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Sequence Number: 06-06-11
Notice ID(s): 1627
File Date: 06/03/2011

Notice of Rulemaking Hearing

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

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

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

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

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

Address 1:	17 th Floor Conference Room, L&C Tower		
Address 2:	401 Church Street		
City:	Nashville, Tennessee		
Zip:	37243-1532		
Hearing Date :	08/08/11		
Hearing Time:	1:00 p.m.	<input checked="" type="checkbox"/> CST	<input type="checkbox"/> EST

Additional Hearing Information:

Oral or written comments are invited at the hearing. In addition, written comments may be submitted to Beth Murphy at the Division of Radiological Health, Central Office, address below, prior to or following the public hearing. However, the Division must receive comments in its Central Office by 4:30 p.m. (CST), August 8, 2011, in order to assure consideration.

Copies of draft rules are available for review in the Public Access Areas of the following Department Environmental Field Offices:

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

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

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

Memphis Environmental Field Office
 8383 Wolf Lake Drive
 Bartlett, TN 38133-4119
 (901) 371-3000

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

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

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

Revision Type (check all that apply):

- Amendment
 New
 Repeal

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

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0400-20-07-.04	Reserved
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(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 1200-02-07 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-.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		

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.

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.

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.

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

0400-20-07-.05 Definitions.

When used in this 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 paragraph (1) of Rule 0400-20-07-.24 and 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 paragraph (1) of Rule 0400-20-07-.25 and 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 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 Rule 0400-20-07-.27 and subparagraph (1)(a) of Rule 0400-20-07-.39, subparagraph (1)(a) of Rule 0400-20-07-.43, subparagraph (1)(a) of Rule 0400-20-07-.47, subparagraph (1)(a) of Rule 0400-20-07-.48, subparagraph (1)(a) of Rule 0400-20-07-.49, subparagraph (1)(a) of Rule 0400-20-07-.59, Rule 0400-20-07-.60, subparagraph (1)(a) of Rule 0400-20-07-.62, or 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 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 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.
- (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.
- (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.
- (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 Rule 0400-20-07-.20; or
 - (b) In accordance with the directions of the authorized user for procedures performed under Rules 0400-20-07-.38 and 0400-20-07-.40.
- (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.
- (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.
- (32) "Radiation safety officer" means an individual who meets the requirements in paragraph (1) or subparagraph (3)(a) of Rule 0400-20-07-.23 and 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.
 - (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.
 - (34) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
 - (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.
 - (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.
 - (37) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
 - (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.
 - (39) "Temporary job site" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.
 - (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.
 - (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.
 - (42) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
 - (43) "Type of use" means use of radioactive material under Rule 0400-20-07-.38, 0400-20-07-.40, 0400-20-07-.44, 0400-20-07-.51, 0400-20-07-.61, 0400-20-07-.63 or 0400-20-07-.81.
 - (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.
 - (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 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.

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.

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 subparagraph (a) of this paragraph shall be conducted using radioactive material authorized for medical use in the license; and
 - (c) Nothing in 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.

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.

0400-20-07-.09 Implementation.

- (1) A licensee shall implement the provisions in this rule on March 10, 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 March 10, 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 March 10, 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 0400-20-07-.66, 0400-20-07-.72, 0400-20-07-.73 and 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.

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 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 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.

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 Rules 0400-20-07-.38, 0400-20-07-.40, 0400-20-07-.44, 0400-20-07-.51, 0400-20-07-.61, 0400-20-07-.63, and 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 Rules 0400-20-07-.66, 0400-20-07-.72, 0400-20-07-.73, and 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 Rules 0400-20-07-.66, 0400-20-07-.72, 0400-20-07-.73, and 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 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;
 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 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.

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.

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 Rule 0400-20-07-.27 and subparagraph (1)(a) of Rule 0400-20-07-.39, subparagraph (1)(a) of Rule 0400-20-07-.43, subparagraph (1)(a) of Rule 0400-20-07-.47, subparagraph (1)(a) of Rule 0400-20-07-.48, subparagraph (1)(a) of Rule 0400-20-07-.49, subparagraph (1)(a) of Rule 0400-20-07-.59, subparagraph (1)(a) of Rule 0400-20-07-.62, subparagraph (1)(a) of Rule 0400-20-07-.80;
 - 2. For an authorized nuclear pharmacist, an individual who meets the requirements in paragraph (1) of Rule 0400-20-07-.25 and Rule 0400-20-07-.27;
 - 3. For an authorized medical physicist, an individual who meets the requirements in paragraph (1) of Rule 0400-20-07-.24 and 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 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.

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 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 subparagraph (1)(b) of Rule 0400-20-07-.13.

- (2) A licensee shall notify the Division no later than 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 paragraph (2) or 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 0400-20-07-.38 or 0400-20-07-.40.
- (3) The licensee shall send the documents required in this rule to the Division at the address listed in subparagraph (1)(c) of Rule 0400-20-04-.07.

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

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 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 Rule 0400-20-07-.81;
- (2) The provisions of 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 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 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 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.

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 Rule 0400-20-07-.11;
 - (b) The applicant has paid applicable fee under 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 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 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.

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

- (1) In addition to the radiation protection program requirements of 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 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 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 2 or more different types of use of radioactive material under Rules 0400-20-07-.44, 0400-20-07-.51, 0400-20-07-.63, and 0400-20-07-.81, or 2 or more types of units under 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 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 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.

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 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 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.

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 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 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.

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 (μCi)), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 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 μCi) of sodium iodide I-131: the dosage;
 - (b) For an administration of a therapeutic dosage of radioactive drug containing radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;
 - (c) For gamma stereotactic radiosurgery: The total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
 - (d) For teletherapy: The total dose, dose per fraction, number of fractions, and treatment site;
 - (e) For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
 - (f) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
 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 48 hours of the oral revision.

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

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 Rule 0400-20-07-.63 or 0400-20-07-.81.
- (3) A licensee shall retain a copy of the procedures required under paragraph (1) of this rule in accordance with 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.

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 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 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.

0400-20-07-.23 Training for Radiation Safety Officer.

Except as provided in Rule 0400-20-07-.26, a licensee shall require an individual fulfilling the responsibilities of the radiation safety officer under 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 20 college credits in physical science;
 - 2. Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 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 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 0400-20-07-.26, 0400-20-07-.43 or 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. 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. 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 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.

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

Except as provided in 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 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 0400-20-07-.26, 0400-20-07-.59 or 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 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 this rule, Rule 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.

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

Except as provided in Rule 0400-20-07-.26, 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 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 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.

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 March 21, 2010, need not comply with the training requirements of Rule 0400-20-07-.23, 0400-20-07-.24, or 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 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 Rules 0400-20-07-.39, 0400-20-07-.43, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, 0400-20-07-.59, 0400-20-07-.60, 0400-20-07-.62 and 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.

0400-20-07-.27 Recentness of Training.

The training and experience specified in Rules 0400-20-07-.17 through this rule and Rules 0400-20-07-.38 through 0400-20-07-.80 must have been obtained within the 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.

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 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 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.

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 0400-20-05 before first use, annually, and following a repair that affects the calibration.
- (2) To satisfy the requirements of 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 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 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.

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 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 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 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 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 20 percent.
- (5) A licensee shall retain a record of the dosage determination required by this rule in accordance with 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.

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

- (1) Any person authorized by 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 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 paragraph (12) of 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 μ Ci); or
 - 2. 1000 times the quantities in Schedule RHS 8-30 Chapter 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.

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 μ 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 0400-20-05 and 0400-20-10; and
 - (b) File a report within 5 days of the leak test in accordance with 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 μ Ci) or less of beta or gamma-emitting material or 0.37 MBq (10 μ Ci) 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 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.

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.

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 Rule 0400-20-07-.35.
- (9) A licensee shall retain a record of each survey in accordance with 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.

0400-20-07-.35 Release of Individuals Containing Radioactive Drugs or Implants.

- (1) A licensee may authorize the release from its control of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).¹
- (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 Rule 0400-20-07-.92.
- (4) A licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 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.

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;

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

- (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 0400-20-05; and
- (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 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.

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 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.

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 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 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 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 0400-20-07-.43, or Rule 0400-20-07-.47 and item (1)(c)1(ii)(VII) of Rule 0400-20-07-.43; or
 - 3. An individual under the supervision, as specified in Rule 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.

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

- (1) Except as provided in Rule 0400-20-07-.26, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 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 (c)2 of this 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 Rule 0400-20-07-.43 or 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 8 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 0400-20-07-.26, this rule, Rule 0400-20-07-.43, or 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 0400-20-07-.26, this rule, Rule 0400-20-07-.43, or 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 0400-20-07-.38.

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

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 paragraph (2) of Rule 0400-20-07-.20 that is:
- (a) Obtained from
 - 1. A manufacturer or preparer licensed under 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 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 0400-20-07-.43, or Rule 0400-20-07-.47 and item (1)(c)1(ii)(VII) of Rule 0400-20-07-.43, or an individual under the supervision of either as specified in Rule 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.

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 μ 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 μ 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 μ 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 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.

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.

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

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

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

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 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 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 0400-20-

07-.43, Rule 0400-20-07-.47, or an individual under the supervision of either as specified in Rule 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.

0400-20-07-.45 Safety Instructions.

- (1) In addition to the requirements of 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 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 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 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.

0400-20-07-.46 Safety Precautions.

- (1) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 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 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.

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

- (1) Except as provided in Rule 0400-20-07-.26, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 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 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 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 0400-20-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, Rule 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.

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 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 Rule 0400-20-07-.47 for uses listed in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47, 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 0400-20-07-.26, 0400-20-07-.47, 0400-20-07-.48, 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 subparagraph (1)(b) of Rule 0400-20-07-.47, must also have experience in administering dosages as specified in Rule subitem (1)(b)1(ii)(VI)I 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 0400-20-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.47, 0400-20-07-.48, 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 subparagraph (1)(b) of Rule 0400-20-07-.47, must also have experience in administering dosages as specified in Rule subitem (1)(b)1(ii)(VI)I 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.

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 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 Rule 0400-20-07-.47 for uses listed in 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 0400-20-07-.26, 0400-20-07-.47, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in Rule subparagraph (1)(b) of Rule 0400-20-07-.47, must have experience in administering dosages as specified in 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 0400-20-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-

07-.47, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in Rule subparagraph (1)(b) of Rule 0400-20-07-.47, must have experience in administering dosages as specified in 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.

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

- (1) Except as provided in Rule 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 0400-20-07-.47 for uses listed in subitem (1)(b)1(ii)(VI)III or 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 0400-20-07-.59 or 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 0400-20-07-.59 or 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 0400-20-07-.26, 0400-20-07-.47 or 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 0400-20-07-.47 must have experience in administering dosages as specified in 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 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 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 0400-20-07-.26, 0400-20-07-.47, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in Rule 0400-20-07-.47, must have experience in administering dosages as specified in 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.

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 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.

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 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.

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 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.

0400-20-07-.54 Safety Instructions.

- (1) In addition to the requirements of 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 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 subparagraph (1)(a) of Rule 0400-20-05-.60; and
 - (ii) Visitation authorized in accordance with 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 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.

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 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.

0400-20-07-.56 Calibration Measurements of Brachytherapy Sources.

- (1) Before the first medical use of a brachytherapy sealed source on or after March 21, 2010, a licensee shall have:
 - (a) Determined the source output or activity using a dosimetry system that meets the requirements of 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 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.

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 Rule 0400-20-07-.56.
- (2) A licensee shall retain a record of the activity of each strontium-90 source in accordance with 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.

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.

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

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

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

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

- (1) Except as provided in Rule 0400-20-07-.26, a licensee shall require the authorized user of strontium-90 for ophthalmic uses authorized under Rule 0400-20-07-.51 to be a physician who:
 - (a) Is an authorized user under 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 5 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 0400-20-07-.26, 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.

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.

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

- (1) Except as provided in Rule 0400-20-07-.26, a licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 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 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.

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 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.

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 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.

0400-20-07-.65 Installation, Maintenance, Adjustment, and Repair.

- (1) Only a person specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- (2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.
- (3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

- (4) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 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.

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 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 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.

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.

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 2 years and after any servicing that may have affected system calibration; or
 - (b) The system must have been calibrated within the previous 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 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 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 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.

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 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 1 year.

- (2) To satisfy the requirement of paragraph (1) of this rule, full calibration measurements must include determination of:
- (a) The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 - (b) The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 - (d) Timer accuracy and linearity over the range of use;
 - (e) On-off error; and
 - (f) The accuracy of all distance measuring and localization devices in medical use.
- (3) A licensee shall use the dosimetry system described in 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 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 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 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.

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 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 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 ± 5 percent;
 - (b) Source positioning accuracy to within ± 1 millimeter;

- (c) Source retraction with backup battery upon power failure;
 - (d) Length of the source transfer tubes;
 - (e) Timer accuracy and linearity over the typical range of use;
 - (f) Length of the applicators; and
 - (g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- (3) A licensee shall use the dosimetry system described in 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 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 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 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.

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 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 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 ± 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 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 1 month for cobalt-60 and at intervals consistent with 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 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.

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 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 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.

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.

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 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 0400-20-07-.107.

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

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 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 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.

0400-20-07-.76 Radiation Surveys.

- (1) In addition to the survey requirement in Rule 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 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.

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 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 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.

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.

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.

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

- (1) Except as provided in Rule 0400-20-07-.26, a licensee shall require an authorized user of a sealed source for a use authorized under 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 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 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 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this rule, Rule 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 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.

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 paragraphs (2), (3), and (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.

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 paragraph (1) of Rule 0400-20-07-.17 for 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 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 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 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.

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 paragraph (1) of Rule 0400-20-07-.18 for 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.

0400-20-07-.84 Records of Written Directives.

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

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

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.

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.

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 Rule 0400-20-07-.28 for 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.

0400-20-07-.88 Records of Survey Instrument Calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by Rule 0400-20-07-.29 for 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.

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 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 μ Ci); 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.

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.

0400-20-07-.91 Records of Surveys for Ambient Radiation Exposure Rate.

A licensee shall retain a record of each survey required by Rule 0400-20-07-.34 for 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.

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 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.

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 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 subparagraph (1)(d) of Rule 0400-20-07-.36 for 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.

0400-20-07-.94 Records of Decay-in-Storage.

A licensee shall maintain records of the disposal of licensed materials, as required by Rule 0400-20-07-.37, for 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.

0400-20-07-.95 Records of Radionuclide Contaminants.

A licensee shall maintain a record of the radionuclide contaminant concentration tests required by Rule 0400-20-07-.41 for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

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

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

A licensee shall maintain a record of safety instructions and training required by Rules 0400-20-07-.45, 0400-20-07-.54, and paragraph (4) of Rule 0400-20-07-.66 for 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.

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 Rules 0400-20-07-.52 and 0400-20-07-.64 for 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.

0400-20-07-.98 Records of Brachytherapy Source Accountability.

- (1) A licensee shall maintain a record of brachytherapy source accountability required by Rule 0400-20-07-.53 for 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.

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 Rule 0400-20-07-.56 for 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.

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 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 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.

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 Rule 0400-20-07-.65 for 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.

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 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.

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 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 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.

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 Rules 0400-20-07-.69, 0400-20-07-.70, and 0400-20-07-.71 for 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.

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 Rule 0400-20-07-.72 for 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.

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 Rule 0400-20-07-.73 for 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.

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 Rule 0400-20-07-.74 for 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.

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 Rule 0400-20-07-.75 for 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.

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 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.

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 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 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.

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 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 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.

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

A licensee shall retain a copy of the procedures required by 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.

0400-20-07-.113 Report of a Leaking Source.

A licensee shall file a report within 5 days if a leak test required by Rule 0400-20-07-.32 reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination. The report must be filed with the Division, and sent to the Division at the address listed in 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.

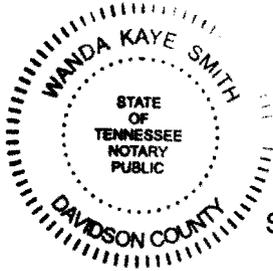
I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: June 2, 2011

Signature: *Debra G. Shults*

Name of Officer: Debra G. Shults

Title of Officer: Director, Division of Radiological Health



Subscribed and sworn to before me on: June 2, 2011

Notary Public Signature: *Wanda K Smith*

My commission expires on: My Commission Expires

November 7, 2012

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Filed with the Department of State on: 6/3/11

Tre Hargett

Tre Hargett
Secretary of State

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