~~ 0400-20-10; and
  - (e) Technetium-99m in amounts as needed.

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

~~4200-02-07-32~~ 0400-20-07-32 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  $\mu$ Ci) 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 ~~1200-02-06~~ 0400-20-05 and ~~1200-02-10~~ 0400-20-10; and
  - (b) File a report within ~~five~~ 5 days of the leak test in accordance with ~~1200-02-07-113~~ Rule 0400-20-07-113.
- (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~~ Rule 0400-20-07-111.

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

~~1200-02-07-33~~ 0400-20-07-33 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-34~~ 0400-20-07-34 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 be 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 ~~1200-02-07-36~~ Rule 0400-20-07-36.
- (9) A licensee shall retain a record of each survey in accordance with ~~1200-02-07-91~~ Rule 0400-20-07-91.

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

~~1200-02-07-36~~ 0400-20-07-36 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).<sup>1</sup>
- (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) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with ~~1200-02-07-92~~ Rule 0400-20-07-92.
- (4) A licensee shall maintain a record of instructions provided to breast-feeding women in accordance with ~~1200-02-07-92~~ Rule 0400-20-07-92.

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

~~1200-02-07-36~~ 0400-20-07-36 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~~ 0400-20-05; and

<sup>1</sup> 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 mobile medical service may not have radioactive 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 subparagraph (1)(a) of this rule and the record of each survey required in subparagraph (1)(d) of this rule in accordance with ~~1200-02-07-93~~ paragraphs (1) and (2) of Rule ~~0400-20-07-93~~, respectively.

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

~~1200-02-07-37~~ 0400-20-07-37 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~~ Rule ~~0400-20-07-94~~.

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

~~1200-02-07-38~~ 0400-20-07-38 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 ~~Rule 1200-02-07-20~~ paragraph (2) of Rule ~~0400-20-07-20~~, a licensee may use any unsealed radioactive material, prepared for medical use for uptake, dilution, or excretion that is:
  - (a) Obtained from:
    - 1. A manufacturer or preparer licensed under ~~1200-02-10-13~~ paragraph (10) of Rule ~~0400-20-10-13~~ or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or
    - 2. A PET radioactive drug producer licensed under ~~Rule 1200-02-10-14~~ paragraph (8) of Rule ~~0400-20-10-11~~ or equivalent Agreement State requirements; or
  - (b) Excluding production of PET radionuclides, prepared by:
    - 1. An authorized nuclear pharmacist;
    - 2. A physician who is an authorized user and who meets the requirements specified in Rule ~~1200-02-07-43~~ 0400-20-07-43, or Rule ~~1200-02-07-47~~ 0400-20-07-47 and Rule ~~1200-02-07-43~~ item (1)(c)1(ii)(VII) of Rule ~~0400-20-07-43~~; or
    - 3. An individual under the supervision, as specified in Rule ~~1200-02-07-19~~ 0400-20-07-19 of the authorized nuclear pharmacist in part 1 of this subparagraph or the physician who is an authorized user in part 2 of this subparagraph; 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~4200-02-07-39~~ 0400-20-07-39 Training for Uptake, Dilution, and Excretion Studies.

- (1) Except as provided in ~~4200-02-07-26~~ Rule 0400-20-07-26, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under ~~4200-02-07-38~~ Rule 0400-20-07-38 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 part (1)(c)2 of this ~~rule~~ paragraph. To be recognized, a specialty board shall require a candidate for certification to:
1. Have 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 ~~4200-02-07-43~~ Rule 0400-20-07-43 or ~~4200-02-07-47~~ 0400-20-07-47 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~~ six 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 Rule ~~4200-02-07-26~~ 0400-20-07-26, ~~4200-02-07-39~~ this rule, ~~4200-02-07-43~~ Rule 0400-20-07-43, or ~~4200-02-07-47~~ 0400-20-07-47 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 Rule ~~1200-02-07-26~~ ~~0400-20-07-26~~, ~~1200-02-07-39~~ this rule, ~~1200-02-07-43~~ Rule 0400-20-07-43, or ~~1200-02-07-47~~ 0400-20-07-47 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 Rule ~~1200-02-07-38~~ 0400-20-07-38.

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

~~1200-02-07-40~~ 0400-20-07-40 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~~ paragraph (2) of Rule 0400-20-07-20 that is:
- (a) Obtained from:
    - 1. A manufacturer or preparer licensed under ~~Rule 1200-02-10-13~~ paragraph (10) of Rule 0400-20-10-13 or equivalent regulations of another Agreement State or U.S. Nuclear Regulatory Commission requirements; or
    - 2. A PET radioactive drug producer licensed under ~~Rule 1200-02-10-11~~ paragraph (8) of Rule 0400-20-10-11 or equivalent Agreement State requirements; or
  - (b) Excluding production of PET radionuclides prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in ~~Rule 1200-02-07-43~~ 0400-20-07-43, or ~~Rule 1200-02-07-47~~ 0400-20-07-47 and ~~Rule 1200-02-07-43~~ item (1)(c)1(ii)(VII) of Rule 0400-20-07-43, or an individual under the supervision of either as specified in ~~Rule 1200-02-07-19~~ 0400-20-07-19; 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~4200-02-07-41~~ 0400-20-07-41 Radionuclide Contaminants.

- (1) A licensee shall not administer to humans a radiopharmaceutical that contains:
- (a) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15  $\mu$ Ci of Mo-99 per mCi of Tc-99m); or
  - (b) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02  $\mu$ Ci of Sr-82 per mCi of Rb-82 chloride), or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2  $\mu$ Ci of Sr-85 per mCi of Rb-82).
- (2) To demonstrate compliance with paragraph (1) of this rule, a 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; and
  - (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 ~~4200-02-07-95~~ Rule 0400-20-07-95.
- (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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~4200-02-07-42~~ 0400-20-07-42 Reserved.

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

~~4200-02-07-43~~ 0400-20-07-43 Training for Imaging and Localization Studies.

- (1) Except as provided in ~~4200-02-07-26~~ Rule 0400-20-07-26, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under ~~4200-02-07-40~~ Rule 0400-20-07-40 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 ~~4200-02-07-47~~ Rule 0400-20-07-47 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, Rule ~~1200-02-07-26~~ 0400-20-07-26, or item (VII) of this subpart and Rule ~~1200-02-07-47~~ 0400-20-07-47 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, Rule ~~1200-02-07-26~~ 0400-02-07-26, or Rule ~~120-02-07-47~~ 0400-20-07-47 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 Rules ~~1200-02-07-38~~ 0400-20-07-38 and ~~1200-02-07-40~~ 0400-20-07-40.

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

~~1200-02-07-44~~ 0400-20-07-44 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;

1. A manufacturer or preparer licensed under ~~Rule 1200-02-07-10-13~~ paragraph (10) of Rule 0400-20-07-10 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or
  2. A PET radioactive drug producer licensed under ~~Rule 1200-02-10-11~~ paragraph (8) of Rule 0400-20-10-11 or equivalent Agreement State requirements; or
- (b) Excluding production of PET radionuclides prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in ~~Rule 1200-02-07-43~~ 0400-20-07-43, ~~Rule 1200-02-07-47~~ 0400-20-07-47, or an individual under the supervision of either as specified in ~~Rule 1200-02-07-19~~ 0400-20-07-19; 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-45~~ 0400-20-07-45 Safety Instructions.

- (1) In addition to the requirements of ~~1200-02-04-12~~ Rule 0400-20-04-12:
  - (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~~ Rule 0400-20-07-35. 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~~ 0400-20-05;
      - (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~~ Rule 0400-20-07-96.

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

~~1200-02-07-46~~ 0400-20-07-46 Safety Precautions.

- (1) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with ~~1200-02-07-35~~ Rule 0400-20-07-35, 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~~ Rule 0400-20-07-35;
  - (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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-47~~ 0400-20-07-47 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.

- (1) Except as provided in ~~1200-02-07-26~~ Rule 0400-20-07-26, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under ~~1200-02-07-44~~ Rule 0400-20-07-44 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 item (1)(b)1(ii)(VI) and part (1)(b)2 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 a candidate 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. Have 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, Rule ~~1200-02-07-26~~ 0400-20-07-26 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~~ 3 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. Have obtained written attestation that the individual has satisfactorily completed the requirements in part (a)1 and item (b)1(ii)(VI) of this paragraph or part 1 of this subparagraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Rule ~~1200-02-07-44~~ 0400-20-07-44. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, Rule ~~1200-02-07-26~~ 0400-20-07-26 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-48~~ ~~0400-20-07-48~~ 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 Millicuries).

- (1) Except as provided in ~~1200-02-07-26~~ Rule 0400-20-07-26, a 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 and who meets the requirements in part (c)3 of this paragraph; (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~~ Rule 0400-20-07-47 for uses listed in ~~1200-02-07-47~~ subitem (1)(b)1(ii)(VI) or II of Rule 0400-20-07-47, ~~1200-02-07-49~~ Rule 0400-20-07-49, 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 Rule 1200-02-07-26 0400-20-07-26, 1200-02-07-47 0400-20-07-47, 1200-02-07-48 0400-20-07-48, 1200-02-07-49 0400-20-07-49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements in Rule 1200-02-07-47 subparagraph (1)(b) of Rule 0400-20-07-47, must also have experience in administering dosages as specified in Rule 1200-02-07-47 subitem (1)(b)1(ii)(VI) or II of Rule 0400-20-07-47. 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 Rule ~~1200-02-07-44~~ 0400-20-07-44. The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-47~~ 0400-20-07-47, ~~1200-02-07-48~~ 0400-20-07-48, ~~1200-02-07-49~~ 0400-20-07-49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirement in Rule ~~1200-02-07-47~~ 0400-20-07-47 subparagraph (1)(b) of Rule 0400-20-07-47, must also have experience in administering dosages as specified in Rule ~~1200-02-07-47~~ 0400-20-07-47 subitem (1)(b)1(ii)(VI) or II of Rule 0400-20-07-47.

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

~~1200-02-07-49~~ 0400-20-07-49 Training for the Oral Administration of Sodium Iodine I-131 Requiring a written Directive in Quantities Greater than 1.22 Gigabecquerels (33 Millicuries).

- (1) Except as provided in ~~1200-02-07-26~~ Rule 0400-20-07-26, a 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, and who meets the requirements in part (1)(c)3 of this rule (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~~ Rule 0400-20-07-47 for uses listed in ~~1200-02-07-47~~ subitem (1)(b)1(ii)(VI)II of Rule 0400-20-07-47, 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 Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-47~~ 0400-20-07-47, ~~0400-20-07-49~~ this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in Rule ~~1200-02-07-47~~ 0400-20-07-47 subparagraph (1)(b) of Rule 0400-20-07-47, must have experience in administering dosages as specified in Rule ~~1200-02-07-47~~ 0400-20-07-47 subitem (1)(b)1(ii)(VI)II of Rule 0400-20-07-47. 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 Rule ~~1200-02-07-44~~ 0400-20-07-44. The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-47~~ 0400-20-07-47, ~~1200-02-07-49~~ this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in Rule ~~1200-02-07-47~~ subparagraph (1)(b) of Rule 0400-20-07-47, must have experience in administering dosages as specified in Rule ~~1200-02-07-47~~ subitem (1)(b)1(ii)(VI)II of Rule 0400-20-07-47.

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

~~1200-02-07-50~~ 0400-20-07-50 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

- (1) Except as provided in Rule ~~1200-02-07-26~~ 0400-20-07-26, a 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 Rule ~~1200-02-07-47~~ 0400-20-07-47 for uses listed in Rule ~~1200-02-07-47~~ subitem (1)(b)1(ii)(VI)III or ~~1200-02-07-47(1)(b)1(ii)(VI)~~ IV of Rule 0400-20-07-47, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or
  - (b) Is an authorized user under Rule ~~1200-02-07-59~~ 0400-20-07-59 or ~~1200-02-07-80~~ 0400-20-07-80, 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 Rule ~~1200-02-07-59~~ 0400-20-07-59 or ~~1200-02-07-80~~ 0400-20-07-80, 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 Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-47~~ 0400-20-07-47 or ~~1200-02-07-50~~ this rule, 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 Rule ~~1200-02-007-47~~ 0400-20-07-47 must have experience in administering dosages as specified in Rule ~~1200-02-07-47~~ subitems (1)(b)1(ii)(VI)III and/or IV of Rule 0400-20-07-47. 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~~ 3 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~~ 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and
3. 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 Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-47~~ 0400-20-07-47, ~~1200-02-07-50~~ this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in Rule ~~1200-02-07-47~~ 0400-20-07-47, must have experience in administering dosages as specified in Rule ~~1200-02-07-47~~ subitems (1)(b)1(ii)(VI)III and/or IV of Rule 0400-20-07-47.

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

~~1200-02-07-54~~ 0400-20-07-51 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 ~~4200-02-07-22~~ Rule 0400-20-07-22 are met.

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

~~4200-02-07-52~~ 0400-20-07-52 Surveys after Source Implants and Removal.

- (1) Immediately after implanting sources in a patient or a human research subject, a 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, a 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 ~~4200-02-07-97~~ Rule 0400-20-07-97.

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

~~4200-02-07-53~~ 0400-20-07-53 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 ~~4200-02-07-98~~ Rule 0400-20-07-98.

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

~~4200-02-07-54~~ 0400-20-07-54 Safety Instructions.

- (1) In addition to the requirements of ~~4200-02-07-12~~ Rule 0400-20-04-12:
  - (a) A 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 ~~4200-02-07-35~~ Rule 0400-20-07-35. 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 ~~4200-02-05-60~~ subparagraph (1)(a) of Rule 0400-20-05-60; and
      - (ii) Visitation authorized in accordance with ~~4200-02-05-60~~ paragraph (2) of Rule 0400-20-05-60; 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 ~~4200-02-07-96~~ Rule 0400-20-07-96.

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

~~1200-02-07-55~~ 0400-20-07-55 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~~ Rule 0400-20-07-35, 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-56~~ 0400-20-07-56 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~~ March 21, 2010, a licensee shall have:
  - (a) Determined the source output or activity using a dosimetry system that meets the requirements of ~~1200-02-07-68~~ Rule 0400-20-07-68;
  - (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~~ Rule 0400-20-07-99.

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

~~1200-02-07-57~~ 0400-20-07-57 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~~ Rule 0400-20-07-56.

- (2) A licensee shall retain a record of the activity of each strontium-90 source in accordance with ~~4200-02-07-100~~ Rule 0400-20-07-100.

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

~~4200-02-07-58~~ 0400-20-07-58 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~4200-02-07-59~~ 0400-20-07-59 Training for Use of Manual Brachytherapy Sources.

- (1) Except as provided in Rule ~~4200-02-07-26~~ 0400-20-07-26, a licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under ~~4200-02-07-51~~ Rule 0400-20-07-51 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, and who meets the requirements in part (b)3 of this paragraph. (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, Rule ~~1200-02-07-26~~ 0400-20-07-26, 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 ~~three~~ 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this rule, Rule ~~1200-02-07-26~~ 0400-20-07-26, 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, Rule ~~1200-02-07-26~~ 0400-20-07-26, 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 Rule ~~1200-02-07-54~~ 0400-20-07-51.

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

~~1200-02-07-60~~ 0400-20-07-60 Training for Ophthalmic Use of Strontium-90.

- (1) Except as provided in ~~1200-02-07-26~~ Rule 0400-20-07-26, a licensee shall require the authorized user of strontium-90 for ophthalmic uses authorized under ~~1200-02-07-54~~ Rule 0400-20-07-51 to be a physician who:
  - (a) is an authorized user under ~~1200-02-07-50~~ Rule 0400-20-07-59 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, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five ~~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 Rule ~~1200-02-07-26~~ 0400-20-07-26, ~~1200-02-07-59~~ 0400-20-07-59, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in subparagraph (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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-61~~ 0400-20-07-61 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-62~~ 0400-20-07-62 Training for Use of Sealed Sources for Diagnosis.

- (1) Except as provided in ~~1200-02-07-26~~ Rule 0400-20-07-26, a licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under ~~1200-02-07-61~~ Rule 0400-20-07-61 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~~ 8 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-63~~ 0400-20-07-63 Use of Sealed Source in Remote Afterloader Unit, Teletherapy 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 ~~4200-02-07-22~~ in paragraph (1) of Rule 0400-20-07-22 are met.

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

~~4200-02-07-64~~ 0400-20-07-64 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 ~~4200-02-07-97~~ Rule 0400-20-07-97.

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

~~4200-02-07-66~~ 0400-20-07-66 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 ~~4200-02-07-101~~ Rule 0400-20-07-101.

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

~~4200-02-07-66~~ 0400-20-07-66 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 ~~4200-02-07-96~~ Rule 0400-20-07-96.
- (7) A licensee shall retain a copy of the procedures required by subparagraphs (1)(d) and (4)(b) of this rule in accordance with ~~4200-02-07-102~~ Rule 0400-20-07-102.

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

~~4200-02-07-67~~ 0400-20-07-67 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-68~~ ~~0400-20-07-68~~ 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~~ 4 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~~ 24 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~~ 2 percent. A 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) A 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) A licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with ~~1200-02-07-103~~ Rule 0400-20-07-103.

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

~~1200-02-07-69~~ 0400-20-07-69 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~~ 5 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~~ 1 year.
- (2) To satisfy the requirement of paragraph (1) of this rule, full calibration measurements must include determination of:
- (a) The output within  $\pm 3$  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 ~~4200-02-07-68~~ paragraph (1) of Rule 0400-20-07-68 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~~ 1 month for cobalt-60, ~~six~~ 6 months for cesium-137, or at intervals consistent with ~~one~~ 1 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 ~~4200-02-07-104~~ Rule 0400-20-07-104.

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

~~4200-02-07-70~~ 0400-20-07-70 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~~ 1 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~~ 1 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  $\pm 5$  percent;
  - (b) Source positioning accuracy to within  $\pm 1$  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 ~~4200-02-07-68~~ paragraph (1) of Rule 0400-20-07-68 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~~ 1 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~~ 1 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~~ Rule 0400-20-07-104.

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

~~1200-02-07-71~~ 0400-20-07-71 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~~ 5 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~~ 1 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  $\pm 3$  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 ~~4200-02-07-68~~ paragraph (1) of Rule 0400-20-07-68 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~~ 1 month for cobalt-60 and at intervals consistent with ~~one~~ 1 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 ~~4200-02-07-104~~ Rule 0400-20-07-104.

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

~~4200-02-07-72~~ 0400-20-07-72 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 ~~4200-02-07-68~~ paragraph (2) of Rule 0400-20-07-68; 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~~ Rule 0400-20-07-105.

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

~~1200-02-07-73~~ 0400-20-07-73 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) A 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 0400-20-07-.106.

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

~~1200-02-07-.74~~ 0400-20-07-.74 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery 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~~ paragraph (2) of Rule 0400-20-07-.68;
    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 ~~4200-02-07-107~~ 0400-20-07-107.

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

~~4200-02-07-75~~ 0400-20-07-75 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 ~~4200-02-07-73~~ Rule 0400-20-07-73, 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 ~~4200-02-07-108~~ Rule 0400-20-07-108.

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

~~4200-02-07-76~~ 0400-20-07-76 Radiation Surveys.

- (1) In addition to the survey requirement in Rule ~~4200-02-07-70~~ 0400-20-05-70, 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) A 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 ~~4200-02-07-109~~ Rule 0400-20-07-109.

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

~~4200-02-07-77~~ 0400-20-07-77 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~~ 5 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 ~~4200-02-07-110~~ Rule 0400-20-07-110.

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

~~4200-02-07-78~~ 0400-20-07-78 Therapy-Related Computer Systems.

- (1) A 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-79~~ ~~0400-20-07-79~~ Reserved.

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

~~1200-02-07-80~~ ~~0400-20-07-80~~ Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

- (1) Except as provided in ~~1200-02-07-26~~ ~~Rule 0400-20-07-26~~, a licensee shall require an authorized user of a sealed source for a use authorized under ~~1200-02-07-63~~ ~~Rule 0400-20-07-63~~ 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~~ 3 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, Rule ~~1200-02-07-26~~ ~~0400-20-07-26~~, 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~~ 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this rule, Rule ~~1200-02-07-26~~ 0400-20-07-26, 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, Rule ~~1200-02-07-26~~ 0400-20-07-26, 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-81~~ 0400-20-07-81 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~~ paragraphs (2), ~~1200-02-07-11~~(3), and ~~1200-02-07-11~~(4) of Rule ~~0400-20-07-11~~; 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-82~~ 0400-20-07-82 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~~ paragraph (1) of Rule ~~0400-20-07-17~~ for ~~five~~ 5 years. The record must include a summary of the actions taken and a signature of licensee management.
- (2) A licensee shall retain a copy of both authority, duties, and responsibilities of the radiation safety officer as required by ~~1200-02-07-17~~ paragraph (5) of Rule ~~0400-20-07-17~~, 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~~ paragraph (2) of Rule ~~0400-20-07-17~~. 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~~ paragraph (8) of Rule 0400-20-07-17 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-83~~ 0400-20-07-83 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~~ paragraph (1) of Rule 0400-20-07-18 for five 5 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-84~~ 0400-20-07-84 Records of Written Directives.

A licensee shall retain a copy of each written directive as required by ~~1200-02-07-20~~ Rule 0400-20-07-20 for three 3 years.

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

~~1200-02-07-85~~ 0400-20-07-85 Reserved.

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

~~1200-02-07-86~~ 0400-20-07-86 Reserved.

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

~~1200-02-07-87~~ 0400-20-07-87 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~~ Rule 0400-20-07-28 for three 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-88~~ 0400-20-07-88 Records of Survey Instrument Calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by ~~1200-02-07-29~~ Rule 0400-20-07-29 for three 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-89~~ 0400-20-07-89 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~~ Rule 0400-20-07-30 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-80~~ 0400-20-07-90 Reserved.

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

~~1200-02-07-81~~ 0400-20-07-91 Records of Surveys for Ambient Radiation Exposure Rate.

A licensee shall retain a record of each survey required by ~~1200-02-07-34~~ Rule 0400-20-07-34 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-82~~ 0400-20-07-92 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~~ paragraph (2) of Rule 0400-20-07-35 were provided to a breast-feeding woman.

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

~~1200-02-07-83~~ 0400-20-07-93 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~~ subparagraph (1)(a) of Rule 0400-20-07-36. 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~~ subparagraph (1)(d) of Rule 0400-20-07-36 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-84~~ 0400-20-07-94 Records of Decay-in-Storage.

A licensee shall maintain records of the disposal of licensed materials, as required by ~~1200-02-07-37~~ Rule 0400-20-07-37, for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-85~~ 0400-20-07-95 Records of Radionuclide Contaminants.

A licensee shall maintain a record of the radionuclide contaminant concentration tests required by ~~1200-02-07-44~~ Rule 0400-20-07-44 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-96~~ 0400-20-07-96 Records of Safety Instruction and Training.

A licensee shall maintain a record of safety instructions and training required by ~~1200-02-07-45~~ Rules 0400-20-07-45, ~~1200-02-07-54~~ 0400-20-07-54, and ~~1200-02-07-56~~ paragraph (4) of Rule 0400-20-07-66 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-97~~ 0400-20-07-97 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~~ Rules 0400-20-07-52 and ~~1200-02-07-64~~ 0400-20-07-64 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-98~~ 0400-20-07-98 Records of Brachytherapy Source Accountability.

- (1) A licensee shall maintain a record of brachytherapy source accountability required by ~~1200-02-07-53~~ Rule 0400-20-07-53 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-99~~ 0400-20-07-99 Records of Calibration Measurements of Brachytherapy Sources.

A licensee shall maintain a record of the calibrations of brachytherapy sources required by ~~1200-02-07-55~~ Rule 0400-20-07-55 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-100~~ 0400-20-07-100 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~~ Rule 0400-20-07-56 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~~ Rule 0400-20-07-56, and for each decay calculation, the date, the source activity, and the signature of the authorized medical physicist.

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

~~1200-02-07-101~~ 0400-20-07-101 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~~ Rule 0400-20-07-65 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-102~~ 0400-20-07-102 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~~ Rule 0400-20-07-66 until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

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

~~1200-02-07-103~~ 0400-20-07-103 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~~ Rule 0400-20-07-68 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~~ paragraphs (1) and (2) of Rule 0400-20-07-68;
  - (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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-104~~ 0400-20-07-104 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~~ Rules 0400-20-07-69, ~~1200-02-07-70~~ 0400-20-07-70, and ~~1200-02-07-71~~ 0400-20-07-71 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-105~~ 0400-20-07-105 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~~ Rule 0400-20-07-72 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-106~~ 0400-20-07-106 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~~ Rule 0400-20-07-73 for ~~three~~ 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-107~~ 0400-20-07-107 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~~ Rule 0400-20-07-74 for three 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-108~~ 0400-20-07-108 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~~ Rule 0400-20-07-75 for three 3 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-109~~ 0400-20-07-109 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~~ Rule 0400-20-07-76 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-110~~ 0400-20-07-110 Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

- (1) A licensee shall maintain a record of the ~~five-~~ 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by ~~1200-02-07-77~~ Rule 0400-20-07-77 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-111~~ 0400-20-07-111 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~~ paragraph (2) of Rule 0400-20-07-32 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~~ paragraph (5) of Rule 0400-20-07-32 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

~~1200-02-07-112~~ 0400-20-07-112 Records for Procedures for Administrations Requiring a Written Directive.

A licensee shall retain a copy of the procedures required by ~~1200-02-07-21~~ paragraph (1) of Rule 0400-20-07-21 for the duration of the license.

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

~~1200-02-07-113~~ 0400-20-07-113 Report of a Leaking Source.

A licensee shall file a report within ~~five~~ 5 days if a leak test required by ~~1200-02-07-32~~ Rule 0400-20-07-32 reveals the presence of 185 Bq (0.005  $\mu$ Ci) 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~~ subparagraph (1)(c) of Rule 0400-20-04-07. 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. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.

**G.O.C. STAFF RULE ABSTRACT**

DEPARTMENT: Environment and Conservation  
DIVISION: Radiological Health  
SUBJECT: Rule Reorganization  
STATUTORY AUTHORITY: Tennessee Code Annotated, Section 68-202-101 et seq.  
EFFECTIVE DATES: May 22, 2012 through June 30, 2013  
FISCAL IMPACT: Minimal  
STAFF RULE ABSTRACT:

These rulemaking changes reflect a reorganization of all TDEC rules in order to be more logical and user friendly. This rulemaking affects Chapters 1200-02-04, 1200-02-05, 1200-02-06, 1200-02-07, 1200-02-08, 1200-02-09, 1200-02-10, 1200-02-11 and 1200-02-12. Its various additions and modifications will incorporate:

- a. Changes to the numbering designation of Radiological Health rules from 1200-02 to 0400-20;
- b. Correcting typographical errors throughout all Chapters; and
- c. Deleting obsolete language.

### **Public Hearing Comments**

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

No comments were received during the comment period.

**Regulatory Flexibility Addendum**

Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

- (1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule:

This rulemaking that changes the rule numbers from Chapter 1200-20-08 and that makes other housekeeping changes makes no substantive changes. Therefore, there is no impact on small business.

- (2) The projected reporting, recordkeeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

There are no projected additional reporting, recordkeeping or administrative costs as a result of this rulemaking.

- (3) A statement of the probable effect on impacted small businesses and consumers:

There is no expected adverse affect on small businesses as a result of this rulemaking.

- (4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business:

The Department is unaware of alternatives to the proposed rules.

- (5) A comparison of the proposed rule with any federal or state counterparts:

There is no exact match with any federal or state counterparts.

- (6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

Due to the administrative nature of this rulemaking small businesses could not be exempt from this rulemaking.

### **Impact on Local Governments**

Pursuant to T.C.A. 4-5-220 and 4-5-228 "any rule to proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The Department does not anticipate that these amended rules will have a financial impact on local governments.

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 Division of Publications  
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For Department of State Use Only

Sequence Number: REDLINE  
 Rule ID(s): \_\_\_\_\_  
 File Date: \_\_\_\_\_  
 Effective Date: \_\_\_\_\_

## Rulemaking Hearing Rule(s) Filing Form

*Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205*

Agency/Board/Commission:	Environment and Conservation
Division:	Radiological Health
Contact Person:	Beth Murphy
Address:	3 <sup>rd</sup> Floor L&C Annex 401 Church Street Nashville, Tennessee
Zip:	37243-1532
Phone:	(615) 532-0392
Email:	<a href="mailto:beth.murphy@tn.gov">beth.murphy@tn.gov</a>

Revision Type (check all that apply):

- Amendment  
 New  
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
0400-20-08	Radiation Safety Requirements for Industrial Radiography
Rule Number	Rule Title
0400-20-08-01	Purpose
0400-20-08-02	Scope
0400-20-08-03	Definitions
0400-20-08-04	Equipment Control
0400-20-08-05	Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants
0400-20-08-06	Precautionary Procedures in Radiographic Operations
0400-20-08-07	Minimum Subjects to be Covered in Training Radiographers
0400-20-08-08	Cabinet Radiography
0400-20-08-09	Fluoroscopic Radiography
0400-20-08-10	Required Administrative Procedures for Industrial Radiography Program
0400-20-08-11	Shielded Room X-Ray Radiography
0400-20-08-12	Reporting Requirements
0400-20-08-13	Reserved
0400-20-08-14	Reserved
0400-20-08-15	Recordkeeping Requirements
0400-20-08-16	Schedule RHS 8-35: Radiographer Certification

Chapter Number	Chapter Title
1200-02-08	Radiation Safety Requirements for Industrial Radiography
Rule Number	Rule Title

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

(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://tn.gov/sos/rules/1360/1360.htm>)

Repeal

Chapter 1200-02-08 Radiation Safety Requirements for Industrial Radiography is repealed.

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

New Rules

Chapter 0400-20-08

Radiation Safety Requirements for Industrial Radiography

Table of Contents

0400-20-08-.01	Purpose	0400-20-08-.08	Cabinet Radiography
0400-20-08-.02	Scope	0400-20-08-.09	Fluoroscopic Radiography
0400-20-08-.03	Definitions	0400-20-08-.10	Required Administrative Procedures for Industrial Radiography Program
0400-20-08-.04	Equipment Control	0400-20-08-.11	Shielded Room X-Ray Radiography
0400-20-08-.05	Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants	0400-20-08-.12	Reporting Requirements
0400-20-08-.06	Precautionary Procedures in Radiographic Operations	0400-20-08-.13	Reserved
0400-20-08-.07	Minimum Subjects To Be Covered In Training Radiographers	0400-20-08-.14	Reserved
		0400-20-08-.15	Recordkeeping Requirements
		0400-20-08-.16	Schedule RHS 8-35: Radiographer Certification

~~1200-02-08-.01~~ 0400-20-08-.01 Purpose.

This Chapter establishes requirements for the use of sources of radiation for industrial radiography operations. Except for the requirements of this Chapter clearly applicable only to devices employing sealed radioactive sources, e.g., ~~1200-02-08-.04~~ paragraphs (1) and (5) of Rule 0400-20-08-.04, both radiation machines and sealed radioactive sources are covered by this Chapter. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

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

~~1200-02-08-.02~~ 0400-20-08-.02 Scope.

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

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

~~1200-02-08-03~~ 0400-20-08-03 Definitions.

- (1) "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions and receive answers to their safety questions.
- (2) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides or comes in contact with the source (e.g., guide tube, control tube, control (drive) cable, removable source stop, 'J' tube and collimator) when it is used as an exposure head.
- (3) "Cabinet radiography" means industrial radiography using radiation machines in an enclosed interlocked cabinet in which:
  - (a) The radiation machine will not operate unless all openings are closed with interlocks activated.
  - (b) The cabinet is so shielded that every location on the exterior meets the conditions for an unrestricted area as defined in Chapter ~~1200-02-05~~ 0400-20-05, and
  - (c) The cabinet is so constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.
  - (d) Baggage entrance and exit openings of airport baggage systems need not be interlocked. All other openings in these systems shall be interlocked. The operator shall be present during operation to ensure no individual enters the device through the baggage entrance or exit opening(s).
- (4) "Certifying entity" means an independent certifying organization meeting the requirements in Appendix A to 10 CFR 34 or an Agreement State meeting the requirements in Appendix A to 10 CFR 34 (see Schedule RHS 8-35, Rule ~~1200-02-08-16~~ 0400-20-08-16).
- (5) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.
- (6) "Control (drive) cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.
- (7) "Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.
- (8) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.
- (9) "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a "source stop".)
- (10) "Field station" means a facility where licensed or registered material may be stored or used and from which equipment is dispatched.
- (11) "Guide tube" (or "projection sheath") means a flexible or rigid tube (i.e., 'J' tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

- (12) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.
- (13) "Independent certifying organization" means an independent organization that meets all of the criteria of appendix A to 10 CFR 34 (see Rule ~~1200-02-08-18~~ 0400-20-08-16).
- ~~(30)~~(14) "Industrial Radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.
- ~~(44)~~(15) "Permanent radiographic installation" means an enclosed shielded room, cell or vault, not located at a temporary job-site, in which radiography is performed.
- ~~(45)~~(16) "Personal supervision" means supervision with the radiographer:
- (a) Physically present at the site where sources of radiation and associated equipment are being used.
  - (b) Observing the radiographer's assistant's performance; and
  - (c) In such proximity that immediate assistance can be given if required.
- ~~(46)~~(17) "Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.
- ~~(47)~~(18) "Radiographer" means any individual who performs or who, in attendance at the site where the radiographic exposure devices are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Division's regulations and the conditions of the license or registration.
- ~~(48)~~(19) "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing and experience criteria.
- ~~(49)~~(20) "Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.
- ~~(20)~~(21) "Radiographic exposure device" (also called a 'camera' or a 'projector') means:
- (a) Any instrument having a sealed source in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure; or
  - (b) Any apparatus that may produce, when the associated controls are operated, one or more forms of radiation used for making a radiographic exposure.
- ~~(24)~~(22) "Radiographic operations" means all activities associated with the presence of sources of radiation in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport); to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.
- ~~(22)~~(23) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.
- ~~(23)~~(24) "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.
- ~~(24)~~(25) "Shielded room x-ray radiography" means industrial radiography using radiation machines that is conducted in an enclosed room.

~~(25)(26)~~ "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

~~(26)(27)~~ "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

~~(27)(28)~~ "Storage area" means any location, facility or vehicle which is used to store or to secure a radiographic exposure device, a storage container or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with or unauthorized removal of the device, container or source.

~~(28)(29)~~ "Storage container" means a container in which sealed sources are secured and stored.

~~(29)(30)~~ "Temporary job site" means a location where industrial radiography is performed and where licensed or registered material may be stored other than the location(s) of use authorized on the specific license or registration.

Authority: T.C.A. §§68-202-101 et seq., 68-202-201 et seq. and 4-5-201 et seq.  
~~1200-02-08-04 0400-20-08-04~~ Equipment Control.

(1) Limits on levels of radiation from storage containers and source changers.

The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface and 10 millirem (0.1 millisieverts) per hour at 1-meter from any exterior surface with the sealed source in the shielded position.

(2) Locking of radiographic exposure devices, storage containers and source changers:

(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental production of radiation or removal of a sealed source from its shielded position. Each radiographic exposure device or storage container shall be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in paragraph ~~1200-02-08-06 (1) of Rule 0400-20-08-06~~. In addition, during radiographic operations a sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

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

(3) Storage precautions:

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

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

(4) Radiation survey instruments:

(a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make physical radiation surveys as required by this chapter and Chapter ~~1200-02-05 0400-20-05~~ of these regulations.

Instrumentation required by this paragraph shall have a range such that 2 millirems (0.02 millisieverts) per hour through 1 rem (0.01 sievert) per hour can be measured.

- (b) Each radiation survey instrument shall be calibrated:
1. At energies appropriate for use and at intervals not to exceed ~~six~~ 6 months and after each instrument servicing, except for battery changes.
  2. Such that accuracy within plus or minus ~~twenty~~ 20 percent (~~±20%~~) can be demonstrated; and
  3. For linear scale instruments, at 2 points located approximately one-third and two-thirds of full scale on each scale; for logarithmic scale instruments, at mid-range of each decade and at 2 points of at least one decade; and for digital instruments, at 3 points between 2 and 1,000 millirems (0.02 and 10 millisieverts) per hour.
- (c) In accordance with Rule ~~1200-02-08-15~~ 0400-20-08-15, the licensee or registrant shall maintain records of calibrations, dates and results thereof for inspection by the Division for ~~three~~ 3 years after the date of calibration.
- (5) Leak testing, repairing, tagging, opening, modifying and replacing of sealed sources:
- (a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Division, the U.S. Nuclear Regulatory Commission, or any Agreement State.
  - (b) Each sealed source shall be tested for leakage at intervals not to exceed ~~six~~ 6 months. In the absence of a certificate from a transferor that a test has been made within the ~~six~~ 6 months prior to the transfer, the sealed source shall not be put into use until tested.
  - (c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to ~~1200-02-10-13~~ subparagraph (6)(e) of Rule 0400-20-10-13. Records of leak test results shall identify each sealed source and its container by serial number and shall be kept in units of microcuries or disintegrations per minute (dpm) and maintained for inspection by the Division for ~~three~~ 3 years after the test is made.
  - (d) Any test conducted pursuant to subparagraphs (b) and (c) of this paragraph that reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Division regulations. Two copies of a report shall be filed within ~~five~~ 5 days after obtaining results of the test with the Division at its office located at L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1632 ~~the address provided in Rule 0400-20-04-07~~, describing the equipment involved, the test results and the corrective action taken.
  - (e) A sealed source that is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least ~~one~~ 1 inch (2.54 centimeters) square bearing the conventional radiation caution symbol, as described in Chapter ~~1200-02-05~~ 0400-20-05, and at least the instructions:

"DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE -  
NOTIFY CIVIL AUTHORITIES IF FOUND"

- (f) Each exposure device using depleted uranium (DU) shielding and an 'S' tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. The analysis shall be

capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and shall be performed by a person specifically authorized by the Division, the U.S. NRC or an Agreement State to perform the analysis.

1. Should such testing reveal the presence of 185 Bq (0.005 microcuries) or more of removable DU contamination, the exposure device shall be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again.
2. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device shall be tested for DU contamination if the interval of storage exceeded 12 months.

(6) Quarterly inventory.

Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation received and possessed by him. The records of the inventories shall be maintained for ~~three~~ 3 years from the date of the inventory for inspection by the Division. The records shall include the quantities and kinds of radioactive material, location of all sources of radiation, and the date of inventory. Each sealed source and each radiographic exposure device shall be identified by serial number.

(7) Utilization logs.

- (a) Each licensee or registrant shall maintain, at the address specified in the license or registration, current utilization logs showing for each source of radiation the following information:
  1. A description (make, model and serial number) of each radiographic exposure device or transport or storage container in which the sealed source is located;
  2. The identity and signature of the radiographer to whom assigned; and
  3. The plant or site where used and dates of use, including the dates removed and returned to storage.
- (b) In accordance with ~~Rule 1200-02-08-04 paragraph (7) Rule 0400-20-08-04~~, the licensee shall retain the logs required by subparagraph (a) of this paragraph for inspection by the Division for ~~three~~ 3 years after the log is made.
- (c) Locations (plant or site) where used and dates of use.

(8) Inspection and maintenance of radiographic exposure devices, source changers, transport and storage containers, associated equipment and survey instruments.

- (a) The licensee shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers prior to use each day the equipment is used to ensure that the equipment is in good working condition, that the sources are adequately shielded and that required labeling is present. Survey instrument operability shall be performed using check sources or other appropriate means. If equipment problems are found, the equipment shall be removed from service until repaired.
- (b) The licensee shall have written procedures for:
  1. Inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers at intervals not to exceed ~~three~~ 3 months, or before the first use thereafter, to assure proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

2. Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program shall include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(9) Permanent radiographic installations.

- (a) Permanent radiographic installations having high radiation area entrance controls of the types described in Chapter ~~1200-02-05~~ 0400-20-05 shall also meet the special requirements in subparagraphs (b) and (c) of this paragraph.
- (b) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed or a radiation area is generated. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed or a radiation area is generated.
- (c) The alarm system shall be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test shall include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry shall be tested monthly. If an entrance control device or an alarm is operating improperly, it shall be immediately labeled as defective and repaired within ~~seven~~ 7 calendar days. The facility may continue to be used during this seven-day period, provided the licensee implements the continuous surveillance requirements of paragraph ~~1200-02-08-06 (1)~~ of Rule 0400-20-08-06 and uses an alarming ratemeter. The licensee or registrant shall retain records of these tests for ~~three~~ 3 years for inspection by the Division.

(10) Performance requirements for sealed source radiographic exposure devices and associated equipment. Equipment utilizing radioactive material used in industrial radiographic operations shall meet the following minimum criteria:

- (a) Each radiographic exposure device and all associated equipment shall meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981) American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018 (ANSI N432). An applicant or licensee may submit engineering analyses to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Division may find this an acceptable alternative to actual testing of the component under the above referenced standard.
- (b) In addition to the requirements specified ~~above~~ in subparagraph (a) of this paragraph, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.
  1. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:
    - (i) Chemical symbol and mass number of the radionuclide in the device;
    - (ii) Activity and the date on which this activity was last measured;
    - (iii) Model (or product code) and serial number of the sealed source;
    - (iv) Manufacturer's identity of the sealed source; and
    - (v) Licensee's name, address and telephone number.
  2. Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable requirements of 10 CFR Part 71.

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

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

1. The coupling between the source assembly and the control cable shall be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
2. The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.
3. The outlet fittings, lock box and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers, which shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

4. (i) Each sealed source or source assembly shall have attached to it or engraved on it, a durable, legible, visible label with the words:

"CAUTION (or "DANGER")-RADIOACTIVE."

- (ii) The label may not interfere with the safe operation of the exposure device or associated equipment.
5. The guide tube shall be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.
6. Guide tubes shall be used when moving the source out of the device.
7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during industrial radiography operations.
8. The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432-1980.
9. Source changers shall provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, shall comply with the requirements of this paragraph.

(e) All radiographic exposure devices and associated equipment in use after January 10, 1996, shall comply with the requirements of this paragraph.

(f) Notwithstanding subparagraph (10)(a) ~~above~~ of this rule, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in American

National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

(11) Labeling, storage and transportation.

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

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

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

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

~~1200-02-08-05~~ 0400-20-08-05 Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants.

(1) Training.

- (a) The licensee or registrant shall not permit any individual to act as a radiographer as defined in this Chapter until such individual:
1. Has been instructed in the subjects outlined in ~~1200-02-08-07~~ Rule 0400-20-08-07 and has demonstrated understanding thereof by successful completion of a written test and a field examination on the subjects covered that has been approved by the Division;
  2. Has received copies of and instruction in:
    - (i) The regulations contained in this Chapter;
    - (ii) The applicable rules of Chapters ~~1200-02-05~~ Chapter 0400-20-05 and ~~1200-02-08~~ this Chapter;
    - (iii) License or registration conditions; and
    - (iv) The licensee's or registrant's operating and emergency procedures and shall have been tested in a manner approved by the Division to demonstrate understanding thereof; and
  3. Has physically demonstrated competence to use the sources of radiation, related handling tools, and survey instruments that will be employed in his assignment.

- (b) The licensee or registrant shall not permit any individual to act as a radiographer's assistant as defined in this Chapter until such individual:
1. Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures and shall have been tested in a manner approved by the Division to demonstrate understanding thereof; and
  2. Has physically demonstrated competence to use, under the personal supervision of the radiographer, the sources of radiation, related handling tools, and survey instruments that will be employed in his assignment.
- (c) Each licensee or registrant shall maintain the following records of training and certification for ~~three~~ 3 years after the record is made for inspection by the Division.
1. Records of training of each radiographer and each radiographer's assistant. The record shall include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and
  2. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records shall list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records shall also include a list showing the items checked and any non-compliance(s) observed by the radiological safety officer.
- (d) Whenever a radiographer's assistant uses sources of radiation or related handling tools or conducts radiation surveys required by ~~4200-02-08-06~~ subparagraph (3)(b) of Rule ~~0400-20-08-06~~ to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer.
- (2) Operating and emergency procedures. The licensee or registrant shall submit to the Division a copy of current operating and emergency procedures prior to the issuance or renewal of a license or registration. The licensee or registrant shall retain a copy of the operating and emergency procedures until the Division terminates the license or registration that authorizes the activity for which the procedures were developed. If the operating and emergency procedures are superseded, the superseded procedures shall be retained by the licensee or registrant for ~~three~~ 3 years after each change. These procedures shall include specific instructions in at least the following:
- (a) The handling and use of sources of radiation to be employed such that no individual shall be exposed to radiation doses in excess of the limits established in Chapter ~~4200-02-05~~ 0400-20-05 ~~of these regulations;~~
  - (b) Methods and occasions for conducting radiation surveys;
  - (c) Methods for controlling access to radiographic areas;
  - (d) Methods and occasions for locking and securing sources of radiation;
  - (e) Personnel monitoring and the use of personnel monitoring equipment;
  - (f) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles and control of sources of radiation during transportation;
  - (g) Minimizing exposure of individuals in the event of an accident;
  - (h) The procedure for notifying proper persons in the event of an accident;
  - (i) Maintenance of records;

- (j) The inspection and maintenance of radiographic exposure devices and storage containers; and
  - (k) Steps that shall be taken immediately by radiographic personnel in the event a pocket dosimeter is found to be off-scale.
- (3) Personnel monitoring.
- (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.
    - 1. Pocket dosimeters shall have a range from zero to 2 millisieverts (200 millirems) and shall be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.
    - 2. Each personnel dosimeter shall be assigned to and worn only by one individual.
    - 3. Film badges shall be replaced at periods not to exceed ~~one~~ 1 month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at periods not to exceed ~~three~~ 3 months.
    - 4. After replacement, each personnel dosimeter shall be processed as soon as possible.
  - (b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be read and the exposures recorded at the beginning and end of each shift. In accordance with Rule ~~1200-02-08-15~~ 0400-20-08-15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for ~~three~~ 3 years after the record is made.
  - (c) Pocket dosimeters, or electronic personal dosimeters, shall be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent (~~+20%~~) of the true radiation exposure. In accordance with Rule ~~1200-02-08-15~~ 0400-20-08-15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for ~~three~~ 3 years after the record is made.
  - (d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter shall be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination shall be made by the RSO or the RSO's designee. The results of this determination shall be included in the records maintained in accordance with Rule ~~1200-02-08-15~~ 0400-20-08-15.
  - (e) If the personnel dosimeter that is required by subparagraph (a) of this section ~~paragraph~~ is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in ~~subparagraph (a) of this paragraph~~ is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the period for which the personnel dosimeter was lost or damaged shall be included in the records maintained in accordance with Rule ~~1200-02-08-15~~ 0400-20-08-15.
  - (f) Dosimetry reports received from the accredited NVLAP personnel dosimeter processor shall be retained for inspection by the Division in accordance with Rule ~~1200-02-08-15~~ 0400-20-08-15.

(g) Each alarm ratemeter shall:

1. Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;
2. Be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;
3. Require special means to change the preset alarm function; and
4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with Rule ~~4200-02-08-15~~ 0400-20-08-15.

(4) Conducting industrial radiographic operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, at least one other qualified radiographer or an individual who has at a minimum met the requirements of paragraph ~~4200-02-08-07~~ (3) of Rule ~~0400-20-08-07~~ shall accompany the radiographer. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography shall not be performed if only one qualified individual is present.

(b) Reserved.

(5) Radiation safety officer (RSO) for industrial radiography:

The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

(a) The minimum qualifications, training and experience for RSOs for industrial radiography are as follows:

1. Completion of the training and testing requirements of ~~4200-02-08-07~~ paragraph (1) of Rule ~~0400-20-08-07~~;
2. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and
3. Formal training in the establishment and maintenance of a radiation protection program.

(6) Supervision of radiographers' assistants.

Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by subparagraph ~~4200-02-08-06~~ (3)(b) of Rule ~~0400-20-08-06~~ to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision shall include:

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

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

~~4200-02-08-06~~ 0400-20-08-06 Precautionary Procedures in Radiographic Operations.

(1) Security.

During each radiographic operation the radiographer, or the other individual present, as required by subparagraph ~~4200-02-08-06~~ (4)(a) of Rule ~~0400-20-08-05~~, shall maintain continuous, direct, visual surveillance of the operation to protect against unauthorized entry into a high radiation area as defined in Chapter ~~4200-02-05~~ ~~0400-20-05~~ except at permanent radiographic installations where all entryways are locked and the requirements of paragraph ~~4200-02-08-04~~ (9) of Rule ~~0400-20-08-04~~ are met.

(2) Posting.

Areas in which radiography is being performed shall be conspicuously posted according to the standards set out in Chapter ~~4200-02-05~~ ~~0400-20-05~~, without exceptions.

(3) Radiation surveys and survey records.

(a) The licensee or registrant shall ensure that at least one calibrated and operable radiation survey instrument is available:

1. At the location of its radiographic operations; and
2. At the storage area, as defined in ~~4200-02-08-03~~ Rule ~~0400-20-08-03~~, whenever a radiographic exposure device, a storage container or source is being placed in storage.

(b) After each exposure, the licensee or registrant shall ensure that a survey with a calibrated and operable radiation survey instrument is made to determine that the sealed source has been returned to its shielded position or that the radiation from the radiation machine has been terminated. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube. The survey shall determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head or dismantling equipment.

(c) Any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area, the licensee shall ensure that a survey with a calibrated and operable radiation survey instrument is made to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. The results of the last storage survey of the workday, required by this subparagraph (c), shall be recorded and retained for ~~three~~ 3 years.

(d) Records shall be kept of the duration of each radiographic exposure and the number of exposures made. In addition, for each radiographic exposure employing a radiation machine the voltage and current used shall be noted. These records shall be maintained for ~~three~~ 3 years for inspection by the Division and for field work may be kept on the area survey form.

(e) Each licensee or registrant conducting industrial radiography at a temporary job-site shall have the following documents available at that site for inspection by the Division:

1. Appropriate license or registration;
2. Operating and emergency procedures;
3. Applicable regulations;
4. Survey records required pursuant to ~~4200-02-08-06~~ this rule and Chapter ~~4200-02-05~~ ~~0400-20-05~~ for the period of operation at the site;
5. Daily pocket dosimeter records for the period of operation at the site; and

6. The latest instrument calibration and leak test records for specific devices in use at the site. Acceptable records include tags or labels that are affixed to the device or survey meter.

(4) Radiation surveys.

- (a) Conduct surveys with a calibrated and operable radiation survey instrument that meets the requirements of ~~Rule 1200-02-08-04~~ paragraph (4) of Rule 0400-20-08-04.
- (b) Using a survey instrument meeting the requirements of subparagraph (a) ~~of this paragraph~~, conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey shall determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.
- (c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in ~~paragraph 1200-02-08-03(27)~~ Rule 0400-20-08-03, to ensure that the sealed source is in its shielded position.
- (d) Maintain records in accordance with ~~Rule 1200-02-08-15~~ 0400-20-08-15.

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

~~1200-02-08-07~~ 0400-20-08-07 Minimum Subjects To Be Covered in Training Radiographers.

(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~~ 0400-20-08-16). (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~~ 0400-20-05 and ~~1200-02-10~~ 0400-20-10, 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; and
- (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 ~~1200-02-06~~ 0400-20-05 and ~~1200-02-10~~ 0400-20-10, 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.
- (5) Except as provided below in subparagraph ~~(5)(d) of this paragraph~~, the radiological safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Division's regulations, license requirements and the applicant's operating and emergency procedures are followed. The inspection program shall:
- (a) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed ~~six~~ 6 months; and
  - (b) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than ~~six~~ 6 months since the last inspection, the radiographer shall demonstrate knowledge of the training requirements of subparagraph ~~1200-02-08-07 (2)(c) of this rule~~ and the radiographer's assistant shall re-demonstrate knowledge of the training requirements of subparagraph ~~1200-02-08-07 (3)(b) of this rule~~ by a practical examination before these individuals can next participate in a radiographic operation.
  - (c) The Division may consider alternatives in those situations where the individual serves as both radiographer and radiological safety officer.
  - (d) In those operations where a single individual serves as both radiographer and radiological safety officer and performs all radiography operations, an inspection program is not required.
- (6) The licensee shall maintain records of the ~~above~~ training required by this rule to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with subparagraph 1200-02-08-05 (1)(c) of Rule 0400-20-08-05.
- (7) The licensee shall include the following subjects required ~~above~~ in paragraph (1) of this rule:
- (a) Fundamentals of radiation safety including:
    1. Characteristics of gamma radiation;
    2. Units of radiation dose and quantity of radioactivity;
    3. Hazards of exposure to radiation;
    4. Levels of radiation from licensed material; and
    5. Methods of controlling radiation dose (time, distance and shielding);
  - (b) Radiation detection instruments including:
    1. Use, operation, calibration and limitations of radiation survey instruments;

2. Survey techniques; and
  3. Use of personnel monitoring equipment;
- (c) Equipment to be used including:
1. Operation and control of radiographic exposure equipment, remote handling equipment and storage containers, including pictures or models of source assemblies (pigtailed).
  2. Storage, control and disposal of licensed material; and
  3. Inspection and maintenance of equipment.
- (d) The requirements of pertinent Federal regulations; and
- (e) Case histories of accidents in radiography.

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

~~4200-02-08-08~~ 0400-20-08-08 Cabinet Radiography.

- (1) The only requirement of this Chapter which applies to cabinet radiography as defined in this Chapter ~~Rule 0400-20-08-03~~ is that no registrant shall permit any individual to operate a cabinet radiography unit until such individual has:
- (a) Received a copy of the operating procedures for the unit;
  - (b) Received instruction in the operating procedures;
  - (c) Demonstrated an understanding of the operating procedures; and
  - (d) Demonstrated competence in the use of the unit.

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

~~4200-02-08-09~~ 0400-20-08-09 Fluoroscopic Radiography.

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

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

~~4200-02-08-10~~ 0400-20-08-10 Required Administrative Procedures for Industrial Radiography Program.

- (1) Licensees and registrants shall have a program for training radiographers and radiographer's assistants and submit to the Division for approval a schedule or description of such program that includes the:
- (a) Initial training:
    1. This initial training shall consist of a complete training program as outlined in ~~4200-02-08-07~~ Rule 0400-20-08-07; or
    2. Resumes of prior training and experience of individuals that show fulfillment of the requirements of ~~4200-02-08-07~~ subparagraphs (7)(a) and (b) of Rule 0400-20-08-07 and the initial training of such individuals in the licensee's or registrant's specific radiography program as outlined in ~~4200-02-08-07~~ subparagraphs (7)(c), (d) and (e) of Rule 0400-20-08-07;

- (b) Periodic training (shall be at least annual);
  - (c) On-the-job training;
  - (d) Means to be used by the licensee or registrant to determine the radiographer's knowledge and understanding of and ability to comply with:
    - 1. Division regulations and licensing or registration requirements; and
    - 2. The licensee's or registrant's operating and emergency procedures; and
  - (e) Means to be used by the licensee or registrant to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the licensee's or registrant's operating and emergency procedures;
- (2) The licensee or registrant shall establish and submit to the Division for approval written operating and emergency procedures as described in ~~4200-02-08-05~~ paragraph (2) of Rule 0400-20-08-05;
  - (3) The licensee or registrant shall establish and submit to the Division a description of its inspection program adequate to ensure that its radiographers and radiographer's assistants follow the Division's regulatory requirements and the licensee's or registrant's operating and emergency procedures. The inspection program shall:
    - (a) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed ~~six~~ 6 months;
    - (b) Provide that if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than ~~six~~ 6 months since the last inspection, that individual's performance shall be observed and recorded the next time the individual participates in a radiographic operation; and
    - (c) Include the retention of inspection records on the performance of radiographers or radiographer's assistants for ~~three~~ 3 years;
  - (4) The licensee or registrant shall submit to the Division a description of his overall organizational structure pertaining to the radiography program, including specified delegations of authority and responsibility for operation of the program; and
  - (5) The licensee who desires to conduct his own leak tests shall establish procedures to be followed in testing sealed sources for possible leakage and/or contamination and shall submit to the Division for approval a description of such procedures including:
    - (a) Instrumentation to be used;
    - (b) Method of performing tests, e.g., points on equipment to be smeared and method of taking the smear; and
    - (c) Pertinent experience of the person who will perform the test.

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

~~4200-02-08-11~~ 0400-20-08-11 Shielded Room X-Ray Radiography.

- (1) The only requirements of this Chapter applying to shielded room x-ray radiography are as follows:
  - (a) All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.

- (b) Emergency shut-off switches shall be located within the high radiation areas so as to be accessible to individuals therein within the warning period in 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.
- (c) The interlock system and the emergency shut-off system shall be separate electrical and/or mechanical systems.
- (d) The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be so positioned that they can be observed from any position or orientation within the room.
- (e) An audible warning signal within the room shall be actuated for at least ten 10 seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel.
- (f) The x-ray equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of x-ray radiation by the equipment.
- (g) All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced.
- (h) Surveys shall be made as required in ~~4200-02-08-08~~ subparagraph (3)(b) of Rule ~~0400-20-08-06~~. Personnel devices providing an audible signal when activated by radiation will be acceptable for this survey. Proper operation of this device shall be checked daily and a record maintained of this check. All personnel working with the x-ray equipment shall be provided with such a device. This device shall be designed so as to clearly indicate entry into a 2 milliroentgen per hour x-ray radiation field.
- (i) All personnel associated with the x-ray equipment shall be provided with personnel monitoring devices that shall be calibrated for the x-ray energies being utilized. Records of personnel exposure shall be maintained as required in Chapter ~~4200-02-05~~ ~~0400-20-05~~.
- (j) No registrant shall permit any individual to operate a radiation machine for shielded room x-ray radiography until such individual has received a copy of, instruction in, and demonstrated an understanding of operating and emergency procedures for the unit, and competence in its use. (See ~~4200-02-08-05~~ subparagraphs (2)(a), (c), (d), (e), (g), (h), (i), (j) and (k) of Rule ~~0400-20-08-05~~). These operating and emergency procedures shall be submitted to the Division for approval prior to their adoption.
- (k) All safety and warning devices, including interlocks and emergency shut-off switches, shall be tested at intervals not to exceed ~~three~~ 3 months to determine that they are functioning properly. Records shall be maintained of all tests.
- (l) If a safety or warning device malfunctions, the x-ray control panel shall be locked in the "off" position. It shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

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

~~4200-02-08-12~~ ~~0400-20-08-12~~ Reporting Requirements.

- (1) In addition to the reporting requirements specified in other chapters of these regulations, each licensee or registrant shall provide a written report to the Division at the address in Rule ~~4200-02-04-07~~ 0400-20-04-07, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:
- (a) Unintentional disconnection of the source assembly from the control cable.
  - (b) Inability to retract the source assembly to its fully shielded position and secure it in this position.
  - (c) Failure of any component (critical to safe operation of the device) to properly perform its intended function.
- (2) The licensee or registrant shall include the following information in each report submitted under paragraph (1) of this rule:
- (a) A description of the equipment problem.
  - (b) Cause of each incident, if known.
  - (c) Manufacturer and model number of equipment involved in the incident.
  - (d) Place, time and date of the incident.
  - (e) Actions taken to establish normal operations.
  - (f) Corrective actions taken or planned to prevent recurrence.
  - (g) Qualifications of personnel involved in the incident.
- (3) Reports of overexposure submitted under Chapter ~~4200-02-05~~ 0400-20-05 that involve failure of safety components of radiographic exposure devices or associated equipment shall also include the information specified in paragraph (2) of this rule.

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

~~4200-02-08-13~~ 0400-20-08-13 Reserved.

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

~~4200-02-08-14~~ 0400-20-08-14 Reserved.

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

~~4200-02-08-15~~ 0400-20-08-15 Recordkeeping Requirements.

- (1) Location of documents and records.
- (a) Each licensee and registrant shall maintain copies of records required by this rule and other applicable parts of this chapter at the location specified in the license or registration.
  - (b) Each licensee and registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;
    1. The license or registration authorizing the use of licensed material or registered equipment;
    2. A copy of "State Regulations for Protection Against Radiation;"
    3. Utilization records for each radiographic exposure device dispatched from that location as required by paragraph ~~4200-02-08-04~~ (7) of Rule 0400-20-08-04.

4. Records of equipment problems identified in daily checks of equipment as required by paragraph ~~4200-02-08-04 (8) of Rule 0400-20-08-04~~. The licensee or registrant shall maintain each record for ~~three~~ 3 years after it is made. The record shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.
5. Records of alarm system and entrance control checks required by paragraph ~~4200-02-08-04 (9) of Rule 0400-20-08-04~~, if applicable. The licensee or registrant shall maintain each record for ~~three~~ 3 years after it is made.
6. Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by paragraph ~~4200-02-08-05 (3) of Rule 0400-20-08-05~~. The licensee or registrant shall maintain each record for ~~three~~ 3 years after it is made.
7. Records of dosimetry reports received from the accredited NVLAP personnel dosimeter processor as required by paragraph ~~4200-02-08-05 (3) of Rule 0400-20-08-05~~. The licensee or registrant shall maintain each record until the Division terminates the license or registration.
8. Operating and emergency procedures required by paragraph ~~4200-02-08-05 (2) of Rule 0400-20-08-05~~. The licensee or registrant shall maintain a copy of current operating and emergency procedures until the Division terminates the license or registration. Superseded material shall be retained for ~~three~~ 3 years after the change is made.
9. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by paragraph ~~4200-02-08-04 (4) of Rule 0400-20-08-04~~. The licensee or registrant shall maintain each record for ~~three~~ 3 years after it is made.
10. Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by paragraph ~~4200-02-08-05 (3) of Rule 0400-20-08-05~~. The licensee or registrant shall maintain each record for ~~three~~ 3 years after it is made.
11. Latest survey records required by paragraph ~~4200-02-08-05 (4) of Rule 0400-20-08-05~~. The licensee or registrant shall maintain the record of each exposure device survey conducted before the device is placed in storage, if that survey is the last one performed in the workday, for ~~three~~ 3 years after it is made.
12. The shipping papers for the transportation of radioactive materials required by Chapter ~~4200-02-10 0400-20-10~~.
13. When operating under reciprocity pursuant to Rule ~~4200-02-10-29 0400-20-10-29~~, a copy of the Agreement State license authorizing the use of licensed materials; and
14. Records of estimates of exposures because of off-scale personal direct reading dosimeters or of lost or damaged personnel dosimeters until the Division terminates the license or registration.

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

~~4200-02-08-16 0400-20-08-16~~ Schedule RHS 8-35: Radiographer Certification.

- (1) Requirements for an independent certifying organization. An independent certifying organization shall:
  - (a) Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography.

- (b) Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;
  - (c) Have a certification program open to nonmembers, as well as members;
  - (d) Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;
  - (e) Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board;
  - (f) Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
  - (g) Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
  - (h) Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;
  - (i) Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;
  - (j) Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;
  - (k) Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the same company or corporation (or a wholly owned subsidiary of such company or corporation) does not employ the individuals proctoring each examination as any of the examinees;
  - (l) Exchange information about certified individuals with the Division and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and
  - (m) Provide a description to the Division of its procedures for choosing examination sites and for providing an appropriate examination environment.
- (2) Requirements for certification programs. All certification programs shall:
- (a) Require applicants for certification to:
    1. Receive training in the topics set forth in Rule ~~4200-02-08-07~~ 0400-20-08-07; and
    2. Satisfactorily complete a written examination covering these topics;
  - (b) Require applicants for certification to provide documentation that demonstrates that the applicant has:
    1. Received training in the topics set forth in Rule ~~4200-02-08-07~~ 0400-20-08-07;
    2. Satisfactorily completed a minimum period of on-the-job training; and
    3. Received verification by an Agreement State or a U.S. NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;
  - (c) Include procedures to ensure that all examination questions are protected from disclosure;

- (d) Include procedures for denying an application, revoking, suspending and reinstating a certificate;
  - (e) Provide a certification period of not less than ~~three~~ 3 years or more than ~~five~~ 5 years;
  - (f) Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training in industrial radiography.
  - (h) Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.
- (3) Requirements for written examinations. All examinations shall be:
- (a) Designed to test an individual's knowledge and understanding of the topics listed in Rule ~~4200-02-08-07~~ 0400-20-08-07;
  - (b) Written in a multiple-choice format;
  - (c) Have test items drawn from a question bank containing psychometrically valid questions based on the material in Rule ~~4200-02-08-07~~ 0400-20-08-07.

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